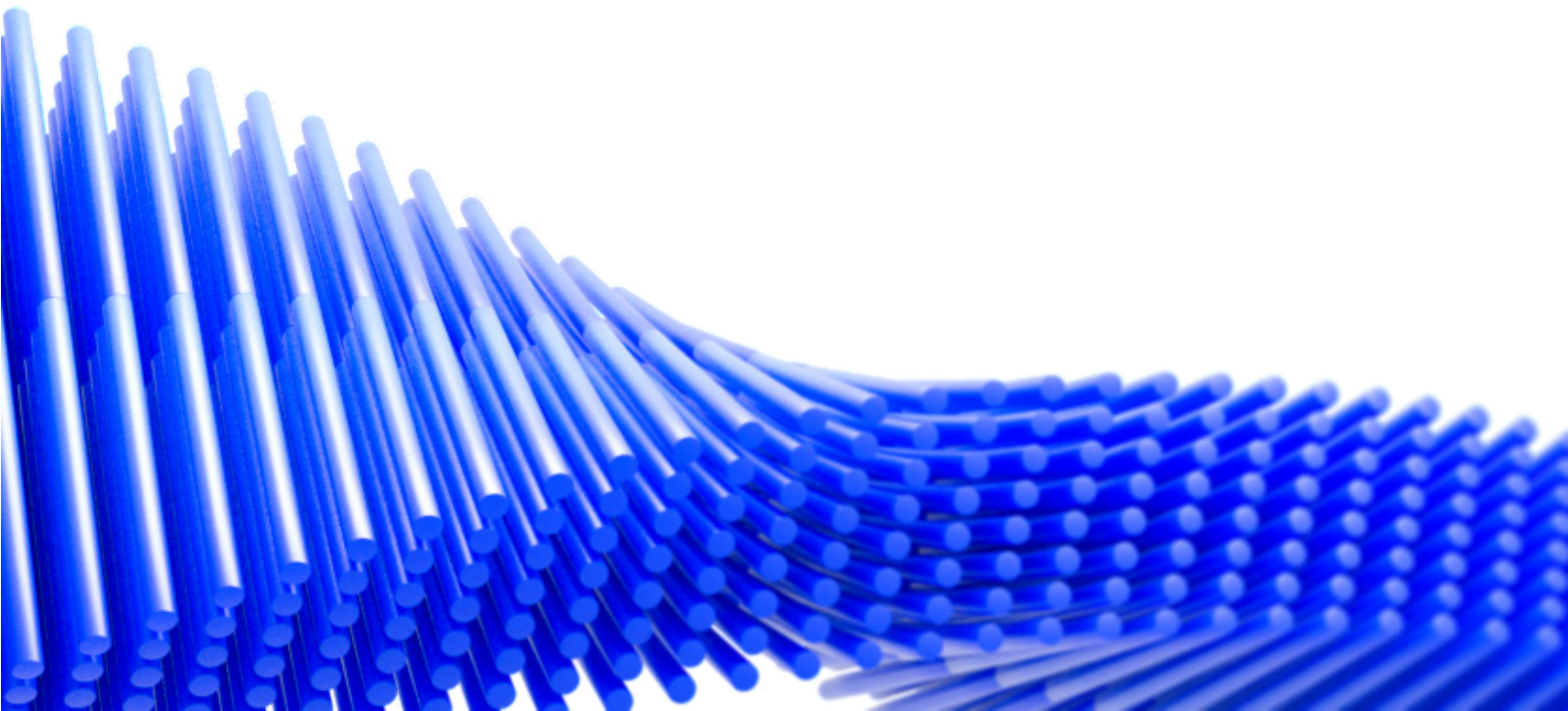




2022 Annual Review

Breakthroughs changing  
more than 1.3 billion lives

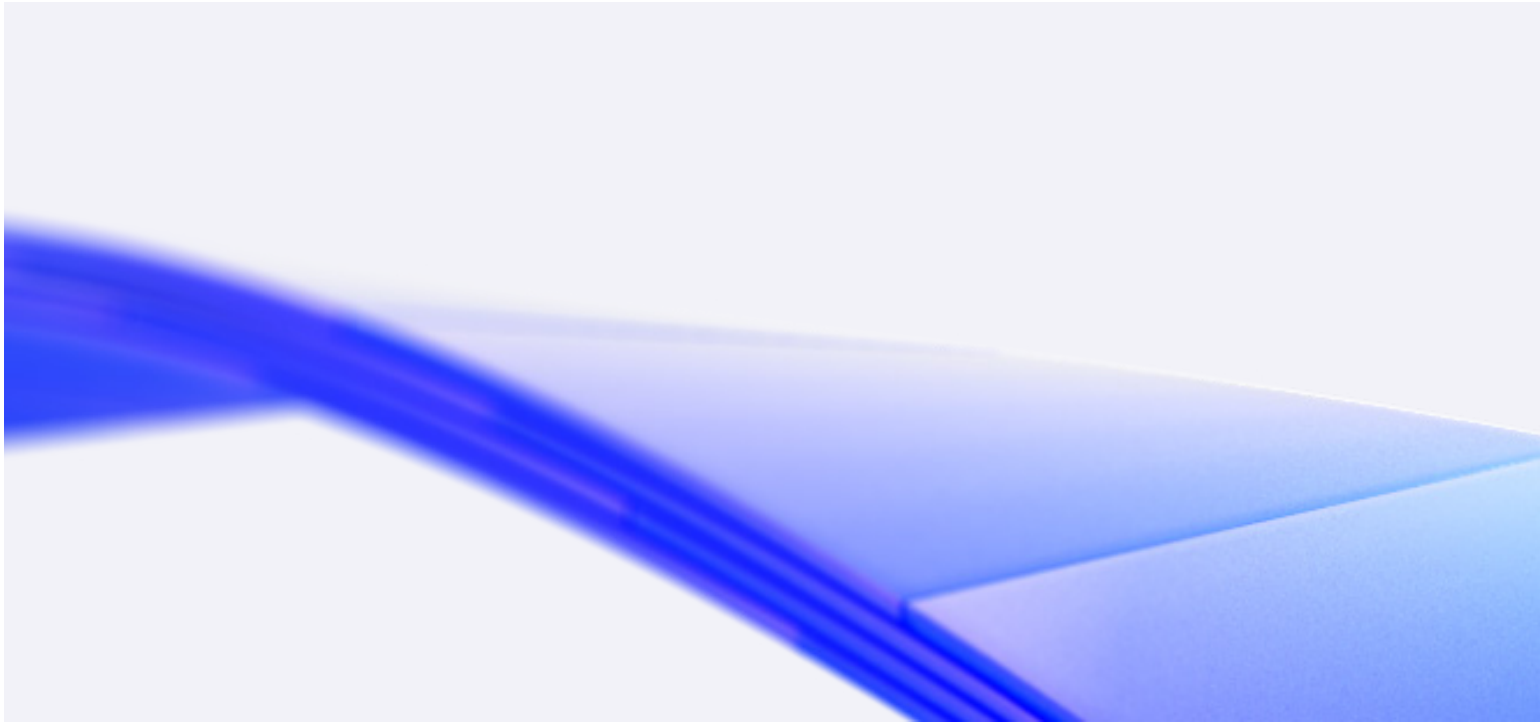
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# A Year in Review

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Breakthroughs changing more than 1.3 billion lives

In 2022, we applied the lightspeed principles that drove the development of our COVID-19 vaccine and treatment to help address unmet needs across all therapeutic areas. Our people continued to live our values—courage, excellence, equity, and joy—pursuing their passions and impacting an evolving world.

# A Letter from Our Chairman & CEO



## To Our Shareholders

A little more than four years ago, Pfizer unveiled a new purpose: *Breakthroughs that change patients' lives*. Pfizer has always had a noble purpose rooted in our commitment to patients, but we wanted to make our purpose more memorable, more inspiring and, most important, more actionable.

I am happy to say that in the 50 months since then, Pfizer's more than 80,000 colleagues around the world have lived this purpose every day. They have pursued impactful breakthroughs with the goal of dramatically changing the lives of patients for the better. As a result of this unwavering commitment to innovation and patients, 2022 was a simply remarkable year for our company on multiple fronts.

- We secured eight key regulatory approvals, completed 13 regulatory submissions and initiated 10 pivotal study starts, as we continue to advance our robust R&D pipeline of potential breakthrough medicines and vaccines.
- We maintained our industry-leading clinical success rates<sup>i</sup> and further improved our cycle times, which already were among the industry's best,<sup>ii</sup> and we did all of this while maintaining our high standards of quality, safety, and scientific rigor.
- We completed four acquisitions—Arena Pharmaceuticals, Biohaven Pharmaceuticals, Global Blood Therapeutics, and ReViral—which have further strengthened both

our pipeline and our current portfolio of innovative offerings for patients.

- We were named to 10 different “best employer” lists, including those published by Forbes, LinkedIn, Glassdoor, and others.
- We exceeded \$100 billion in revenues for the first time in our 174-year history.
- And, most important, more than 1.3 billion patients around the world were treated with our medicines and vaccines.<sup>iii</sup> A truly humbling achievement.

## Maintaining Our COVID-19 Leadership

During the year, we also continued to lead the battle against COVID-19. As the virus continued to evolve, Pfizer scientists were up to the challenge—using our flexible mRNA platform to swiftly create a new vaccine candidate based on the emerging Omicron BA.4 and BA.5 subvariants. By September, our BA.4/BA.5-adapted bivalent vaccine had been authorized by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as a booster dose for ages 12 years and older. By November, both agencies had authorized it for 5 years of age and older. Then in December, the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine received FDA authorization as the third 3-µg dose in the three-dose primary series for children 6 months through 4 years of age.

We are proud to have maintained our leadership position throughout the public health booster

<sup>i</sup> Success rates for Phase 1 are based on a 3-year rolling average (2020-2022); rates for Phase 2 and Phase 3/Registration represent a 5-year rolling average (2018-2022).

<sup>ii</sup> First in Human (FIH) to approval median phase cycle times are based on 3-year rolling cohort for Phase 1 and 5-year rolling cohort for Phase 2 to Registration. The analysis is at the new molecular entity (NME) level. Industry-leading is defined as Top Quartile amongst peer group companies.

<sup>iii</sup> The patients treated metric is calculated from Pfizer and third-party datasets. Figures may be limited given the coverage provided by external sources (e.g., calendar duration, geographic and product coverage). Numbers are estimates and in some cases use global volume, daily dosage and number of treatment days to facilitate calculations. Methodologies to calculate estimates may vary by product type given the nature of the product and available data. Patients taking multiple Pfizer products may be counted as multiple patients towards total. Numbers include estimated patient counts from U.S. Patient Assistance Programs, ex-U.S. access & affordability programs, product donations and Global Commercial Access Partnerships (this does not include An Accord for a Healthier World). Historical estimates may periodically be subject to revision due to restatements in the underlying data source.

campaign. As of February 22, 2023, we held a 64% market share of bivalent boosters in the U.S.<sup>iv</sup>—which is a significant expansion on the booster share leadership position that we already held before the bivalent booster launch—and our bivalent booster market shares are even higher in several key markets outside the U.S. We believe our best-in-class mRNA capability, coupled with our proven and reliable manufacturing network, will ensure we are well positioned to continue to adapt our vaccine as needed and get it to people around the world.

Our COVID-19 oral treatment, PAXLOVID® (nirmatrelvir tablets and ritonavir tablets), has shown to be an important complementary tool to vaccination strategies for the estimated 40% of the global population at high risk for progressing to severe disease.<sup>v</sup> PAXLOVID has demonstrated robust efficacy, a consistent safety profile, and potential to help mitigate the burden of COVID-19 on patients and their families, health systems, and society<sup>vi</sup>. As of March 1, 2023, we have shipped 44 million treatment courses to 63 countries around the world.

## Leading the Charge for Equitable Access

During the year, we also took bold action to help ensure our breakthroughs get into the hands of those who need them.

We're living in a time when science is increasingly demonstrating the ability to take on the world's most devastating diseases. Unfortunately, there's a huge health equity gap in our world that determines which of us can access these innovations—and which of us can't. At Pfizer, we are committed to helping close this gap as quickly as possible. That's why we launched An Accord for a Healthier World. Through this groundbreaking initiative, Pfizer now offers on a not-for-profit basis the full portfolio of medicines and vaccines for which we have global rights to 45 lower-income countries—with the hope of giving the 1.2 billion people living in these countries access to hundreds of lifesaving and life-changing products that they couldn't access before.

But as we learned in the COVID-19 vaccine rollout, ensuring supply is only the first step to helping patients. For this reason,

another key element of the Accord is collaborating with global health leaders to make improvements in diagnosis, education, infrastructure, innovative financing, and more. I'm proud to say that the first shipments of our products arrived in Rwanda in September 2022, and we are working with them and other governments—including in Ghana, Malawi, and Senegal—on future deliveries, as well as health system improvements to help make sure our products reach those in need.

Here in the U.S., I'm equally proud of the important work being done by Pfizer's Multicultural Health Equity Collective, which recently convened more than 100 health equity luminaries from across the U.S. to engage in candid conversations about the drivers and impact of systemic racism on healthcare. The dialogue highlighted creative solutions that are already starting to reduce health disparities in local communities across the country.

## A Bright Future for Pfizer and for Patients

Looking ahead, Pfizer's future appears to be even brighter than our present. We're in the midst of an 18-month period during which we expect to have up to an unprecedented 19 new products or indications in the market. Fifteen of these 19 are from our internal pipeline with the remaining four coming to Pfizer via recent business development deals. These potential medicines and vaccines cut across a range of therapeutic areas and include candidates for multiple myeloma, prostate cancer, respiratory syncytial virus (RSV), flu, pneumococcal disease, migraine, ulcerative colitis, and sickle cell disease—among others. This represents a tremendous opportunity to improve health outcomes for patients around the world. This is the promise of our science at work.

And, of course, we have many more potential vaccines and medicines in our pipeline, with numerous launches expected in the 2024-2030 timeframe, if successful in clinical trials and approved. Some of the most promising assets include our oral GLP-1 candidate for diabetes and obesity; potential combination vaccines for flu, COVID-19, and RSV; our potential vaccines for Lyme disease and shingles; multiple new oncology product candidates, including

<sup>iv</sup> CDC data through Jan 4, 2023.

<sup>v</sup> Clark A, Jit M, Warren-Gash C, et al. Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: A modelling study. *The Lancet Global Health*. 2020;8(8):1003-1017. doi:10.1016/s2214-109x(20)30264-3.

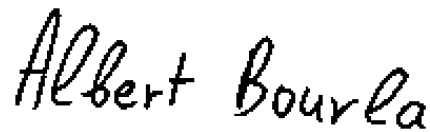
<sup>vi</sup> Pfizer Announces Additional Phase 2/3 Study Results Confirming Robust Efficacy of Novel COVID-19 Oral Antiviral Treatment Candidate in Reducing Risk of Hospitalization or Death. (2021, December 14). Pfizer. Retrieved November 1, 2022, from <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-additional-phase-23-study-results>.

ARV-471 and our CDK4 inhibitor for endocrine receptor-positive breast cancer; our gene therapy candidates for hemophilia A, hemophilia B, and Duchenne muscular dystrophy, and many more.

In addition, given the strength of our balance sheet and cash flows, we will continue to leverage business development opportunities to advance our business strategies and objectives. Our business development efforts remain focused on compelling external science in the form of both later-stage assets, as well as earlier medical innovations, that have the potential to be breakthroughs for patients. We will be looking primarily at therapeutic areas and platforms where we believe we have the scientific skills and acumen to add substantial value and select the most successful targets.

In summary, 2022 was an outstanding year for our company, with our key growth drivers providing evidence of the depth and breadth of our portfolio. With the unprecedented wave of innovations expected to emerge from our scientific pipeline in the near term, potential business development activities, our increased investments in our R&D and commercial capabilities, and additional potential new products and indications coming in the second half of the decade, we believe we can build on the momentum we have created to deliver life-changing innovations to even more patients around the world.

Thank you for your continued support of our important work.



**Dr. Albert Bourla**  
Chairman & Chief Executive Officer

*Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.*

*PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.*

*The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.*

*We encourage you to read our 2022 Annual Report on Form 10-K, which includes our audited consolidated financial statements as of and for the year ended December 31, 2022, and the sections captioned "Risk Factors" and "Forward Looking Information and Factors that May Affect Future Results," for a description of the substantial risks and uncertainties related to the forward-looking statements included herein. Expected product launches are subject to, among other risks, assumptions and uncertainties, clinical trial, regulatory and commercial success and availability of supply.*

# Partnerships that Change Patients' Lives

Pfizer's relationships with academics, biotechs, advocates, and technological revolutionaries help us realize our innovation goals. Some of our partners:



## OPKO Health

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of NGENLA® for the treatment of growth hormone deficiency.

## U.S. Government (PAXLOVID®)

In January, we inked an agreement with the U.S. government to deliver 20 million PAXLOVID treatment courses in 2022. Outside of the U.S., PAXLOVID (nirmatrelvir tablets and ritonavir tablets) is either approved or authorized for conditional or emergency use in more than 70 countries.

## Tigerlily

Our work with Tigerlily aims to empower Black women with breast cancer—who are at a higher risk of disease—to feel more educated and supported to participate in clinical trials.

## Global Governments Against Anti-Microbial Resistance (AMR)

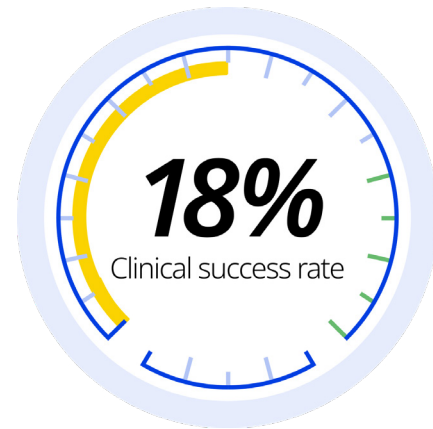
We partnered with NHS England, NICE, and the UK Government on a 'subscription-type' model for antibiotics, to encourage the appropriate use of existing antibiotics and incentivize the discovery of new ones.

# Breakthroughs at lightspeed

Pfizer can reach more patients with life-saving treatments, sooner.



Since 2019, we've decreased our median first-in-human to approval development timeline for new medicines and vaccines from nine years to approximately five years in 2022.



By the end of 2022, Pfizer achieved an end-to-end success rate of 18%—from first-in-human to approval at a new molecular entity level—which is nearly 10 times our 2010 performance.

We are in the midst of an 18-month period during which we expect to launch up to an unprecedented 19 new products or indications:

- 6 Vaccines
- 3 Primary care medicines
- 6 Specialty medicines
- 4 Oncology medicines

After surpassing our existing goals ahead of schedule, there is no limit to how far we can go in research and development in 2023 and beyond.



# People-Driven Initiatives

These passionate Pfizer colleagues transformed personal visions into large-scale realities that are positively impacting people all over the world.



**Zoriana Tsilyk**  
Ukraine Country Manager

“Pfizer’s support during this time makes me even prouder of my company. The millions of product donations arranged and the \$30 million committed for humanitarian support\* has and will continue to, quite literally, save lives.”



**Mona Babury**  
Director of Diversity, Equity and Inclusion and Pfizer Refugee Leadership Initiative Founder

“The Pfizer Refugee Leadership Initiative is not a hand-out. We see what refugees can bring to the table, and we welcome their diverse perspectives and experience.”



**Zainab Wasti**  
U.S. COVID-19 Vaccine Consumer Experience Lead

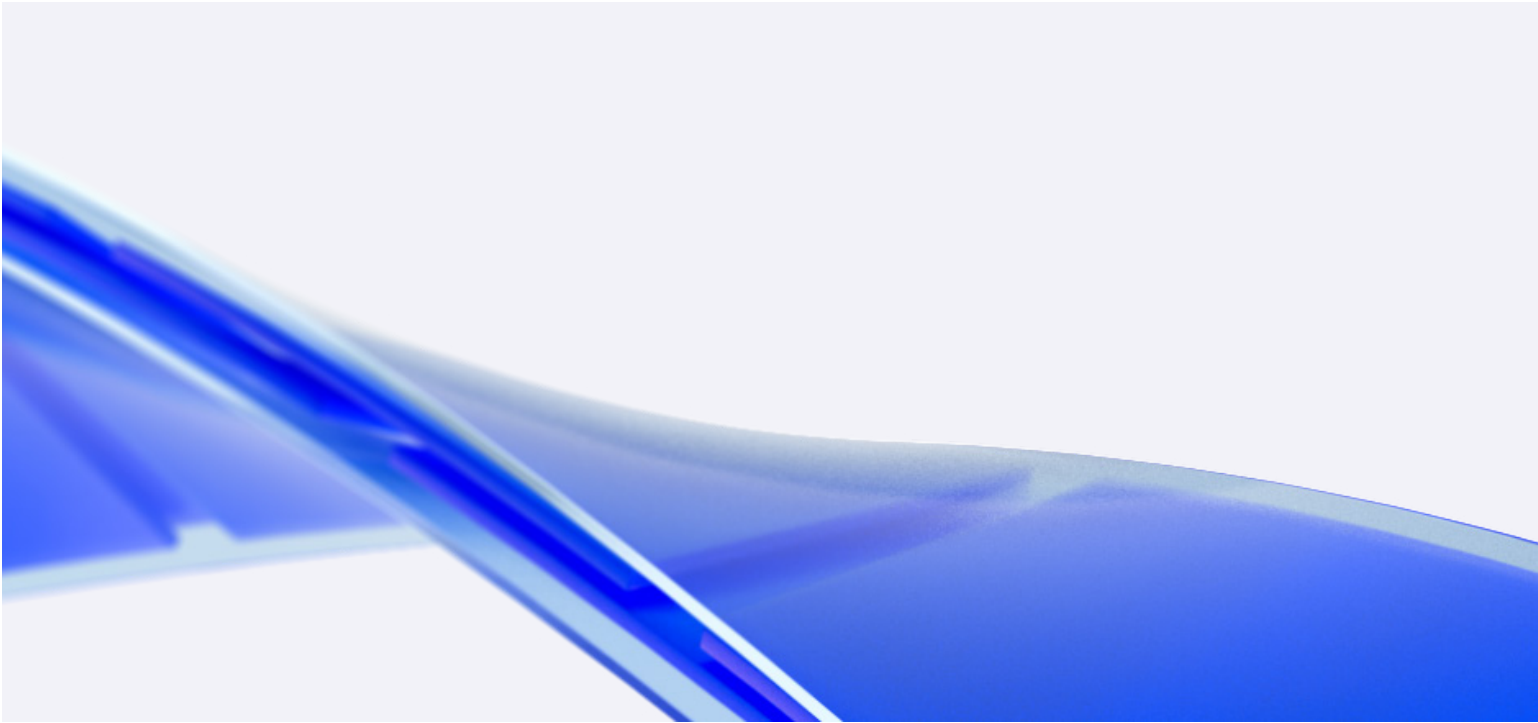
“Women are the Chief Health Officers of their families. At Essence Fest, we listened to their stories and we learned. And we will continue to do so in order to better serve them.”



**Emma Andrews**  
PharmD, VP Global Patient Advocacy

"Patients in Focus is a dedicated time where Pfizer colleagues, around the world, across all our markets and functions, take time to reflect on the impact patients and advocates have on our work."

\* Donations and humanitarian support were arranged by the Pfizer Foundation, a charitable organization established by Pfizer Inc. It is a separate legal entity from Pfizer Inc. with distinct legal restrictions.



# 2022 Stories

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Explore some of the most important breakthroughs from 2022.

U.S. Food and Drug Administration approvals in a rare disease and women’s health, advancing treatment for dermatological conditions and respiratory illnesses, and our ongoing efforts to bring the Pfizer-BioNTech COVID-19 vaccine and treatment to countries in all regions of the world.

Internal Medicine

# MYFEMBREE® Offers a Treatment Option in Two Woman's Health Conditions

Additional indication in endometriosis-associated pain reflects Pfizer's commitment to advancing women's health.

On August 5, 2022, Pfizer and Myovant Sciences' MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) was [approved](#) by the U.S. Food and Drug Administration (FDA) as a one-pill, once-a-day therapy for the management of moderate to severe pain associated with endometriosis in premenopausal women, with a treatment duration of up to 24 months.<sup>1</sup> Approval was supported by [data](#) from the Phase 3 SPIRIT 1 and SPIRIT 2 trials, which showed a reduction in dysmenorrhea and non-menstrual pelvic pain versus placebo at week 24. Adverse reactions occurring in at least 3% of women treated with MYFEMBREE and greater than placebo were: headache, vasomotor symptoms, mood disorders, abnormal uterine bleeding, nausea, toothache, back pain, decreased sexual desire and arousal, arthralgia, fatigue, and dizziness.<sup>2</sup>

This additional indication for MYFEMBREE underscores Pfizer and Myovant's commitment to addressing areas of significant unmet need in women's health.

In the U.S., there are approximately 7.5 million premenopausal women with endometriosis and approximately 75-80% of them are symptomatic.<sup>3,4,5,6</sup> Many women who experience endometriosis associated-pain are not able to manage their symptoms with current treatment options, highlighting the high unmet need for this disease.<sup>7</sup> It can take between four and eleven years to get an endometriosis diagnosis,<sup>8,9,10</sup> and for some women, current treatment options do not provide relief.<sup>11</sup>

This approval builds on the momentum from 2021's [approval](#) of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months. It also marks an important milestone in our mission to address women's health needs that are often overlooked by expanding treatment options for these conditions, which can be debilitating.



MYFEMBREE (relugolix, estradiol, and norethindrone acetate) is a once-daily oral treatment approved by the U.S. Food and Drug Administration for the management of moderate to severe pain associated with endometriosis, with a treatment duration of up to 24 months.

\*For full efficacy and safety information about MYFEMBREE, please see the full prescribing information [here](#).

<sup>1</sup> Myovant Sciences and Pfizer Receive FDA Approval for MYFEMBREE®, the First Once-Daily Treatment for Heavy Menstrual Bleeding Associated With Uterine Fibroids. May 26, 2021. <https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-receive-fda-approval-myfembree>. Accessed October 31, 2022.

<sup>2</sup> Myovant Sciences and Pfizer Receive U.S. FDA Approval of MYFEMBREE®, a Once-Daily Treatment for the Management of Moderate to Severe Pain Associated With Endometriosis August 05, 2022. [https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-receive-us-fda-approval#:~:text=MYFEMBREE%20\(relugolix%2C%20estradiol%2C%20and,of%20up%20to%2024%20months](https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-receive-us-fda-approval#:~:text=MYFEMBREE%20(relugolix%2C%20estradiol%2C%20and,of%20up%20to%2024%20months). Accessed October 31, 2022.

<sup>3</sup> US census 2019 (table 1; approx. 7.5 million women in the US ages 15-49). Available online at <https://data.census.gov/cedsci/table?q=United%20States&t=Age%20and%20Sex>. Accessed October 31, 2022.

<sup>4</sup> Shafir. Best Pract Res Clin Obstet Gynaecol. 2018 Aug;51:1-15 Accessed October 31, 2022.

<sup>5</sup> Fuldeore Gynecol Obstet Invest. 2017;82:453-461 Accessed October 31, 2022.

<sup>6</sup> Bulletti J Asist Reprod Genet 2010 Accessed October 31, 2022.

<sup>7</sup> Becker CM, et al. Fertil Steril. 2017 Jul;108(1):125-136. Accessed October 31, 2022.

<sup>8</sup> Zondervan KT, et al. NEJM. 2020;382(13):1244-1256 Accessed October 31, 2022.

<sup>9</sup> Nnoaham KE et al. Fertil Steril. 2011;96(2):366.e8-373.e8 Accessed October 31, 2022.

<sup>10</sup> Ballard K et al. Fertil Steril. 2006;86:1296-301 Accessed October 31, 2022.

<sup>11</sup> Soliman et al. J Women's Health. 2017. 26(7): 788-797 Accessed October 31, 2022.

Internal Medicine

# A New Option to Treat and Prevent Migraines for Patients in Europe

The only migraine medication that treats and prevents all in one.

In April 2022, VYDURA® (rimegepant) became the first medicine approved for both acute and prophylactic treatment of migraine in the European Union (EU). Migraine is a leading cause of disability worldwide, with approximately one in ten people living with the condition in Europe alone.<sup>1</sup> The burden of illness causes a large economic impact, with the EU spending an estimated ~€50-111 billion in 2011.<sup>2</sup> Globally, migraine disproportionately affects women by three to four times compared to men, and over 1 billion patients suffer from migraine.<sup>3,4</sup> It is a prevalent and disabling illness, and the personal impact causes missed moments with family, friends, and everyday life.<sup>5</sup>

“Migraine is often overlooked and undertreated, resulting in substantial disability with suboptimal care for patients,” said Professor Peter Goadsby, Director of the National Institute for Health and Care Research (NIHR) Clinical Research Facility and Professor of Neurology at King’s College London. “VYDURA’s promising efficacy and favorable benefit-risk profile spark hope for people in need of new migraine treatment options.”



Ellie W, actual Nurtec ODT patient

differences versus placebo on pain freedom, freedom from most bothersome symptoms, and ability to function normally at two hours post-dose, and the effects were sustained in some patients through 48 hours.<sup>6,7</sup> In a prevention trial, rimegepant taken every other day provided superior reduction in the number of days per month with migraine in weeks 9–12 of the 12-week treatment period compared to placebo.<sup>6</sup> The most frequent adverse event in clinical trials with VYDURA was nausea, occurring in 3% of patients compared to 1% with placebo, while hypersensitivity reactions including rash occurred in less than 1% of patients.<sup>7</sup>



Ellie W, actual Nurtec ODT patient

“This approval has the potential to advance the standard of care for migraine in the EU and I believe it will be an important new treatment option for the many people living with the burden of this prevalent neurological disease,” Goadsby said.

VYDURA has been found to be safe and efficacious. A trial in acute migraine demonstrated statistically significant

<sup>1</sup> Global Burden of Disease (GBD) 2016 Headache Collaborators. *Lancet Neurol.* 2018;17(11):954-976.

<sup>2</sup> Ashina M. *Migraine.* *N Engl J Med.* 2020;383(19): 1866-76.

<sup>3</sup> AHS consensus statement 2021 Ailani J et al. *Headache* 61:1021-1039.

<sup>4</sup> Global Burden of Disease (GBD) 2016 Headache Collaborators. *Lancet Neurol.* 2018;17(11):954-976.

<sup>5</sup> CaMEO study data: Buse C headache 2019;59;1286-99, 2018;58:512-14, Mayo Clin Proc 2016;91:596-611. Adapted from Ashina *Lancet* 2021;397:1485-1496.

<sup>6</sup> VYDURA (rimegepant) [package insert]. Dublin, Ireland: Pfizer Incorporated/Biohaven Pharmaceutical Holding; Company Ltd; 2022.

<sup>7</sup> Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for; the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. *Lancet.* 2019;394; (10200):737-745

## Inflammation &amp; Immunology

# Working to Advance Care for People Living With Ulcerative Colitis

Etrasimod has the potential, if approved, to be a best-in-class therapy for moderately-to-severely active UC.

As of 2019, it is estimated that ulcerative colitis (UC) affects 2.6 million people in Europe and an estimated 1 million people in the US.<sup>1,2</sup> It is a chronic, life-long immune-mediated inflammatory disease associated with unpredictable patterns of relapse and remission. The disease causes irritation and ulcers on the inner lining of the large intestine. It is one of a group of diseases called inflammatory bowel disease (IBD). Signs of ulcerative colitis often present as recurring diarrhea, which may contain blood, mucus or pus, abdominal pain, and urgency amongst further symptoms. UC is associated with lower patient quality of life that is comparable to other serious chronic conditions and is worse in inadequately controlled patients. Sphingosine-1-phosphate (S1P) modulates the inflammatory pathway by regulating the egress of lymphocytes from lymph nodes, and lymphocytes have a pivotal role in the pathogenesis of inflammation in patients with IBD.<sup>3</sup> Etrasimod, a once-daily, oral, S1P receptor modulator selectively activates S1P receptor subtypes 1, 4, and 5, which are believed to be involved in modulating the body's immune response by limiting movement of lymphocytes to sites of inflammation, while avoiding S1P receptors (S1P2,3) associated with serious AEs.

In May 2022, we announced positive results from our phase 3 trials demonstrating potential substantial positive benefits of etrasimod. In the 52-week study, clinical remission was 27.0% for patients receiving etrasimod compared to 7.4% for patients receiving placebo at week 12 and was 32.1% compared to 6.7% at week 52. In the 12-week study, clinical remission was achieved among 24.8% of patients receiving etrasimod compared to 15.2% of patients receiving placebo. Safety findings were consistent with those reported in previous studies of etrasimod. The most common treatment-emergent AEs in 3% or more of etrasimod-treated patients and greater than placebo up to week 52 in either trial were headache, worsening of UC, COVID-19 infection, dizziness, pyrexia, arthralgia, abdominal pain and nausea. These data were presented as a late-breaker presentation at Digestive Disease Week (DDW) 2022.<sup>4</sup> Additional subgroup analyses presented at United European Gastroenterology Week (UEGW) 2022 suggest that etrasimod may be particularly efficacious in patients naïve to or with one prior advanced therapy.<sup>5</sup> Many

patients living with ulcerative colitis might never achieve or maintain remission with the currently available treatment options. If approved by regulatory authorities, etrasimod has the potential to provide a new once-daily, oral option that could be an attractive first-line advanced therapy for patients with moderately-to-severely active ulcerative colitis. Key potential differentiators for etrasimod are that the data may support once-daily oral dosing without a complex dose titration scheme to start treatment. Lack of titration combined with its 30 hour half-life provide a fast onset of symptom relief along with fast offset/washout which can be advantageous in family planning and when the rate of immune reconstitution is critical.



Pfizer researchers are working hard to address the unpleasant symptoms commonly reported by patients living with ulcerative colitis: recurring diarrhea, which may contain blood, mucus or pus, and abdominal pain and urgency amongst further symptoms.

“Etrasimod could offer a meaningful clinical profile for people living with moderately-to-severely active ulcerative colitis considering the clear benefit it has shown over 52 weeks in a treat-through trial design, its mechanism of action, and its unique pharmacologic properties,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “Patients often need multiple options to help manage their disease, and there is a significant need for new therapies. In the ELEVATE clinical program, etrasimod has shown an encouraging balance of efficacy and safety that we believe could have a meaningful impact for patients and physicians if approved.”

<sup>1</sup> Seyedian SS, Nokhostin F, Malamir MD. A review of the diagnosis, prevention, and treatment methods of inflammatory bowel disease. *J Med Life*. 2019 Apr-Jun;12(2):113-122. doi: 10.25122/jml-2018-0075. PMID: 31406511; PMCID: PMC6685307.

<sup>2</sup> Extrapolation to US population today from *Clin Gastroenterol Hepatol*. 2017 June;15

<sup>3</sup> Aoki M, et al. *Mediators Inflamm*. 2016;2016:8606878

<sup>4</sup> Sandborn WJ, et al. Etrasimod 2 mg once daily as treatment for moderately to severely active ulcerative colitis: results from the phase 3 ELEVATE UC 52 and ELEVATE UC 12 trials. Lecture 968a, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

<sup>5</sup> MP289 Etrasimod 2mg Once Daily as Treatment for Biologic/Janus Kinase Inhibitor-Naïve and -Experienced Patients With Moderately to Severely Active Ulcerative Colitis: Subgroup Analysis From the Phase 3 ELEVATE UC 52 and ELEVATE UC 12 Trials. <https://programme.ueg.eu/week2022/#/details/presentations/779>

## Inflammation &amp; Immunology

# How Two Alopecia Areata Advocates Found and Spread Support on Social Media

Kylie and Supriya join Pfizer's Reflections of Alopecia Areata to share their stories.

Support networks can be life changing for individuals who are experiencing something people in their regular social circles don't understand—as was the case for Kylie Bamberger and Supriya Surrender, two women who have alopecia areata.

When Kylie first lost her hair at 12 years old, there weren't many online support systems where people could discuss the impact hair loss had on them. She would create hand-written notes to pass out at school to help people understand why she looked different.

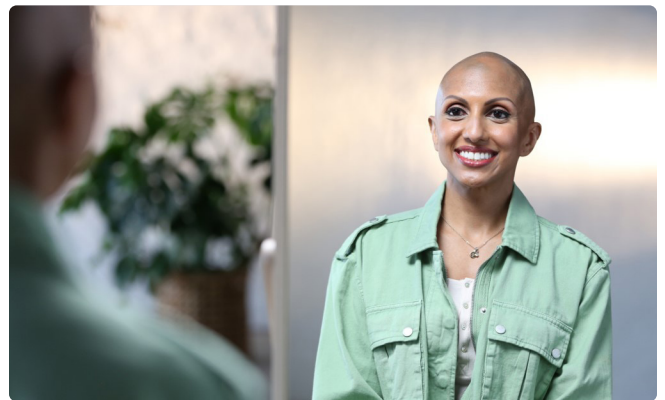


Kylie, a participant in Pfizer's Reflections of Areata campaign.

Late one night in college, she was inspired to do something impactful: share [her first bald photo](#) on social media. “When I lost my hair, there wasn't much in terms of alopecia areata awareness. There weren't online support groups or social media outlets. I knew I had to break that trend,” said Kylie. The response to her post was overwhelming and made Kylie, who has now amassed a large social media following, realize the true power of awareness and support.

Supriya began to lose her hair in her early 30s. She spent a lot of time feeling alone and in denial, but eventually found her first support group through social media, where she connected with a group of individuals also living with alopecia areata, including Kylie. “Connecting with the alopecia areata community completely changed my perspective on what my life could be,” said Supriya. “I was inspired by incredible

women, like Kylie, who so effortlessly lived in their truth and owned the disease.”



Supriya, a participant in Pfizer's Reflections of Areata campaign.

Supriya was inspired to start growing her own social media platform. Now, she shares her journey with alopecia areata with her social media followers, emphasizing the importance of a support system when navigating hair loss.

Supriya and Kylie are now sharing their stories as part of a Pfizer campaign, called [Reflections of Alopecia Areata](#), to help raise awareness, dispel myths and drive understanding of the autoimmune disease.

“Many people don't know that alopecia areata is more than just hair loss — it's an autoimmune disease. By sharing my story through my platform and through Reflections of Alopecia Areata, I hope to help raise awareness about this disease and the experience of those living with it,” said Kylie. “Alopecia areata can be a very isolating and emotional disease, and I want others to know they aren't alone ... they have a huge support system full of people like me who understand firsthand what they're going through.”

## Oncology

# Working to Deliver a Potential Breakthrough in a Type of Prostate Cancer

If approved, combination therapy has potential to become new standard of care.

Approximately 1.4 million new cases of prostate cancer are diagnosed worldwide each year, making prostate cancer the second most common cancer in men and the fourth most common cancer overall.<sup>1</sup> It is so common that all men are at risk for developing the cancer, but factors such as age, family history, and obesity increase the odds. Prostate cancer also has one of the widest racial disparities of any cancer, and these disparities are prevalent at every stage of the cancer continuum.



Pfizer's R&D efforts have led to a robust pipeline where we leverage therapeutic approaches to benefit patients.

For those diagnosed with prostate cancer, the majority occur in the early stages<sup>2</sup>, where the disease is considered curable with definitive therapy, such as surgery or radiation therapy. But a proportion of patients will progress after definitive therapy, or worse, be diagnosed at an advanced stage of the disease. It is often then considered incurable. The median overall survival for patients who have increasing levels of the protein prostate-specific antigen (PSA) after localized treatment survive between eight and nine years.<sup>3</sup> For those with a certain type of advanced prostate cancer, known as metastatic castration-resistant prostate cancer (mCRPC), the prognosis is dire—survival is only about 13 months.<sup>4,5</sup>

Research over the past decade has focused on improving outcomes for men with mCRPC, and while advances have been made with the introduction of therapies known as novel

hormonal therapies (NHTs), some patients eventually develop resistance and are left with no other treatment options.

This is where Pfizer is aiming to deliver the next scientific breakthrough.

Pfizer's R&D efforts have led to a robust pipeline allowing us to explore various therapeutic approaches of potential benefit to patients in clinical trials. One such trial is the Phase 3 TALAPRO-2 trial which found that the combination of TALZENNA® (talazoparib), our oral poly ADP-ribose polymerase (PARP) inhibitor, with XTANDI®\* (enzalutamide) yielded a statistically significant and clinically meaningful improvement in radiographic progression-free survival compared with placebo plus XTANDI. Benefits in other key endpoints, such as overall survival, prostate-specific antigen (PSA) response, time to PSA progression, and overall response rate, were also observed.

"For men with mCRPC, time is especially important, and we want to give people living with this disease the possibility of more time with their loved ones," said Chris Boshoff, MD, PhD, Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. "If approved, we believe TALZENNA may offer a new treatment option."

TALAPRO-2 is a two-part, two-cohort, multicenter, randomized, double-blind, placebo-controlled, Phase 3 study of 1,095 patients with mCRPC. TALZENNA or the combination of TALZENNA plus XTANDI has not been approved by any regulatory agency for the treatment of mCRPC.

"TALAPRO-2 underscores our long-term commitment to men living with advanced prostate cancer," said Suneet Varma, Global Oncology and U.S. President, Pfizer. "Based on the compelling combination data from TALAPRO-2, we believe TALZENNA in prostate cancer may become the next potential blockbuster opportunity in our leading Pfizer Oncology portfolio, subject to regulatory approval."

*\*Pfizer and Astellas jointly commercialize XTANDI in the United States, and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.*

<sup>1</sup> World Cancer Research Fund International. Prostate Cancer Statistics. <https://www.wcrf.org/cancer-trends/prostate-cancer-statistics/>. Last accessed October 31, 2022.

<sup>2</sup> Aging.com. prostate Cancer: A Guide for Aging Men. <https://aging.com/prostate-cancer-a-guide-for-aging-men/#:~:text=Most%20prostate%20cancer%20%28about%20four%20out%20of%20every.presence%2C%20and%20it%E2%80%99s%20still%20localized%20in%20the%20gland.> Last accessed October 31, 2022.

<sup>3</sup> Crook JM, et al. N Engl J Med. 2012;367:895-903.

<sup>4</sup> Moreira DM, et al. Clin Genitourin Cancer . 2017;15:60-66.

<sup>5</sup> De Bono J, et al. Abstract 93. ASCO GU 2021.

## Oncology

# LORVIQUA® Authorized as First-Line Treatment in European Union

Advanced ALK+ non-small cell lung cancer patients can now access next-generation precision medicine earlier in treatment paradigm.

Precision medicine has transformed cancer care in recent decades, often enabling doctors to pinpoint and then precisely target the sub-cellular abnormality from which the cancer sprung. Even so, by the time cancer has spread to the brain, it is often difficult to treat.

That's because of the blood-brain barrier, which evolved to block pathogens and toxins from entering the brain and can also prevent the passage of beneficial medications. LORVIQUA® (lorlatinib), available in the U.S. under the brand name LOREBENA®, is a third-generation medicine developed by Pfizer to treat advanced non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive. The drug was designed to specifically break through the blood-brain barrier.<sup>1</sup>

Approximately 25 to 40% of patients with ALK+ NSCLC either have brain metastases—cancer that has spread to the brain, at baseline, or develop brain metastases within two years of diagnosis.<sup>2</sup>

[Now](#), adults with advanced ALK+ NSCLC living in the European Union (EU) have access to LORVIQUA monotherapy as a first-line treatment under a marketing authorization granted by the European Commission in January 2022. Previously, LORVIQUA was available in the EU only under a conditional marketing authorization and only to a subset of patients with advanced ALK+ NSCLC whose cancer progressed after earlier ALK-targeting therapies.

LORVIQUA attacks the cancer at its source by tamping down the activity of the ALK protein, which is altered in ALK+ NSCLC, causing runaway cell growth.<sup>3</sup>

In the pivotal Phase 3 head-to-head CROWN clinical trial, ALK+ NSCLC patients who received LORVIQUA had 72% lower risk of progression or death than those who received XALKORI® (crizotinib).<sup>4</sup> Importantly, 82% of participants with brain

metastases that could be measured saw their brain tumors shrink or disappear entirely following LORVIQUA treatment, compared to 23% for XALKORI, which also works by targeting ALK protein but with less brain penetration.<sup>5</sup> Out of 112 patients who did not have brain metastases when enrolled in the trial who were treated with LORVIQUA, only one developed brain metastases.



Precision medicine for lung cancer takes individual biomarkers into account for treatment decisions. Credit: Pfizer.

XALKORI is another Pfizer product and was [authorized](#) in the EU as a first-line treatment for ALK+ NSCLC in 2015. But we didn't stop there. We kept pushing the envelope.

And now, in 2022, the success of LORVIQUA is a testament to our culture of never settling. At Pfizer, we continue to work tirelessly to help address unmet needs for people living with advanced, biomarker-driven lung cancers.

<sup>1</sup> Akamine T, Toyokawa G, Tagawa T, Seto T. Spotlight on lorlatinib and its potential in the treatment of NSCLC: the evidence to date. *Onco Targets Ther*. 2018 Aug 22;11:5093-5101. doi: 10.2147/OTT.S165511. PMID: 30174447; PMCID: PMC6110295.

<sup>2</sup> Abdallah SM, Wong A. Brain metastases in non-small-cell lung cancer: are tyrosine kinase inhibitors and checkpoint inhibitors now viable options? *Curr Oncol*. 2018 Jun;25(Suppl 1):S103-S114. doi: 10.3747/co.25.3733. Epub 2018 Jun 13. PMID: 29910653; PMCID: PMC6001769.

<sup>3</sup> Du X, Shao Y, Qin HF, Tai YH, Gao HJ. ALK-rearrangement in non-small-cell lung cancer (NSCLC). *Thorac Cancer*. 2018 Apr;9(4):423-430. doi: 10.1111/1759-7714.12613. Epub 2018 Feb 28. PMID: 29488330; PMCID: PMC5879058.

<sup>4</sup> Shaw AT, Bauer TM, de Marinis F, et al. First-Line Lorlatinib or Crizotinib in Advanced ALK-Positive Lung Cancer. *N Engl J Med*. 2020;383(21):2018-2029. doi:10.1056/NEJMoa2027187

<sup>5</sup> Bauer TM, Shaw AT, Johnson ML, et al. Brain Penetration of Lorlatinib: Cumulative Incidences of CNS and Non-CNS Progression with Lorlatinib in Patients with Previously Treated ALK-Positive Non-Small-Cell Lung Cancer. *Target Oncol*. 2020 Feb;15(1):55-65. doi: 10.1007/s11523-020-00702-4. PMID: 32060867; PMCID: PMC7028836.



Rare Disease

# Advancing Care for Pediatric Growth Hormone Deficiency

## Once-weekly treatment reduces the frequency of required injections for pediatric patients with GHD in the EU.

Growth hormone deficiency (GHD) is a rare disease that can take a substantial toll on children living with the condition and their families.<sup>1</sup> Without treatment, affected children will have persistent growth attenuation, very short height in adulthood, and puberty may be delayed.<sup>1</sup> Children may also experience other problems with physical health and mental well-being.<sup>1,2</sup>

The earlier GHD is identified, and consistent treatment is provided, the better a child's chances will be to achieve near-normal height.<sup>1</sup>

Prior to once weekly options, for decades, children living with GHD have been treated with daily injectable treatments, which often are administered for several years.<sup>3</sup> While effective and safe, daily injections require patience, flexibility, and can take an emotional toll on parents and caregivers.<sup>4,5,6</sup> In fact, it's estimated that up to two-thirds of children with GHD may miss more than one daily dose per week, which could negatively affect treatment outcomes.<sup>4</sup>

Pfizer has been focused on solutions to help minimize the disease management burden and to increase treatment adherence for children, their caregivers, loved ones, and healthcare providers.

In February 2022, Pfizer received marketing authorization in the European Union (EU) for NGENLA® (somatrogon), a once-weekly injection to treat children and adolescents from three years of age with growth disturbance due to insufficient secretion of growth hormone.<sup>7,8</sup> NGENLA provides pediatric patients, their caregivers and healthcare providers with a treatment option for GHD that reduces the frequency of required injections from once daily to once weekly.<sup>7,8</sup>

"Growth hormone deficiency takes a substantial toll on children living with this rare disease and their families, and for

many years, daily injections have been the standard of care, adding to the challenges they face," noted a Pfizer leader at the time of approval. "With NGENLA, we are proud to continue to advance the care of children in Europe who are impacted by growth hormone deficiency with a new, longer-acting option that significantly reduces treatment burden from once-daily to once-weekly injections."



NGENLA reduces the frequency of required injections from once daily to once weekly for children living with GHD, their caregivers, and healthcare professionals.

For decades, Pfizer has remained committed to helping the GHD community. This commitment will continue as we work to deliver this treatment, addressing unmet needs for the pediatric GHD community and raise awareness for this rare disease.

For full efficacy and safety information about NGENLA, please see the full prescribing information [here](#).

<sup>1</sup> Brod, M, Højbjerg, L, Alolga, SL, Beck, JF, Wilkinson, L, Rasmussen, MH. Understanding treatment burden for children treated for growth hormone deficiency. The Patient-Patient-Centered Outcomes Research. 2017;10(5):653-666.

<sup>2</sup> Toft D. Growth Hormone Deficiency Basics. EndocrineWeb. <https://www.endocrineweb.com/conditions/growth-disorders/growth-hormonedeficiency-basics>. Accessed October 25, 2022.

<sup>3</sup> Rose S, Cook D, Fine M. Growth Hormone Therapy Guidelines: Clinical and Managed Care Perspectives. Am J Pharm Benefits. 2014;6(5):e134-e146.

<sup>4</sup> Cutfield WS, Derraik JG, Gunn AJ, Reid K, Delany T, Robinson E, Hofman PL. Non-compliance with growth hormone treatment in children is common and impairs linear growth. PLoS One. 2011; 6(1):e16223.

<sup>5</sup> Koledova, E, Stoyanov, G, Ovbude, L, Davies, PS. Adherence and long-term growth outcomes: results from the easypod™ connect observational study (ECOS) in paediatric patients with growth disorders. Endocrine connections. 2018;7(8):914-923.

<sup>6</sup> Marini, MG, Chesi, P, Mazzanti, L, Guazzarotti, L, Toni, TD, Salerno, MC, Officioso, A, Parnagnoli, M, Angeletti, C, Faienza, MF, Iezzi, ML, Aversa, T, Sacchetti, C. Stories of experiences of care for growth hormone deficiency: the CRESCERE project. Future Science OA. 2016;2(1). doi.org/10.4155/fso.15.82.

<sup>7</sup> NGENLA EPAR - Product Information can be found here: [https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/ngenla-epar-product-information_en.pdf)

<sup>8</sup> Pfizer.com. Pfizer and OPKO's Once-Weekly NGENLA™ (somatrogon) Injection Receives Marketing Authorization in European Union for Treatment of Pediatric Growth Hormone Deficiency. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-opkos-once-weekly-ngenlatm-somatogon-injection>. Accessed October 27, 2022.

## Vaccines

# Advancing a Potential Meningococcal Vaccine to Simplify Vaccine Schedules

Study results announced potentially support pentavalent meningococcal vaccine candidate (MenABCWY) in adolescents.

On September 15, 2022, Pfizer announced the top line results from its Phase 3 clinical trial showing that its investigational pentavalent meningococcal vaccine (MenABCWY) demonstrated non-inferiority to licensed vaccines for the five meningococcal serogroups that cause the majority of invasive meningococcal disease: serogroups A, B, C, W and Y.)

Today, there are approximately 52 million adolescents and young adults who are in the age range recommended for meningococcal vaccination according to Centers for Disease Control and Prevention (CDC) guidance. However, less than a third of U.S. adolescents receive even one dose of a neisseria meningitidis group B (MenB) vaccine, and fewer complete the two-dose series, resulting in many adolescents being unprotected against meningococcal disease caused by serogroups A, B, C, W, and Y.<sup>1,2</sup> Routine use of a MenABCWY vaccine could help improve meningococcal vaccination rates and coverage, thereby helping to reduce cases of invasive meningococcal disease and associated mortality.<sup>3</sup>

"We are very pleased with these positive Phase 3 data, which are the first for a MenABCWY vaccine candidate. A pentavalent vaccine has the potential to help simplify what is currently a complex meningococcal vaccination schedule and improve vaccine coverage. Our goal is to help ensure as many adolescents and young adults as possible are protected against this devastating disease," said Annaliesa Anderson, PhD, Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer.

If approved, this vaccine candidate may help protect more young people from meningococcal disease and supports Pfizer's resolve to become a global leader in the prevention of this disease.



Meningococcal disease, while uncommon, has the potential to turn fatal within 24 hours, so it is important to be protected against all serogroups.

<sup>1</sup> Pingali C, Yankey D, Elam-Evans LD, et al. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2021. *MMWR Morb Mortal Wkly Rep* 2022;71:1101–1108. DOI: <http://dx.doi.org/10.15585/mmwr.mm7135a1>

<sup>2</sup> La EM, Garbinsky D, Hunter S, Poston S, Novy P, Ghaswalla P. Meningococcal B vaccination coverage among older adolescents in the United States. *Vaccine*. 2021;39(19):2660–2667.

<sup>3</sup> National Library of Medicine. Potential Public Health Impact of a Neisseria Meningitidis A, B, C, W, and Y Pentavalent Vaccine in the United States. 2022. Available at: <https://pubmed.ncbi.nlm.nih.gov/33615973/>

## Vaccines

# Helping Protect Patients Against Pneumococcal Pneumonia

EMA approves Pfizer's 20-valent pneumococcal conjugate vaccine in individuals 18 years of age and older.

On February 15, 2022, the European Medicines Agency (EMA) authorized the use of Pfizer's 20-valent pneumococcal conjugate vaccine (PCV20) under the brand name APEXXNAR®. The vaccine is approved in the European Union (EU) for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.

Anyone can become ill with potentially serious infectious respiratory diseases, including invasive pneumococcal disease and pneumonia. However, adults who are 65 years of age or older are 10 times more likely to be hospitalized with pneumococcal pneumonia than adults younger than 50.<sup>1,2</sup> Pneumococcal disease is also a major cause of communicable disease morbidity and mortality in Europe and the rest of the world.<sup>3</sup>

"APEXXNAR is the first pneumococcal conjugate vaccine to help protect adults against the 20 serotypes responsible for the majority of invasive disease and pneumococcal pneumonia. It offers the broadest serotype protection of any available pneumococcal conjugate vaccine in Europe and is a testament to our ongoing commitment to help protect patients against certain potentially serious infectious respiratory diseases," said Luis Jodar, Infectious Disease and Evidence Generation, Chief Medical Affairs Officer, Pfizer.

APEXXNAR helps address the burden of pneumococcal disease in adults and is one example of Pfizer's growing vaccine portfolio.



APEXXNAR helps address the burden of pneumococcal disease in adults and is one example of Pfizer's growing vaccine portfolio.

<sup>1</sup> Know Pneumonia. What is Pneumococcal Pneumonia?. <https://www.knowpneumonia.com/what-is-pneumococcal-pneumonia>. Published 2021. Accessed October 27, 2022.

<sup>2</sup> Ramirez JA, et al. Clin Infect Dis. 2017;65(11):1806-1812.

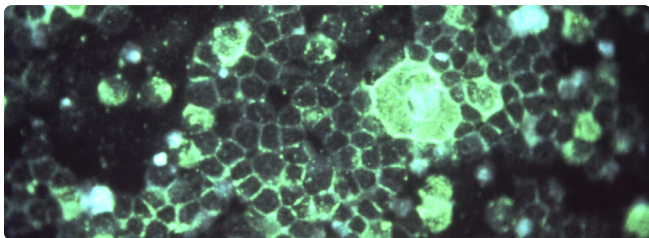
<sup>3</sup> European Centre for Disease Prevention and Control. Invasive pneumococcal disease. <https://www.ecdc.europa.eu/en/invasive-pneumococcal-disease>. Accessed October 27, 2022.

## Vaccines

# A Step Closer in the Fight Against Respiratory Syncytial Virus

Pfizer's advancement of a novel vaccine candidate.

Respiratory syncytial virus (RSV) is a contagious, common and pervasive cause of acute respiratory illness among older adults and young children.<sup>1</sup> In the U.S. alone, each year, RSV infections in older adults account for approximately 177,000 hospitalizations and 14,000 deaths, and in children younger than five years old, nearly 2.1 million outpatient visits and 58,000 hospitalizations.<sup>2</sup>



Using indirect immunofluorescence microscopy, this photomicrograph revealed the presence of the respiratory syncytial virus (RSV) in an unidentified tissue sample. RSV is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Photo credit: U.S. Centers For Disease Control and Prevention

The burden of this infectious disease is evident, but there is currently no U.S. Food and Drug Administration (FDA)-approved RSV vaccine on the market.

For more than five years, Pfizer has been advancing a novel vaccine candidate for RSV called PF-06928316 or RSVpreF.<sup>1</sup> There has been significant progress in 2022 with Pfizer's RSVpreF candidate:

- In December, Pfizer [announced](#) that the U.S. FDA accepted for priority review a Biologics License Application (BLA) for its RSV vaccine candidate, as submitted for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older. Priority Review designation by the FDA reduces the standard BLA

review period by four months. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA on the RSVpreF application is in May 2023.<sup>7</sup>

- In November, Pfizer [announced](#) positive top-line data from the Phase 3 clinical trial RENOIR (RSV vaccine Efficacy study **i**NOlder adults **I**mmunized against **R**SV disease) when administered to pregnant participants to help protect their infants from RSV disease after birth.<sup>3</sup>
- In August, Pfizer [announced](#) top-line data from the Phase 3 clinical trial RENOIR (RSV vaccine Efficacy study **i**NOlder adults **I**mmunized against **R**SV disease) when administered to adults 60 years of age or older.<sup>4</sup>
- In March, Pfizer announced two separate Breakthrough Therapy Designations from the U.S. FDA: one for the prevention of lower respiratory tract disease caused by [RSV in individuals 60 years of age or older](#); and the second for [RSV-associated lower respiratory tract illness in infants](#) from birth up to six months of age by active immunization of pregnant women.<sup>5,6</sup>

Pfizer is currently the only company with an investigational vaccine with regulatory applications for both infants through maternal immunization and older adults to help protect against RSV disease.

"Pfizer recognizes the urgency to get an RSV vaccine to the market—it's a priority for us, especially given the highly contagious nature of this infectious disease. If approved, our RSVpreF vaccine candidate has the potential to help protect older adults and infants from RSV.<sup>3,4</sup> We look forward to advancing our dialogue with regulatory authorities to help bring a potentially transformative solution for RSV to at-risk populations," said Annaliesa Anderson, PhD, Senior Vice President and Chief Scientific Officer, Vaccine Research & Development, Pfizer.

<sup>1</sup> One Step Closer in the Global Fight Against Respiratory Syncytial Virus (RSV). Pfizer.com. [https://insights.pfizer.com/global-fight-against-rsv/?utm\\_source=Google&utm\\_medium=Search&utm\\_campaign=PfizerInsights&utm\\_content=RSV&gclid=Cj0KCOjwsrWZBhC4ARIsAGGUJupST5jx9FLvW2jtGF\\_KEPhEd76ie8jykoHcMLsj\\_AKTylUuWubodCwaAiuPEALw\\_wcB](https://insights.pfizer.com/global-fight-against-rsv/?utm_source=Google&utm_medium=Search&utm_campaign=PfizerInsights&utm_content=RSV&gclid=Cj0KCOjwsrWZBhC4ARIsAGGUJupST5jx9FLvW2jtGF_KEPhEd76ie8jykoHcMLsj_AKTylUuWubodCwaAiuPEALw_wcB). Published 2022. Accessed October 26, 2022.

<sup>2</sup> Bracht M, Basevitz D, Cranis M, Paulley R. Impact of respiratory syncytial virus: the nurses perspective. *Drugs RD*. 2011;11(3):215-226. doi:10.2165/11593140-000000000-00000

<sup>3</sup> Pfizer Announces Positive Top-Line Data of Phase 3 Global Maternal Immunization Trial for its Bivalent Respiratory Syncytial Virus (RSV) Vaccine Candidate. Pfizer.com. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-data-phase-3-global>. Published 2022. Accessed December 12, 2022.

<sup>4</sup> Pfizer Announces Positive Top-Line Data from Phase 3 Trial of Older Adults for its Bivalent Respiratory Syncytial Virus (RSV) Vaccine Candidate. Pfizer.com. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-data-phase-3-trial-older>. Published 2022. Accessed December 12, 2022.

<sup>5</sup> Pfizer Granted FDA Breakthrough Therapy Designation for Respiratory Syncytial Virus Vaccine Candidate for the Prevention of RSV in Older Adults. Pfizer.com. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-granted-fda-breakthrough-therapy-designation-0>. Published 2022. Accessed October 26, 2022.

<sup>6</sup> Pfizer Granted FDA Breakthrough Therapy Designation for Respiratory Syncytial Virus (RSV) Vaccine Candidate for the Prevention of RSV in Infants from Birth up to Six Months of Age by Active Immunization of Pregnant Women. Pfizer.com. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-granted-fda-breakthrough-therapy-designation>. Published 2022. Accessed October 26, 2022.

<sup>7</sup> U.S. FDA Accepts for Priority Review the Biologics License Application for Pfizer's Respiratory Syncytial Virus Vaccine Candidate for the Prevention of RSV Disease in Older Adults. Pfizer.com. <https://www.pfizer.com/news/press-release/press-release-detail/us-fda-accepts-priority-review-biologics-license-0>. Published 2022, Accessed December 12, 2022

## Vaccines

# U.S. Travelers Get New Vaccine Option

## ACIP recommendation provides new option for protection against tick-borne encephalitis (TBE) for U.S. travelers

Over the past four decades, the world has seen many changes—from varying heads of states to technological advances, new cultural phenomena to global crises. One constant in this time has been Pfizer’s tick-borne encephalitis (TBE) vaccine, FSME-Immun®/TicoVac™. In 1976 the vaccine was first introduced to the pharmaceutical market in Austria, with over 170 million doses of the vaccine having been distributed since launch.<sup>1,2</sup>

In 2022, following an approval by the U.S. Food and Drug Administration (FDA) in 2021, the U.S. Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices’ (ACIP) voted to recommend\* TicoVac for active immunization to prevent TBE in U.S. populations one year of age and older who travel or move to TBE endemic areas and will have exposure to ticks, and laboratory workers with potential exposure to the TBE virus (TBEV).



Ticks live near the ground in long grass and can be found in parks and gardens, as well as forests and meadows, both within or outside cities.

### The burden of TBE

TBE is a rare infection involving the central nervous system, affecting the brain and spine.<sup>3</sup> It can lead to serious and complicated long-term consequences, including cognitive

changes, muscle weakness or permanent paralysis.<sup>3,4</sup> There is currently no cure or specific treatment for TBE, only management of symptoms.<sup>5</sup> Therefore, it’s important to help protect against TBE if spending time outdoors in an area where there is a risk of being infected with the TBE virus.

These areas where there is a risk of TBE are increasing as geographical reach of TBE is expanding.<sup>5</sup> To date, TBE has been reported in more than 36 countries, from across Western Europe to parts of Asia, meaning that U.S. citizens traveling to or living in these regions may be at risk of TBE if bitten by a tick.<sup>5</sup>

### Providing a new option for protection

Following discussions amongst the TBE Vaccine Work Group and a detailed analysis of extensive data from more than 20 years of evidence of use from outside the U.S., ACIP voted to recommend TicoVac for specific groups of at-risk individuals in February 2022. These included:

- Persons who are moving or traveling to a TBE-endemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary
- Persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas ticks are likely to be found may consider vaccination (where the decision to vaccinate should be based on an assessment of their planned activities and itinerary, risk factors for a poorer medical outcome, and personal perception and tolerance of risk)
- Laboratory workers with a potential exposure to the TBE virus (TBEV)

"This recommendation clearly demonstrates our ongoing commitment to patients, helping ensure that a vaccine with 46 years of heritage continues to be made available to new groups of at-risk individuals. This vote is important as it provides clear guidance for healthcare providers on when a TBE vaccine should be recommended to prevent infection, supporting conversations between patients and healthcare providers about whether vaccination is the right option for them," said Alejandro Cane, VP, US/IDM Vaccines and Antivirals Medical and Scientific Affairs Lead, Pfizer.

As the world opens up again in the wake of COVID-19, this ACIP recommendation\* means that U.S. individuals who are traveling or moving abroad to TBE-endemic areas in Europe or Asia, potentially including military personnel and

\* ACIP recommendations are provisional until published in the *Morbidity and Mortality Weekly Report (MMWR)*.

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their families, or those at risk of virus exposure through laboratory work have access to another option to help protect themselves.

Ensuring that broader populations have the option to help protect themselves from a potentially serious infection whilst traveling forms part of Pfizer's ongoing commitment to helping address tick-borne diseases.



Spending time outdoors may put you at risk of tick bites.

<sup>1</sup> Pfizer. Data on file. 2021 FSME-IMMUN® doses

<sup>2</sup> Barrett PN. Tick-borne encephalitis virus vaccines, p 773–88. In: Plotkin SA, Orenstein WA, PA O, (ed). Vaccines. Sixth edition. Elsevier Saunders; 2013, Philadelphia, PA

<sup>3</sup> Lindquist L, et al. Tick-borne encephalitis. The Lancet. 2008;371(9627):1861-71

<sup>4</sup> Kaiser R. Tick-borne encephalitis. Infect Dis Clin North Am. 2008;22(3):561-75.

<sup>5</sup> Dobler G, Erber W, Bröker M, Schmitt HJ, eds. The TBE Book. 5th ed. Singapore: Global Health Press; 2022. Available from <https://tbeneews.com/tbe/>. Accessed: November 2022.

## Vaccines

# Harnessing the Power of mRNA to Transform Medicine

Building on the successful application of mRNA for COVID-19, our scientists are exploring the use of mRNA technology in infectious disease and beyond.

The COVID-19 pandemic crystalized the scientific opportunity of mRNA, and the application of this adaptable novel technology platform has far-reaching potential. Messenger RNA or mRNA is a set of instructions that cells in the body follow to make specific proteins. Proteins play many essential roles in our bodies, including helping to prevent infections and potentially treat diseases. Many of the advantages of mRNA technology—its flexibility, speed, and potency—have scientists around the globe excited about its potential future applications.

The next wave of scientific innovation is upon us and Pfizer is working hard to harness the power of mRNA. We believe our expertise in disease biology, along with our robust, rapid manufacturing capabilities and talented scientific minds, will help propel the potential of this technology forward. In 2022, we've advanced our work and collaborated with new partners to help realize this incredible technology's full potential and expand our ability to leverage this scientific platform beyond COVID-19.

Our current exploration of mRNA is focused on infectious diseases with development programs in flu and shingles, as well as exploring mRNA's versatility in the areas of rare genetic diseases. Throughout the past year, we have made significant progress.

## Influenza or Flu

Flu continues to cause hospitalizations and deaths across the world every year, so we recognize an important opportunity to develop a potentially more efficacious vaccine. In 2022, we started our pivotal Phase 3 studies for an mRNA-based influenza vaccine candidate. The ability to nimbly "edit" mRNA could provide a huge benefit when it comes to vaccines that must be updated annually. With traditional flu vaccines, scientists try to predict many months in advance which strains might circulate and match the vaccines to the predicted strains. mRNA technology could be leveraged to generate vaccines much closer to the onset of each flu season, which could result in better matches to circulating strains. This flexibility, paired with the ability to rapidly manufacture mRNA vaccines, could potentially allow greater reliability of supply and better strain match, which could lead to improved efficacy.

## Shingles

Shingles is a debilitating, disfiguring and painful disease that affects people all over the world. In January, we announced a

collaboration with BioNTech to develop a potential first mRNA-based vaccine for the prevention of shingles. We plan to start human studies for this vaccine candidate in 2023.

## Rare genetic diseases

We've established a research collaboration with Beam Therapeutics to develop mRNA technology as a potential new approach to gene editing, which is a form of gene therapy. Gene editing works by delivering "tools" encased in lipid nanoparticles (fatty bubbles) that have the potential to replace, remove, or correct faulty genes in patients with rare diseases—providing a potential one-time treatment for these debilitating conditions. Our work is focused on rare genetic diseases of the liver, muscle, and central nervous system.



mRNA COVID-19 vaccines have sparked continued scientific innovation in infectious diseases and rare genetic diseases.

Of course, Pfizer's work in COVID-19 continues. We are also working to address emerging variants of concern with the introduction of the BA.1 and BA.4/5 bivalent vaccines to many countries across the world. Along with our collaboration partner BioNTech, we are advancing the next-generation of vaccines for SARS-CoV-2 and investigating a novel combination vaccine candidate against COVID-19 and influenza that could provide protection against these two infections with one vaccine.

We are looking forward to more scientific advances with Pfizer's mRNA efforts in 2023 and beyond.

Anti-infectives

# Breakthroughs in the Fight Against Antimicrobial Resistance

Our industry-leading initiatives to address this growing threat to global health.

The COVID-19 pandemic has been a stark reminder of the health and economic hardships caused by infectious diseases. It has also worsened drug-resistant infections and reinforced the need to invest in responsible antimicrobial use, diagnostics, surveillance, and research and development to help minimize the impact of future global health crises—like antimicrobial resistance (AMR).<sup>1,2</sup>

AMR is one of the biggest threats to global health today and can affect anyone, of any age, in any country. If it continues to rise unchecked, minor infections could become life-threatening, serious infections could become impossible to treat, and many routine medical procedures could become too risky to perform.<sup>3,4</sup> Without action by governments, industry, and society, AMR is expected to cause 10 million deaths each year by 2050.<sup>4</sup>

As a global anti-infective leader, we're committed to tackling AMR. Pfizer was proud to start the year ranked as a joint industry leader by the Access to Medicines Foundation AMR Benchmark report, which highlighted our innovative policies to improve access to our medicines and our leadership in antimicrobial stewardship.<sup>5</sup>

Good antimicrobial stewardship—a systematic, rational approach to the responsible use of antimicrobials—is foundational to help curb AMR.

Diagnostics can play an important role in stewardship practices and are an under-used resource. This year, Pfizer announced a collaboration with BD (Becton, Dickinson and Company) and Wellcome to better understand the role of diagnostics in advancing antimicrobial stewardship practices around the world.<sup>6</sup>

Antimicrobial surveillance—the monitoring of changes in populations of microbes to help understand patterns of resistance to anti-infectives—is critical for effective infection prevention. Access to such data allows key decision-makers to better adapt antimicrobial stewardship programs to help combat the spread of resistant pathogens.

In 2022 we led the way as a founding contributor to the non-profit Vivli's AMR Register, sharing raw antimicrobial surveillance data from our pioneering Antimicrobial Testing

Leadership and Surveillance (ATLAS) database.<sup>7</sup> Vivli's AMR Register will allow researchers, national governments, and multi-lateral organizations to access multiple industry datasets in one place to aid in identifying the emergence of new antimicrobial-resistant pathogens.



Antimicrobial surveillance—the monitoring of changes in populations of microbes to help understand patterns of resistance to anti-infectives—is critical for effective infection prevention.

A robust pipeline of new antimicrobials is essential to restoring the balance against increasing rates of AMR. However, significant economic hurdles have made research and development in this area a challenge. No novel class of antibiotics has been launched for almost 40 years, and even when newly approved treatments come to market, they may be used sparingly to support good antimicrobial stewardship practices—making it difficult to recover the high cost associated with development. New reimbursement models that more fully reflect the complete value of antimicrobials are critical.

We continued our leadership in finding creative solutions to address AMR in 2022 in a world-first cross-industry innovative reimbursement model for antimicrobials.

In June, Pfizer partnered with NHS England, NICE, and the UK Government on an innovative 'subscription-type' model for antibiotics.<sup>8</sup> The model aims to move away from



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reimbursement based on number of prescriptions and instead focus on the value antibiotics bring to the public. This encourages the appropriate use of existing antibiotics and incentivizes the discovery of new ones—both crucial tools in our arsenal against AMR.

This pilot could help to inspire change on a global scale. It's hoped that this model will set a precedent for governments across Europe and beyond to progress their own incentive and reimbursement models to attract much-needed investment in antimicrobial research and development.

<sup>1</sup> Pelfrene E, Botgros R, Cavaleri M. Antimicrobial multidrug resistance in the era of COVID-19: a forgotten plight? *Antimicrob Resist Infect Control*. 2021;10:21

<sup>2</sup> Yam ELY. COVID-19 will further exacerbate global antimicrobial resistance. *J Travel Med*. 2020;27:taaa098

<sup>3</sup> World Health Organization. Antibiotic resistance factsheet. July 2020. Available at: <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>

<sup>4</sup> Review on Antimicrobial Resistance. Tackling drug-resistant infections globally: final report and recommendations. May 2016. Available at: [https://amr-review.org/sites/default/files/160525\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf)

<sup>5</sup> Access to Medicine Foundation. Antimicrobial resistance benchmark 2021. Available at [https://accessmedicinefoundation.org/media/uploads/downloads/61ee760d03810\\_Antimicrobial%20Resistance%20Benchmark%20report%202021.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/61ee760d03810_Antimicrobial%20Resistance%20Benchmark%20report%202021.pdf)

<sup>6</sup> BD, BD, Pfizer, Wellcome Collaborate to Improve Global Hospital Antimicrobial Stewardship Practices. January 2022. Available at: <https://news.bd.com/2022-01-11-BD.-Pfizer.-Wellcome-Collaborate-to-Improve-Global-Hospital-Antimicrobial-Stewardship-Practices>

<sup>7</sup> Vivli. Groundbreaking Data-Sharing Initiative Launches to Increase Understanding of Antimicrobial Resistance. June 2022. Available at: <https://amr.vivli.org/groundbreaking-data-sharing-initiative-launches-to-increase-understanding-of-antimicrobial-resistance/>

<sup>8</sup> NHS England. NHS lands breakthrough in global battle against superbugs. June 2022. Available at: <https://www.england.nhs.uk/2022/06/nhs-lands-breakthrough-in-global-battle-against-superbugs/#:~:text=The%20NHS%20is%20set%20to,of%20the%20NHS%20announced%20today.>

R&amp;D

# Ensuring Diversity in Clinical Trials to Develop Breakthroughs for All™

Clinical trials can advance medical breakthroughs, and so does supporting equal access to clinical trials.

While most people are likely familiar with the concept of a clinical trial, they may not be as familiar with its purpose. For Pfizer, delivering lifesaving treatments for all means ensuring that our clinical trials accurately represent the diverse communities impacted by the diseases we seek to treat or prevent. As part of these efforts, Breakthroughs for All™ is Pfizer's commitment to diverse and inclusive participation in clinical trials through equitable access and practices.

Race, ethnicity, age, biological sex, and cultural background all inform how effective vaccines and medicines are for individual people. Pfizer has increased its efforts to design and conduct clinical trials that more accurately reflect the racial and ethnic diversity of the locations where our trials are conducted and the epidemiology of the diseases we intend to treat or prevent.

To accomplish this goal, we must proactively, intentionally, and regularly address the historic barriers that have partially resulted in underrepresentation in clinical trials, including community mistrust and lack of clinical trial awareness. Building trust and increasing awareness in diverse communities requires strong relationships with influential and embedded community organizations, including major universities, research organizations, and trusted community voices in local pharmacies, hospitals, and religious institutions.

One example is our recent partnership with the Tigerlily Foundation to launch Health Equity, Advocacy, and Leadership (HEAL) sessions to advance education around clinical trials for Black women with breast cancer. This effort is critically important as, in addition to historic underrepresentation in breast cancer clinical trials,<sup>1</sup> Black women are often diagnosed at a later stage and have a worse prognosis compared to white women.<sup>2</sup> During these sessions, we focus on shedding light on the breast cancer journey for women of color, improving access to breast cancer clinical trials, building trust and enhancing relationships between cancer patients and their care providers, and identifying barriers and solutions to improve access to trials, with the intent that this knowledge will be shared across other treatment areas.

"Every person deserves the right to a healthy life, and our effort to improve diversity in clinical trials to increase the

overall population's benefit from clinical research is a matter of equity. Our work alongside Tigerlily aims to empower Black women with breast cancer, who are at a higher risk of disease but less likely to enroll in a clinical trial that may prove to be lifesaving. Our goal—through this partnership and others like it—is to provide communities with the knowledge to feel more educated and supported to participate in clinical trials, furthering the real-life impact of important scientific discovery," said Judy Sowards, Pfizer Vice President, Head of Clinical Trial Experience.



For Pfizer, delivering lifesaving treatments for all means ensuring that our clinical trials accurately represent the diverse communities impacted by the diseases we seek to treat or prevent.

Although there is still work to be done, we have made important progress in raising awareness, building trust, and increasing access to clinical trials for even more people. Breakthroughs for All™ are made possible by those who choose to participate in clinical trials, and we're committed to working closely with all potential partners, including communities, their leaders, and industry professionals, to not only ensure that all who are interested in joining a clinical trial have the right information and opportunity to do so, but also that the therapies we bring to market are truly beneficial to patients and their families.

<sup>1</sup> Bonner D, Cragun D, Reynolds M, Vadaparampil ST, Pal T. Recruitment of a Population-Based Sample of Young Black Women with Breast Cancer through a State Cancer Registry. *Breast J.* 2016 Mar-Apr;22(2):166-72. doi: 10.1111/tbj.12545. Epub 2015 Dec 14. PMID: 26661631; PMCID: PMC4775403.

<sup>2</sup> ACS, American Cancer Society (2016) Breast cancer facts & figures, 2015–2016. 2016. American Cancer Society, Atlanta

R&amp;D

# Breaking Industry Standards with Lightspeed

Through focused efforts since 2010, Pfizer transformed R&D output to achieve leading success rates among industry leaders.<sup>1</sup>

It can take more than 10 years to bring a vaccine or treatment from discovery through regulatory approval. The urgency of COVID-19 forced us all to think differently and challenge the typical discovery and development timeline while maintaining our high standards for safety and quality, which led to the development of an authorized vaccine in less than a year and a treatment in less than 18 months.

However, long before the pandemic—over the course of the last decade—Pfizer has been transforming our research and development approach, revving up our engine of innovation and making profound changes across multiple dimensions to empower our scientists for critical decision-making. This important evolution laid the foundation for responding with “lightspeed” in the pandemic and continues to usher in a new wave of breakthroughs at Pfizer. Specifically:

- Since 2019, we’ve decreased our median first-in-human to approval development timeline for new medicines and vaccines from nine years to approximately five years in 2022. We have ambitious goals to reduce timelines even further so we can get medicines to patients even faster.
- By the end of 2022, Pfizer achieved an end-to-end success rate of 18 percent—from first-in-human to approval at a new molecular entity level—which is nearly 10 times our 2010 performance.
- By the end of 2021, we demonstrated a durable performance on Phase 2 success rates for New Molecular Entities of 60% versus an industry median of 37%.<sup>1</sup>
- We’re proud of our achievement to date and intent to maintain our focus in industry leading success rates, enabling us to continue to deliver breakthroughs to patients.

“There is no greater indicator of our commitment to delivering breakthroughs for patients than clinical success rates,” said Mikael Dolsten, MD, PhD, Chief Scientific Officer and President, Worldwide Research, Development and Medical at Pfizer. “And while there is much that goes into making a successful medicine or vaccine, taking bold steps to safely accelerate development timelines of these innovations is the real difference-maker that our lightspeed mindset has had on our organization.”

Lightspeed includes searching for opportunities that upend the standard approach to clinical development in areas with a high unmet need, where Pfizer can make a big impact through our science, capabilities, and thoughtful risk-taking.

Lightspeed is how we instill a pioneering spirit across our teams so that we can keep pushing innovative thinking further and move at the speed of science.



Pfizer’s ability to move at “lightspeed” is enabled by our deep R&D transformation over the past decade, which can be seen through the COVID-19 vaccine development.

Leveraging lessons learned from the COVID-19 pandemic, we’ve solidified the lightspeed approach, which entails pulling multiple levers and deploying different strategies to move faster through the process for the benefit of all patients. While not all levers can be pulled for every program, there are certain elements that are at the core of the lightspeed paradigm and are being applied to key programs across our pipeline:

- **Parallel testing.** This is the ability to design multiple constructs or formulations of a therapy or a vaccine and test them in parallel studies so that the candidate with the best safety, tolerability and/or efficacy can be identified. Parallel instead of sequential testing is perhaps one of the most defining traits of lightspeed.
- **Expert dose selection.** It is important that our vaccines and therapies are meticulously designed and tested so that we are enabled to optimize safety, tolerability, and efficacy.
- **Streamlined governance for rapid decision-making.** A key tenet is to ensure there is a simplified governance model which allows decisions to be made nearly in real-time.
- **Investment at risk.** Guided by the urgency of the need and the ability to roll out certain medicines and vaccines

faster, Pfizer could invest in building up commercial manufacturing capabilities early in the development process, as was the case for the Pfizer-BioNTech COVID-19 Vaccine.

- **Faster regulatory collaboration.** We have witnessed significant regulatory innovation by regulators during the pandemic, which has opened doors to greater digital collaboration and global harmonization of standards to help drive innovation “at light speed.” There is now an opportunity for industry and regulators to emerge stronger than before by applying the lessons that this crisis has taught us and by proactively considering which of those learnings could be adopted permanently in regulatory practice to help create a more efficient and patient-centric “new normal.”

accelerate the development of our Phase 3 vaccine candidate for respiratory syncytial virus (RSV), currently being evaluated for both adults aged 60 and older and pregnant people to help protect their newborns. We look forward to applying the lightspeed approach across key Pfizer clinical programs in the pipeline to bring safe, effective treatments and vaccines to patients faster because we know they are waiting and every day matters.



Lightspeed is how we instill a pioneering spirit across our teams so that we can keep pushing innovative thinking further and move at the speed of science.

For instance, applying some of these principles, for our Phase 2b study of oral glucagon-like peptide-1 Danuglipron (PF-06882961) for type 2 diabetes mellitus (T2DM) and obesity, we were able to reduce clinical development timelines by 12 months. Similarly, the lightspeed mindset was applied to

<sup>1</sup> The Pharmaceutical Benchmarking Forum

Commercial

# A Team-First Approach to Patient Health

Investing strategically to address unmet needs and further serve patients around the world.

Achieving breakthroughs in health care requires constant attention to ensure care evolves alongside the people who rely on it. At Pfizer, we know that global health challenges are too great for any one company or organization to solve alone; to tackle them, we must coordinate tools and minds around the world, including from outside our own walls. Too often, innovations with the potential to change lives face roadblocks not because they lack promise but because innovators may not have access to the resources that can help them live up to their potential. Our decades-long expertise in investment and acquisition has focused on breakthrough products that strategically grow our portfolios, giving us a unique opportunity to identify promising medicines and help ensure more patients in need can access them as we grow.



Partnerships will support ongoing exploration into innovative treatment options for patients

In recent years, Pfizer's investments have supported innovation and product evolution, including preparation for potential approvals and product launches, and support for clinical trials. We are committed to strategically capitalizing on growth opportunities, primarily by advancing our own product pipeline and maximizing the value of our existing products, but also through various business development activities. We view our business development activity as an enabler of our strategies and seek to generate growth by pursuing opportunities and transactions that have the potential to strengthen our business and our capabilities. We assess our business, assets and scientific capabilities/portfolio as part of our regular, ongoing portfolio review process and also continue to consider business development activities that will help advance our business strategy.

We are committed to collaboration, with currently 40% of our portfolio externally sourced or enabled through partnerships at all stages of clinical and technological development and

ongoing business development. In October 2022, Pfizer acquired both Biohaven Pharmaceutical Holding Company Ltd. (Biohaven), a clinical-stage biopharmaceutical firm investigating new therapies for neurological conditions, and Global Blood Therapeutics (GBT), a company focused on the discovery, development and delivery of treatments for people living with sickle cell disease (SCD).

A key part of Pfizer's acquisition of Biohaven was its innovative migraine therapy, rimegepant. Approved for both acute treatment and prevention of episodic migraine in adults, rimegepant is part of a portfolio of promising calcitonin gene-related peptide (CGRP) assets and an ongoing example of Pfizer's patient-focused investment. Pfizer's acquisition of Biohaven is part of our long-term work in pain and women's health, and continued momentum from a 2021 strategic collaboration for the commercialization of rimegepant outside the U.S. Through access to Primary Care Physicians, specialists and health systems, Pfizer can support people living with migraine when they most need it. Our ongoing commitment to rimegepant's global success has helped bring an innovative new treatment option to the millions of patients around the world who live with migraine.

Pfizer's acquisition of GBT brings a portfolio and pipeline that has the potential to address the full spectrum of critical needs for the underserved SCD community, reinforcing Pfizer's commitment to SCD and building on a 30-year legacy in the rare hematology space. With GBT's talent, portfolio and pipeline now a part of the company, combined with the deep market knowledge and insights Pfizer has built along with its leading scientific and clinical capabilities, this acquisition will help accelerate innovation as we aim to bring potential breakthrough treatments to the SCD community as quickly as possible.

By providing access to global resources and scientific and market expertise, Pfizer helps ensure continuity of promising products and programs across industries, sectors and stakeholders. Our sustained success in supporting products through partnership and acquisition addresses some of the most diverse healthcare needs in the industry and cements Pfizer's role as a leader in areas including oncology, neurology, vaccines and antimicrobial resistance. With the expertise, capabilities and reach of an international biopharmaceutical company and the entrepreneurial spirit of a nimble biotech, we are uniquely positioned to help accelerate the next era of innovation through cutting-edge science and business reimagination.

Commercial

# Counterfeit Prescription Drugs: How Organizations are Combating the Sale of Fake Meds

In an expensive healthcare system, everybody wants more affordable medicine, but at what physical or emotional cost?

If you get caught in a medical fraudster's trap, that cost may be steep. By taking counterfeit prescription drugs (which look real but aren't), you not only run the risk of not receiving the benefits of the intended medication, but fakes can also harm you. Unsuspecting buyers may experience allergic reactions, overdose, or other adverse effects caused by unapproved ingredients.<sup>1</sup> Beyond the physical risks, they may also expose themselves to identity theft or financial fraud.

So how can you keep yourself and your family safe from fake meds? Start by learning as much as you can about counterfeit medicines: [what they are](#), where they're found, and what's being done to stop them.



Pfizer is committed to protecting the integrity of medications and putting an end to counterfeits.

## Organizations Tracking the Prevalence of Fake Meds

With counterfeit drugs, the packaging and design of the medicines may appear identical or nearly identical to a legitimate, approved drug that you were prescribed. However, the quality, storage, dosage, and/or ingredients may not be the same. Despite any claims you may see on the box,

counterfeits are not approved by the U.S. Food and Drug Administration (FDA).<sup>1</sup> This is why organizations are so eager to find them and root them out.

In the United States, the FDA works with other agencies as well as private companies to secure the supply chain of medical products. For example, one partnership between the FDA and the U.S. Customs and Border Protection helps to track and intercept counterfeit drugs coming from overseas. The FDA has also created industry standards as part of anti-counterfeiting initiatives, such as guidance about imprinting identifiers on pills, to help drug manufacturers differentiate the real stuff from the fakes.<sup>2</sup>

While the World Health Organization (WHO) has reported that it's difficult to determine exactly how many fake drugs exist, experts do know they're widespread: Counterfeits are found worldwide, from the Americas and Africa to Europe and Asia.<sup>3</sup>

Of all reported counterfeits worldwide, malaria and antibiotic medications are the most common at 19.6% and 16.9%, respectively.<sup>3</sup> One public health expert experienced fake antimalarials firsthand when he developed a dangerous form of malaria after buying an illegitimate drug abroad that turned out to contain just the common fever reducer we all know as acetaminophen.<sup>4</sup>

## Combating Counterfeits Through Technology and Partnerships

Pfizer is committed to protecting the integrity of medications and putting an end to counterfeits. As a participant in the nonprofit campaign [Fight the Fakes](#), Pfizer aims to help raise awareness and share the experience of individuals and families affected by fake drugs. For people looking to help with on-the-ground change, Fight the Fakes has hosted an annual campaign.

Pfizer also combats the sale of counterfeit drugs by building anti-counterfeiting laboratories. In these labs, teams continually evaluate new technologies to analyze increasingly

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complex counterfeits of Pfizer-produced drugs. Additionally, Pfizer's Global Security team partners with the law enforcement community to identify counterfeit medications and respond to reports of counterfeits.

Through these partnerships and using advanced lab equipment that helps determine drug authenticity, Pfizer has helped prevent over 302 million counterfeit doses from reaching patients since 2004.

### What You Can Do to Stop Counterfeit Drugs

Very often, medical fraudsters take advantage of people looking for a good discount on their medications. But there are safer ways to receive medications more affordably, such as asking for a discount card, requesting generics, or using mail-order programs through your insurance.

When looking for lower-priced medicines, be wary of any online drugstores that feature prices that seem too good to

be true or that don't make a licensed pharmacist available to answer questions.<sup>1</sup> Additionally, if buying online, [look for a National Association of Boards of Pharmacy \(NABP\) Verified Internet Pharmacy Practice Site \(VIPPS\)](#) and always check the pharmacy's license through their state agency: The FDA provides [links to each state's lookup tool](#).<sup>5</sup>

If you suspect you may have already taken a counterfeit medication, let your doctor know as soon as possible since counterfeits may lead to serious side effects, allergies, or other health problems. You can also [report the suspected counterfeit operation](#) directly to the FDA.<sup>6</sup>

Nobody should have to suffer just because they sought a good deal. Ask your doctor how to keep drugs more affordable without compromising your safety and help #FightTheFakes.

<sup>1</sup> How to buy medicines safely from an online pharmacy. U.S. Food and Drug Administration. <https://www.fda.gov/consumers/consumer-updates/how-buy-medicines-safely-online-pharmacy>. Last updated January 25, 2018. Accessed November 1, 2021.

<sup>2</sup> Counterfeit medicine. U.S. Food and Drug Administration. <https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine>. Last updated January 5, 2021. Accessed November 22, 2021.

<sup>3</sup> WHO global surveillance and monitoring system for substandard and falsified medical products. World Health Organization. [https://www.who.int/medicines/regulation/ssffc/publications/GSMReport\\_EN.pdf](https://www.who.int/medicines/regulation/ssffc/publications/GSMReport_EN.pdf). Published 2017. Accessed November 1, 2021.

<sup>4</sup> Breman JG. It's time to stop murder by counterfeit medicine. STAT. <https://www.statnews.com/2019/05/07/stopping-murder-counterfeit-medicine/>. Published May 7, 2019. Accessed November 1, 2021.

<sup>5</sup> Know your online pharmacy. U.S. Food and Drug Administration. <https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/know-your-online-pharmacy#Pacific>. Published 2019. Accessed November 1, 2021.

<sup>6</sup> Reporting unlawful sales of medical products on the internet. U.S. Food and Drug Administration. <https://www.accessdata.fda.gov/scripts/email/oc/buyonline/english.cfm>. Last updated November 21, 2019. Accessed November 1, 2021.

Pfizer Global Supply

# Our Humanitarian Efforts and Response to the Crisis in Ukraine

Pfizer stands in opposition to the Russian war in Ukraine and is committed to contributing to humanitarian efforts.

At Pfizer we, like many around the world, are deeply concerned by the human suffering we all are witnessing during the ongoing war in Ukraine. [We stand with the unified global community across the public, private, and civil society sectors in opposition to the Russian treatment of the people of Ukraine](#) and are committed to contributing to ongoing humanitarian efforts and to ensuring the safety of our colleagues and their families. We are equally determined to facilitate continued access to our medicines and vaccines for patients and have made significant progress to this end, activating several humanitarian efforts and we continue to expand our support.



Inside of cargo airplane to Ukraine carrying medical supplies - Photo courtesy of Charity Fund Modern Village and Town (Direct Relief)

To date, we have committed to donating \$30 million through The Pfizer Foundation\* to causes supporting the Ukrainian people. This includes grants derived from [Pfizer's decision to halt its investments in Russia and donate the equivalent of profits from our Russian subsidiary](#) to causes that provide direct humanitarian support to the people of Ukraine.

The Foundation has approved grants for 12 non-governmental organizations (NGOs), including six local organizations in Poland and Ukraine, to support humanitarian relief and response efforts. This includes food security and support services, shelter, education for children, and other pressing needs of the people of Ukraine.

Through The Pfizer Foundation, we have also launched the Ukraine Humanitarian Disaster Campaign matching financial donations already made by thousands of Pfizer colleagues around the world to support organizations. Including The Pfizer Foundation's dollar-for-dollar match, the total donation is U.S. \$1.86 million.

Pfizer is also responding to the immediate need for access to life-saving medicines through targeted product donations to Ukraine and organizations supporting the Ukrainian people including over 1 million doses of Pfizer products to help healthcare providers and relief workers treat patients in Ukraine and neighboring countries.

In partnership with the U.S. Government and USAID, almost 2 million donated doses of the Pfizer/BioNTech COVID-19 vaccine have now reached Ukraine and [we are one of the largest donors to Direct Relief](#). We have also delivered nearly 200,000 courses of PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets).



Man and woman unloading truck with medical supplies for Ukraine - Photo courtesy of Charity Fund Modern Village and Town

## Direct Relief:

"Direct Relief is deeply grateful to Pfizer for its leadership and commitment reflected in this donation for the people of Ukraine. Pfizer's support is a wonderful example of what's



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needed to address this unfolding humanitarian crisis—an infusion of much needed health essentials for the millions of families who have had their lives upended while the health system they rely on has been severely damaged and made them much more vulnerable and facing an uncertain future," said Thomas Tighe, Direct Relief President and CEO.

**Pfizer Ukraine Country Manager:**

"It is hard to express in words just how proud I am of my team here in Ukraine, who have shown unbelievable resilience and an unwavering dedication to putting patients first, even during the most challenging time in Pfizer Ukraine's history. But we have not been alone; there have been countless colleagues from the surrounding countries and all around the world who have supported my team and my country.

From so many donating to The Pfizer Foundation's Ukraine Humanitarian Disaster Campaign—which thanks to matching financial donations has raised almost \$2 million—or colleagues in neighbouring countries offering to support displaced individuals, through to whole cross-functional teams working round clock to support and protect colleagues on the ground and ensure the continued supply of medicines. This show of unity and commitment to people and patients has been so critical. During the pandemic, I thought I could not be more proud to work for Pfizer—but the company's support during this time makes me even more proud. The millions of product donations arranged and the \$30 million of humanitarian support committed by the Pfizer Foundation has and will continue to, quite literally, save lives," said Zoriana Tsilyk, Ukraine Country Manager, Pfizer.

*PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.*

*The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.*

*\* The Pfizer Foundation is a charitable organization established by Pfizer Inc. It is a separate legal entity from Pfizer Inc. with distinct legal restrictions.*

Pfizer Global Supply

# An Accord for a Healthier World

Bringing industry, governments, and global health stakeholders together to close the health equity gap.

We live in a time when science is increasingly demonstrating the ability to take on the world’s most devastating diseases. Unfortunately, there exists a tremendous health equity gap in our world that too often determines who can access innovations—and who cannot. Equity is a core Pfizer value that drives our people and our work every single day. We believe better health is possible for everyone everywhere, and that all people deserve access to quality healthcare. It is this drive that led us to launch An Accord for a Healthier World, a new breakthrough initiative working to close the health equity gap.



An Accord for a Healthier World: Doctor examines child

Through this groundbreaking initiative, launched at the World Economic Forum in Davos, Switzerland in May 2022, we came together with leaders from Rwanda, Ghana, Malawi, Senegal, Uganda and the Bill & Melinda Gates Foundation to announce we will work towards sustained, equitable access of medicines and vaccines for 1.2 billion people living in 45 lower-income countries that have historically been most vulnerable to healthcare inequalities. Alongside governments and global health organizations, the Accord aims to co-create scalable solutions to address systemic barriers that often limit or prevent equitable access. We are focused on working together to find faster, more efficient pathways for supply of medicines and vaccines as well as strengthening the resources, capabilities and platforms that can enable quicker and more efficient access to healthcare innovation.

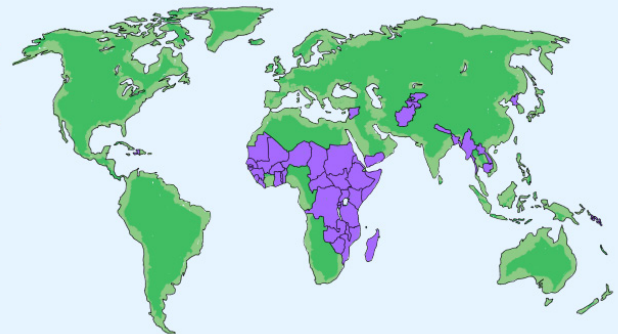
With the launch of the Accord in May 2022, Pfizer committed to provide all its patented medicines and vaccines available in the U.S or EU—both current and future products—on a not-for-profit basis to the 45 lower-income countries. Understanding that product supply is only one part of this challenge, we also put forth the call to action to global health leaders around the world to work with us and these governments to find new ways to remove access barriers and help ensure that these medicines and vaccines can reach those who need them.

We immediately began engagement with a number of Accord-eligible countries, including Rwanda, Malawi, Ghana

and Senegal, to identify the needs and opportunities for sustainable access. Within the first four months of the launch, Rwanda became the first country to procure products through the Accord, receiving nine medicines and vaccines that can help treat life-threatening infectious diseases, inflammatory diseases and certain cancers. Pfizer and the Rwanda Ministry of Health have also begun working together to provide professional healthcare education and training, and in November, Pfizer deployed a Global Health Team to the country to help identify opportunities for long-term supply chain optimization.

## Geographic Scope

Initiative includes ALL low-income countries and 18 lower-middle-income countries that transitioned from low-income classification in the last 10 years, as defined by the World Bank.



Afghanistan*	Guinea-Bissau	Senegal
Bangladesh	Haiti	Sierra Leone
Benin	Kenya	Solomon Island
Burkina Faso	Kyrgyzstan	Somalia
Burundi	Laos	South Sudan
Cambodia	Liberia	Sudan*
Central African Republic	Madagascar	Syria*
Chad	Malawi	Tajikistan
Comoros	Mali	Tanzania
Congo DR	Mauritania	Togo
Eritrea	Mozambique	Uganda
Ethiopia*	Myanmar*	Yemen
Gambia	Nepal	Zambia
Ghana	Niger	Zimbabwe*
Guinea	North Korea*	Rwanda

**Rwanda, Ghana, Malawi, Senegal and Uganda** are the first five countries to commit to join the Accord and solutions identified will then be leveraged for **faster enrollment and access in all 45 countries.**

\*Supply contingent upon compliance with applicable laws including any required sanctions and export control licenses or other authorizations.

"In partnership with Pfizer and 'An Accord for a Healthier World', we are proud to provide rapid and affordable access to these Pfizer medicines and vaccines, which have the power to save and improve patient lives all across Rwanda," said The Minister of Health, Dr. Daniel Ngamije. In these early engagements with country governments, we also heard resoundingly, that there is an immediate need for consistent access to a broader scope of high-quality products. Based on this feedback and our commitment to address unmet patient needs, in early 2023, Pfizer expanded on its initial commitment to offer all patented medicines and vaccines available in the U.S. or EU to now include the full portfolio for which we have global rights. This expanded portfolio offering will include off-patent medicines as well, bringing the product offering from 23 to nearly 500 products that can help to treat or prevent many of the greatest infectious and non-communicable disease threats faced today in lower-income countries. Nearly 40% of the medicines and vaccines now offered appear on the World Health Organization's list of essential medicines. And as Pfizer introduces new medicines and vaccines, those products will also be included in the Accord portfolio.

We will continue to call upon governments, global health leaders and industry who share our vision to join in this

breakthrough effort and to work with us to address access barriers and help to close the health equity gap.

"Only when all the obstacles are overcome can we end healthcare inequities and deliver for all patients," said Pfizer Chairman & Chief Executive Officer Albert Bourla.



Albert Bourla in Davos.

<sup>1</sup> [Pfizer Launches 'An Accord for a Healthier World' to Improve Health Equity for 1.2 Billion People Living in 45 Lower-Income Countries | Pfizer](#)

<sup>2</sup> [Pfizer commits to providing patent-protected medicines at cost in Africa | World Economic Forum \(weforum.org\)](#)

<sup>3</sup> [An Accord for a Healthier World | Pfizer](#)

COVID-19

# Taking PAXLOVID® (nirmatrelvir tablets and ritonavir tablets) from the Lab to Patients to Combat COVID-19

Pfizer is working to enable broad access to PAXLOVID worldwide and evaluate the treatment for more who may benefit.

## PAXLOVID as a tool in the fight against COVID-19

As COVID-19 continues to evolve, PAXLOVID (nirmatrelvir tablets and ritonavir tablets) has shown to be an important complementary tool to vaccination strategies for the estimated 40% of the global adult population at high risk for progressing to severe disease.<sup>1</sup> PAXLOVID has shown efficacy, a consistent safety profile, and the potential to help mitigate the financial burden of COVID-19 on patients and their families, health systems, and society.<sup>2,3</sup>

As societies grapple with how to live with COVID-19, efforts to reduce the ongoing impact are vital to managing the pandemic over the long term and transforming it into a manageable, endemic disease. In January 2022, Pfizer announced an agreement that provided the U.S. government with 20 million PAXLOVID treatment courses in 2022,<sup>4</sup> and in December announced an additional 3.7 million treatment courses to be provided by early 2023.<sup>5</sup> The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) also recognized the potential value of PAXLOVID, granting a conditional marketing authorization. PAXLOVID is currently approved or authorized for conditional or emergency use in more than 70 countries to treat COVID-19.<sup>6</sup>



Pharmacist explaining a prescription to the patient.

## Pfizer's Commitment to Access

Pfizer has continued to look for opportunities to partner with global health leaders to expand access to PAXLOVID. As of

December 31, 2022, Pfizer has shipped 39 million treatment courses to 60 countries around the world\*, continuously working with the World Health Organization-led COVID-19 Tools Accelerator (ACT-A) partners to enable supply to low- and middle-income countries. This includes an agreement with UNICEF for up to 4 million treatment courses for 137 countries and an agreement with Global Fund for up to 6 million treatment courses for 132 countries, subject to local regulatory approval or authorization.<sup>7,8</sup> Pfizer also launched '[An Accord for a Healthier World](#)' to support worldwide access to PAXLOVID, as well as other Pfizer medicines and vaccines, on a not-for-profit basis to 45 lower-income countries.<sup>9</sup> Because product supply is only one step towards improving access, and treatment with PAXLOVID requires a positive COVID-19 test within five days of symptom onset, Pfizer has also joined the Quick Start consortium, an initiative led by Duke University, the Clinton Health Access Initiative (CHAI), COVID Collaborative, and Americares that is focused on rapid scale-up of test and treat capabilities in under-resourced countries.<sup>10</sup> Pfizer is providing donated product and financial support for pilots in 10 countries in Africa and Southeast Asia.

"We are dedicated to helping ensure that everyone at increased risk for becoming seriously ill, no matter where they live, has access to this important treatment option," said JoyL Silva, U.S. Commercial and Global Business Lead, Antivirals.

To further expand access to oral treatment worldwide, Pfizer signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) to facilitate the production and distribution of generic versions of the oral treatment for supply to 95 low- and middle-income countries. MPP has sub-licensed to 37 generic manufacturers who will produce low-cost, generic versions that will be available to approximately 53% of the world's population, subject to local regulatory approval or authorization.<sup>11</sup>

## The Future of PAXLOVID

In parallel to expanding access in 2022, Pfizer progressed the PAXLOVID clinical development program, continuing to explore opportunities to evaluate its potential in vulnerable populations, including children and those who

\* This figure includes treatment courses distributed to customers as well as those stored and ready for distribution.

are immunocompromised and for long COVID. A New Drug Application (NDA) to the U.S. Food and Drug Administration for PAXLOVID for patients who are at high risk for progression to severe illness from COVID-19 is under review.

As COVID-19 evolves,<sup>12</sup> we will continue aiming to stay ahead of the virus, advancing promising science with a multi-pronged strategy that we believe will help serve patients in need. We're proud of the hard work of our colleagues that has contributed to our progress in combatting the virus, and we remain steadfast in these efforts as we prepare for what's ahead.



Packing PAXLOVID to be distributed.

*PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.*

*The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner*

<sup>1</sup> Clark A, Jit M, Warren-Gash C, et al. Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: A modelling study. *The Lancet Global Health*. 2020;8(8):1003-1017. doi:10.1016/s2214-109x(20)30264-3

<sup>2</sup> Pfizer Announces Additional Phase 2/3 Study Results Confirming Robust Efficacy of Novel COVID-19 Oral Antiviral Treatment Candidate in Reducing Risk of Hospitalization or Death. (2021, December 14). *Pfizer*. Retrieved November 1, 2022, from <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-additional-phase-23-study-results>.

<sup>3</sup> Rickard Sandin, Cale Harrison, Florin Draica et al. Estimated Impact of Oral Nirmatrelvir;Ritonavir on Reductions in Hospitalizations and Associated Costs within High-Risk COVID-19 Patients in the US, 30 November 2022, PREPRINT (Version 1) available at Research Square <https://doi.org/10.21203/rs.3.rs-2191067/v1>.

<sup>4</sup> Pfizer to Provide U.S. Government with an Additional 10 Million Treatment Courses of its Oral Therapy to Help Combat COVID-19. (2022, January 4). *Pfizer*. Retrieved October 27, 2022, from <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-provide-us-government-additional-10-million>.

<sup>5</sup> Pfizer to provide U.S. government with an additional 3.7 million treatment courses of PAXLOVID™ to help combat covid-19. *Pfizer*. (2022, December 13). Retrieved December 20, 2022, from <https://www.pfizer.com/news/announcements/pfizer-provide-us-government-additional-37-million-treatment-courses-paxlovidtm>

<sup>6</sup> Covid-19: EMA recommends conditional marketing authorisation for Paxlovid. European Medicines Agency. (2022, January 28). Retrieved October 31, 2022, from <https://www.ema.europa.eu/en/news/covid-19-ema-recommends-conditional-marketing-authorisation-paxlovid>

<sup>7</sup> UNICEF signs supply agreement with Pfizer for oral COVID-19 treatment. (2022, March 22). UNICEF. Retrieved October 27, 2022, from <https://www.unicef.org/liberia/press-releases/unicef-signs-supply-agreement-pfizer-oral-covid-19-treatment>.

<sup>8</sup> The Global Fund Signs Agreement with Pfizer to Expand Access to PAXLOVID™ Antiviral. (2022, September 22). The Global Fund. Retrieved October 27, 2022, from <https://www.theglobalfund.org/en/news/2022/2022-09-22-the-global-fund-signs-agreement-with-pfizer-to-expand-access-to-paxlovid-antiviral/>.

<sup>9</sup> Covid Treatment Quick Start Consortium. COVID Collaborative. (2022, September 7). Retrieved October 31, 2022, from <https://www.covidcollaborative.us/initiatives/quickstart-consortium#:~:text=%E2%80%9CThe%20Quick%20Start%20Consortium%20is,as%20the%20subvariant%20Omicron%20BA>.

<sup>10</sup> Covid Treatment Quick Start Consortium. COVID Collaborative. (2022, September 7). Retrieved October 31, 2022, from <https://www.covidcollaborative.us/initiatives/quickstart-consortium#:~:text=%E2%80%9CThe%20Quick%20Start%20Consortium%20is,as%20the%20subvariant%20Omicron%20BA>.

<sup>11</sup> 35 generic manufacturers sign agreements with MPP to produce low-cost, generic versions of Pfizer's oral covid-19 treatment nirmatrelvir in combination with ritonavir for supply in 95 low- and middle-income countries. Medicines Patent Pool. (2022, March 17). Retrieved October 31, 2022, from <https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and>

<sup>12</sup> COVID-19 Dashboard. World Health Organization. Retrieved January 24, 2023, from <https://covid19.who.int/>.

COVID-19

# Vaccine Boosters: A Year in Review for Our COVID-19 Vaccination

While Omicron-adapted vaccines were being developed, our original COVID-19 vaccine finds new life in booster doses and as first-line protection for the very young.

At the start of 2022, the Omicron variant was causing the greatest surge of COVID-19 cases yet.<sup>1 2</sup>

Fortunately, just days into the new year, the U.S. Food and Drug Administration (FDA) granted our request for emergency use [authorization](#) of a booster dose of our original COVID-19 vaccine for ages 12 years and older. The development and testing of new vaccines tailored specifically to the Omicron variant were underway here at Pfizer, but another solution was needed in the meantime. We would need to use our existing tools to help protect people of all ages against this persistent viral threat.

In March 2022, an additional (fourth) booster dose was authorized for anyone over the age of 65—a limit that was subsequently [lowered to age 50](#)—to help protect those at higher risk of developing severe COVID-19 disease.

In April 2022, the FDA [authorized](#) boosters for 5 through 11 years of age as well. During this time, a Phase 2/3 clinical trial was also underway to test a lower-strength version of our original COVID-19 vaccine as a three-dose primary series for children six months to under 5 years of age. With promising immune response data, the FDA granted an emergency use [authorization](#) for this age group in June.

“Between widespread pandemic fatigue and a leap in viral evolution, 2022 has not been an easy year as we continue to fight COVID-19, but I believe we at Pfizer have risen to the challenge,” said Dr. Albert Bourla, Pfizer Chairman & Chief Executive Officer.



Manufacturing of COVID-19 vaccine booster

*Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.*

<sup>1</sup> World Health Organization. WHO Coronavirus (COVID-19) Dashboard. Available at: <https://covid19.who.int>

<sup>2</sup> Keyel AC, Russell A, Plitnick J, et al. SARS-CoV-2 Vaccine Breakthrough by Omicron and Delta Variants, New York, USA. Emerg Infect Dis. 2022;28(10):1990-1998. doi:10.3201/eid2810.221058

COVID-19

# Evolving with the Virus

While Omicron was surging around the world, we were retooling our arsenal.

The emergence of the Omicron variant in late 2021 presented a real-world test of the agility and manufacturing speed of mRNA vaccine technology.

In January 2022, a mere two months since the Omicron variant was first identified and sequenced in South Africa,<sup>1</sup> we began a Phase 2/3 clinical [trial](#) investigating new vaccine candidates based on the Omicron BA.1 variant, which was rapidly outpacing other variants circulating at the time.<sup>2</sup>



Manufacturing of COVID-19 vaccine

But by the time these vaccines demonstrated positive clinical [results](#), the Omicron BA.4 and BA.5 subvariants had splintered off and gained a foothold. Once again, we leaned on the mRNA platform technology to swiftly create a new vaccine candidate based on these emerging subvariants and began pre-clinical testing.

Having established a global manufacturing and supply chain network demonstrably adept at ramping up novel vaccine production to meet worldwide demand, we were ready to move forward with vaccines targeting either BA.1 or BA.4/BA.5 variants.

*Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.*

<sup>1</sup> Viana, R., Moyo, S., Amoako, D.G. et al. Rapid epidemic expansion of the SARS-CoV-2 Omicron variant in southern Africa. *Nature* 603, 679–686 (2022). <https://doi.org/10.1038/s41586-022-04411-y>

<sup>2</sup> World Health Organization. Two years on, we could be entering a new phase in the pandemic with plausible hope for stabilization, yet too early to drop our guard. <https://www.who.int/europe/news/item/24-01-2022-two-years-on-we-could-be-entering-a-new-phase-in-the-pandemic-with-plausible-hope-for-stabilization-yet-too-early-to-drop-our-guard>

## Values

# Pfizer Refugee Leadership Initiative: Seen, Heard, and Cared For

Helping refugees rebuild their careers and homes as they contribute their much-valued skills and experiences.

We have all seen images of refugees whose lives have been upended by forces beyond their control, fleeing their homes for safety. Watching it as it unfolds means we have a choice to make: do nothing or find a way to help refugees rebuild their careers and their homes. Pfizer chose the latter.

We take pride in hiring the best qualified talent so we can achieve breakthroughs that change patients' lives. Since many refugees have the talent and skills we are looking to hire, in late 2021, the Pfizer Refugee Leadership Initiative was created. To jumpstart the work, we joined the Tent Coalition for Afghan Refugees and later expanded the program to refugees from Ukraine and other refugees in need.

Our first hire, Mohammad Afzal Afzali, was a Chief of Staff at a university in Afghanistan and a translator for the U.S. Embassy. He had to leave Afghanistan with his family at a moment's notice, and he finally joined Pfizer and settled in Texas. Throughout Pfizer, from the U.S. to Greece, Germany, Belgium, Italy, and other offices, we have seen an outpouring of support for the program. We hired more than 100 refugees in 2022 and have also announced our expanded aspirational goal of hiring 500 qualified refugees in the U.S. in the next three years. In addition, we committed to mentoring 300 refugees through 2025, 50 of whom are from the LGBTQ+ community.

In April 2022, Dr. Albert Bourla, Pfizer Chairman & Chief Executive Officer, and 34 other CEOs launched the Welcome.US CEO Council, pledging more than \$75 million to support refugee resettlement organizations and non-profits to welcome Afghan and Ukrainian refugees coming to the U.S.

Since the Pfizer Refugee Leadership Initiative's inception, Payal Sahni, Pfizer's Chief People Experience Officer, has been a champion of the program. An Afghan refugee herself, she understands the importance of having access to opportunities and has made it her life's calling to pay it forward and open doors for others. She now serves as a member of the Tent Advisory Council.

"The Pfizer Refugee Leadership Initiative opens up an untapped talent pool with amazing talent. Many managers have shared positive feedback on the refugee hires' performance and work ethic. They have proven a diverse workforce and an inclusive environment are not only the

right things to do but also a winning business strategy," said Ramcess Jean-Louis, Pfizer's Chief Diversity, Equity and Inclusion Officer.



A joyful day at the Pfizer 2022 World Refugee Day event.

"The Pfizer Refugee Leadership Initiative is not a hand-out. These refugee hires have earned the opportunity and deserve to be here. We see the value they bring to the table and we, Pfizer, welcome their diverse perspectives and contributions. We always hire the most qualified candidates to ensure that candidates are in positions that reflect their education, skills and experiences," said Mona Babury, Pfizer Director of Diversity, Equity and Inclusion and also the colleague who came up with the idea and built the initiative from scratch.

We have seen amazing work from our refugee hires. We also want them to have peace of mind knowing they have joined a workforce where they are seen, heard, and cared for and find a true sense of community at Pfizer.



Values

# With Patients. For Patients: Our Unwavering Focus on Patient Centricity

Recent top PatientView recognition and Patients in Focus Week activities demonstrate Pfizer's commitment to patients globally.

Every year, Patient Engagement Leads across Pfizer collaborate with hundreds of Patient Advocacy Groups around the world to advance shared goals and better support the needs of patients everywhere. Pfizer's Global Patient Advocacy team contributes to Pfizer's end-to-end advocacy strategy by supporting teams to drive deep therapeutic and regional relationship models with patient advocacy groups. These partnerships can help improve patient outcomes by increasing patient engagement in research and development, elevating priority policy and social impact issues, creating meaningful resources and programs that provide value to patients and more.



Patients in Focus Town Hall, Pfizer Spain. From left to right: Carlos Murillo, Spain Country President, Pfizer; Mario Torbado, Regional Lead, Global Patient Advocacy, Europe, Pfizer; Daniel Gallego, President, European Kidney Patients Federation; Ana Castellanos, Coordinator and Project Manager, Plataforma de Organizaciones de Pacientes; Roberto Saldaña, Director of Innovation, EUPATI Spain

## PatientView Corporate Reputation in Pharma Survey

In 2021, Pfizer was recognized as the most patient-centric organization among the world's largest pharmaceutical companies, according to the PatientView Corporate Reputation of Pharma Survey. The survey, reaching more than 2,150 patient advocacy groups across 90 countries, measures their perceptions of pharma companies across nine indicators, including transparency, patient safety, quality information, integrity, support for patients and more. Pfizer colleagues use the feedback shared by advocates to further enhance our strategy for sustaining respectful, equitable, impactful, and culturally appropriate relationships with advocacy groups that help improve patient outcomes.

## Patients in Focus Week

In October, we hosted our second annual Patients in Focus week, themed "With Patients. For Patients." The week is a dedicated time for global Pfizer colleagues to reflect on the impact patients and advocates have on our work. Colleagues

heard directly from patients and advocates in their local communities and met with Patient Engagement Leads who showcased best-in-class examples of patient advocacy and engagement.

Pfizer leaders kicked off the week by sharing our definition of patient centricity, co-created with colleagues, patients, and advocates.

**Patient centricity exists at Pfizer when we listen and learn from the patient perspective, acting as partners with accountability and integrity to deliver outcomes that matter most to patients and those involved in their care.**



Pfizer Hong Kong colleagues visit Rare Disease Hong Kong, a local patient group supporting cross-rare disease patients and their families, during Patients in Focus

From left to right: Krishnamoorthy Sundaresan, Pfizer Hong Kong Country Manager; Kin Ping Tsang, Chairman, Rare Disease Hong Kong and President, Retina Hong Kong and guide dog Vinny; Kelly Fung, Patient Experience Partner, Pfizer Hong Kong

During the kickoff, Dr. Albert Bourla, Pfizer Chairman & Chief Executive Officer and Aida Habtezion, Pfizer Chief Medical Officer, answered questions from advocacy groups about how we are involving patients from the earliest stage of research and drug development to the final approval of our medicines and vaccines.



Pfizer Global Supply colleagues in Vizag, India celebrate Patients in Focus Week  
 Pictured from left to right: Sreenivas, Procurement Lead; Rajesh, Finance Lead; Rachna, CQ Lead; Satjeet, Digital Lead; Vikram, Site Head; Amar, Warehouse Lead; Rajesh, Automation and Instrumentation Lead; Vrushal, RA Lead; Vamsi, Quality Compliance Lead

Throughout the week more than 40,000 colleagues, from across 30 countries, attended patient panels and advocacy lunch-and-learns, blood drives and community volunteering initiatives, and health equity workshops, to name a few. Some Pfizer sites painted murals to display at nearby rehabilitation centers; others matched donations for local patient groups. No matter the event, colleagues reported a greater sense of connectedness, pride in their work, and a deeper understanding of the importance of patient advocacy and engagement.



## Values

# Pfizer at Essence Fest: Celebrating and Connecting with the Black Community

Be where the community is. Listen. Learn. That's how we raise awareness about the importance of vaccinations.

Advancing equitable health outcomes is one of the key pillars of Pfizer's Diversity, Equity, and Inclusion (DEI) strategy. To bring about real change in underserved communities, we must go where they are, listen to their needs, and connect with them in a relatable way. That's why Pfizer went all in at the 2022 Essence Festival of Culture, the largest African American culture and music event in the U.S. celebrating Black women. After a two-year hiatus due to the pandemic, the festival returned with a vengeance this year. More than half a million people gathered in New Orleans, where multigenerational Black women shared and bonded over important topics, including personal development, wealth creation, civic engagement, and community leadership. This year, Pfizer was a part of the conversation.



Pfizer brand ambassadors Deonna Smith, Sandy Jaquez, William Smith, K. Micolle Moffett at our Essence Fest booth.

With the pandemic still affecting every part of society, vaccine hesitancy in the Black community remained a challenge. We wanted to have conversations with the community where they felt safe and understood and address their concerns with transparency and respect.

We sponsored a panel discussion featuring global singer and songwriter, Kelly Rowland from supergroup Destiny's Child, macro influencer and former pharmacist, Brittney Fusilier, and pediatrician, Dr. Kersha Pennicott. The panelists discussed their personal experiences and the choices they made surrounding their family's health amid COVID-19. We continued the conversation with the festival participants at our Pfizer booth located in the Essence Health Hub. We intentionally chose not to have any Pfizer vaccine branding. Visitors to the booth participated in an interactive quiz on Essence Festival, Black History, and COVID-19 and received educational resources on COVID-19 and the importance of vaccinations including boosters.

We also partnered with micro influencers—Lauren Wilson, Madelyn Brené, and Titilola-Sogunro—to help spark social media conversations on COVID-19 vaccinations and encourage attendees to visit the booth and meet Pfizer colleagues. Ramcess Jean-Louis, Pfizer's Chief Diversity, Equity, and Inclusion Officer, members of the Global Black Community colleague resource group, and leaders from across Pfizer were there to share their own unique experiences with festivalgoers.

"Women are often what we call the 'Chief Health Officers' of their families," said Zainab Wasti, Pfizer's U.S. COVID-19 Vaccine Consumer Experience Lead. "Being at Essence was such an important opportunity to meaningfully connect with Black women who are at the center of making healthcare decisions for themselves, their children, and their parents. We listened to their stories and we learned. And we will continue to do so in order to better serve them."

"So many women watched our panel and came to our booth sharing the impact that vaccinations have had on their lives," said Kathryn Simmons, Pfizer Area Business Manager, Internal Medicine. "Being able to see one another in person, to look one another in the eye, helped us build trust. I'm overjoyed that we were able to make this moment happen for so many Black women who represent the communities we serve across the country."

"At Pfizer, we believe we should all feel seen, heard, and cared for. We should feel safe to connect with one another as human beings, with respect and honesty. Partnering with Essence Fest

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gave us an amazing opportunity to celebrate Black women and Black health, wealth, beauty, joy, culture, and purpose,” said Ramcess Jean-Louis. “It was often overwhelming to hear the attendees of the festival come to our booth, some in tears, to express their gratitude, describe their journeys, and reflect on the role that Pfizer and the vaccine have played for them and their loved ones. We were able to make so many connections and show up authentically as a trusted partner and ally in the community.”

Pfizer plans to continue its sponsorship of Essence Festival again in 2023 and will continue to engage the community where they are.

Digital

# Data and AI are Helping to Get Medicines to Patients Faster

Digital innovation helps deliver COVID-19 oral treatment, PAXLOVID® (nirmatrelvir tablets and ritonavir tablets), to patients.

Data, Artificial Intelligence (AI), and supercomputing are accelerating innovation across Pfizer—from discovery to clinical development, manufacturing, distribution, and commercialization—to help bring medicines to patients in need faster than ever before. This was certainly the case with PAXLOVID, Pfizer's COVID-19 oral treatment.

In research and discovery, supercomputing capabilities paired with advanced computational methods helped Pfizer scientists optimize their search for the right molecules to be able to deliver PAXLOVID orally rather than intravenously. This was a game-changer because it meant that patients could take the treatment at home rather than in a hospital setting, which has significantly increased access to treatment for millions of people around the world.



Data, Artificial Intelligence (AI), and supercomputing are accelerating innovation across Pfizer.

AI and machine learning (ML) capabilities also played a key role in running Pfizer's PAXLOVID clinical trials, enabling the team to perform quality-checks and analyze vast amounts of patient data 50% faster than before. Building on this success, AI and

ML capability are used in more than half of all Pfizer's clinical trials.

Pfizer colleagues have also leveraged data and AI to optimize the manufacturing of PAXLOVID, by analyzing supply chain data to identify, address, and monitor issues in production, creating a system of continuous improvement. In one case, the cycle time of a critical step in the supply chain was able to be reduced by 67%, which enabled the production of 20,000 extra doses per batch. With the predictive capabilities of AI, Pfizer can manufacture more medicines to benefit even more patients around the world.

The last important step has been to ensure that patients in need receive treatment in a timely manner. One of the biggest challenges many countries face is underreporting of COVID-19 infection rates. In the U.S., for example, Pfizer applied advanced analytics to analyze wastewater data provided by the Center for Disease Control, validating that infection rates around the country were much higher than had been reported through standard testing. And going deeper, Pfizer scientists have analyzed diagnosis and treatment rates and data from healthcare professionals, to identify and understand where disparities in treatment exist.

These data-driven efforts to identify underserved communities and barriers to treatment access have helped Pfizer engage in informed discussions with governments as they work to improve patient access to diagnosis and treatment. In the U.S., this has helped build the case for government initiatives such as mobile testing sites and authorizing state-licensed pharmacists to prescribe treatments for eligible patients, with certain limitations.

Thanks to the power of data and AI, Pfizer is not only developing more breakthroughs like PAXLOVID, faster than ever before but also increasing the potential for patients to access the breakthroughs they need.

*PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.*

*The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.*

## Digital

# Harnessing Digital Health Solutions to Improve Patients' Lives

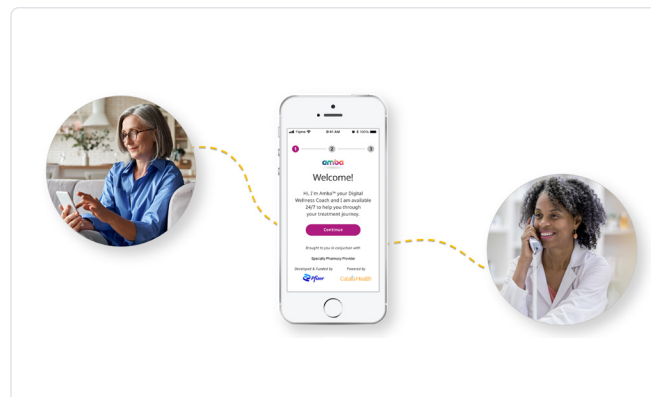
Embracing AI-based technology to provide treatment support for patients with breast cancer.

Digital technology is rapidly changing the world of healthcare, and at Pfizer, we are harnessing this technology to live our purpose: breakthroughs that change patients' lives. This includes providing digital health solutions that support patients when they need help the most—during their treatment journeys.

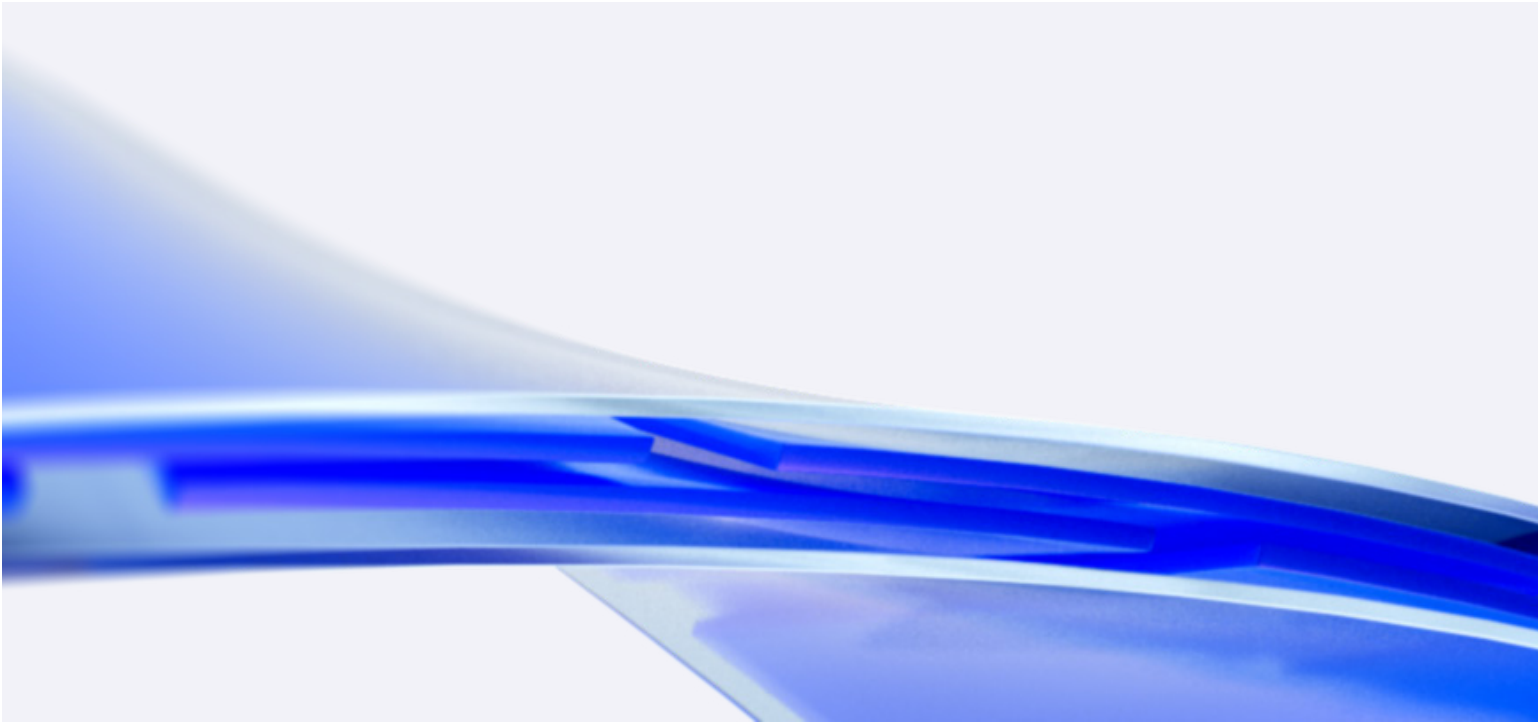
In 2022, we partnered with Walgreens to launch the Amba™ Digital Wellness Coach, an artificial intelligence (AI)-based mobile app that aims to support patients who have been prescribed IBRANCE® (palbociclib) for the treatment of metastatic breast cancer. When patients receive their first prescription from a Walgreens community-based specialty pharmacy, they can enroll in the app, which provides relevant education, tips, self-scheduled medication reminders, a connection with their social support network, and other useful resources as they begin their treatment. Amba can also alert the pharmacy that a patient may need outreach from the pharmacist.

Digital companions such as Amba are designed to help patients understand their medication and provide information in patient-friendly language to help minimize confusion and identify supportive resources. Over time, we anticipate that the AI capabilities developed by Catalia Health, which are a core part of the Amba app, will provide a more personalized patient experience, and we also are monitoring the program to see if it could apply to other therapeutic areas. We see this as a major step forward in the effort to use the power of digital technology to support patients.

At the heart of this effort is Pfizer's abiding commitment to putting patients first. We know that there is so much more we can do to support patients in their treatment journeys, and we are proud to help lead the way for them, into the future of digital health.



Digital companions such as Amba™ help patients understand their medication and provide information in patient-friendly language to help minimize confusion and identify supportive resources.



# Living Our Values

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Our Environmental, Social, and Governance performance helps us to deliver on our purpose every day.

Learn more about our progress on our goals in our [ESG report](#).

# A Closer Look at ESG

## Environment

The health of our global environment impacts everyone. At Pfizer, we are committed to reducing our environmental footprint. Our company purpose—*Breakthroughs that change patients' lives*—guides our environmental priorities, with a focus on impact reduction, conservation of resources, and the minimization of waste arising from our operations.



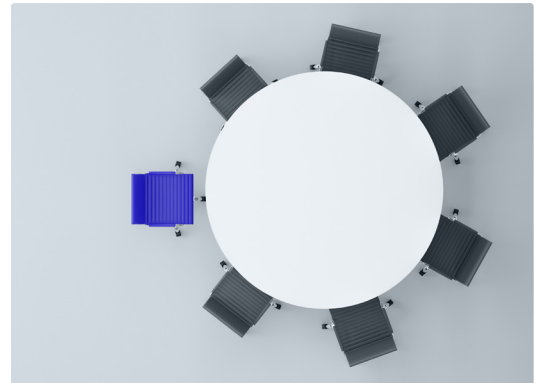
## Social

At Pfizer, our purpose—*Breakthroughs that change patients' lives*—is rooted in achieving social good. We know that when we succeed, our breakthroughs can potentially have life-changing effects. We aim to be the solution for illnesses from widespread infectious diseases to conditions with historically unmet need.

Pfizer is mindful of the urgency of our mission, as the world fights against the spread of deadly new diseases and struggles with inequities in health outcomes among populations. Our goal is to leverage partnerships and programs to allow quick and widespread access to our breakthrough medicines and vaccines across all corners of the world.

## Governance

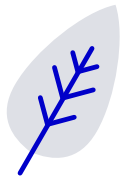
Ethical decision-making guides us as we work to achieve our purpose of delivering *Breakthroughs that change patients' lives*. Through proactive, business-led risk management, Pfizer prioritizes integrity, safety, and quality in every aspect of our business. Our Board of Directors is actively engaged in the governance and oversight of our ESG strategy, which is embedded within our enterprise strategy.



- Read about Pfizer's ESG Report online [here](#).
- Download Pfizer's ESG Report [here](#).



# 2022 Progress and Highlights<sup>1</sup>



## Net-Zero Standard

Aiming to achieve by 2040, which is 10 years earlier than expectations of the standard



Recognized at the

## Leadership Level

for our CDP Climate Change Disclosure



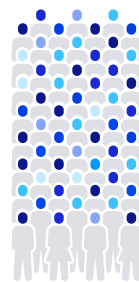
# 11%

Reduction in Scope 1 & 2 greenhouse gas (GHG) emissions from 2019 baseline



# #1

Ranking among the largest Pharma companies in the most recent Global PatientView Survey (#2 overall)



# 43.1%

Representation for women at VP+ levels globally

# 28.1%

Representation for U.S. minorities at VP+ level



# 44%

Pfizer New Molecular Entity and novel biologic applications approved by the FDA between 2018-2022 designated as Breakthrough Therapies



## 4 out of 12

members of the Board of Directors are women



## 3 out of 12

members of the Board of Directors are ethnically diverse



# 30k

Pfizer leaders have ESG KPIs factored into their compensation



Named one of the World's Most Ethical Companies by Ethisphere for the second year in a row

"World's Most Ethical Companies" and "Ethisphere" names and marks are registered trademarks of Ethisphere LLC.

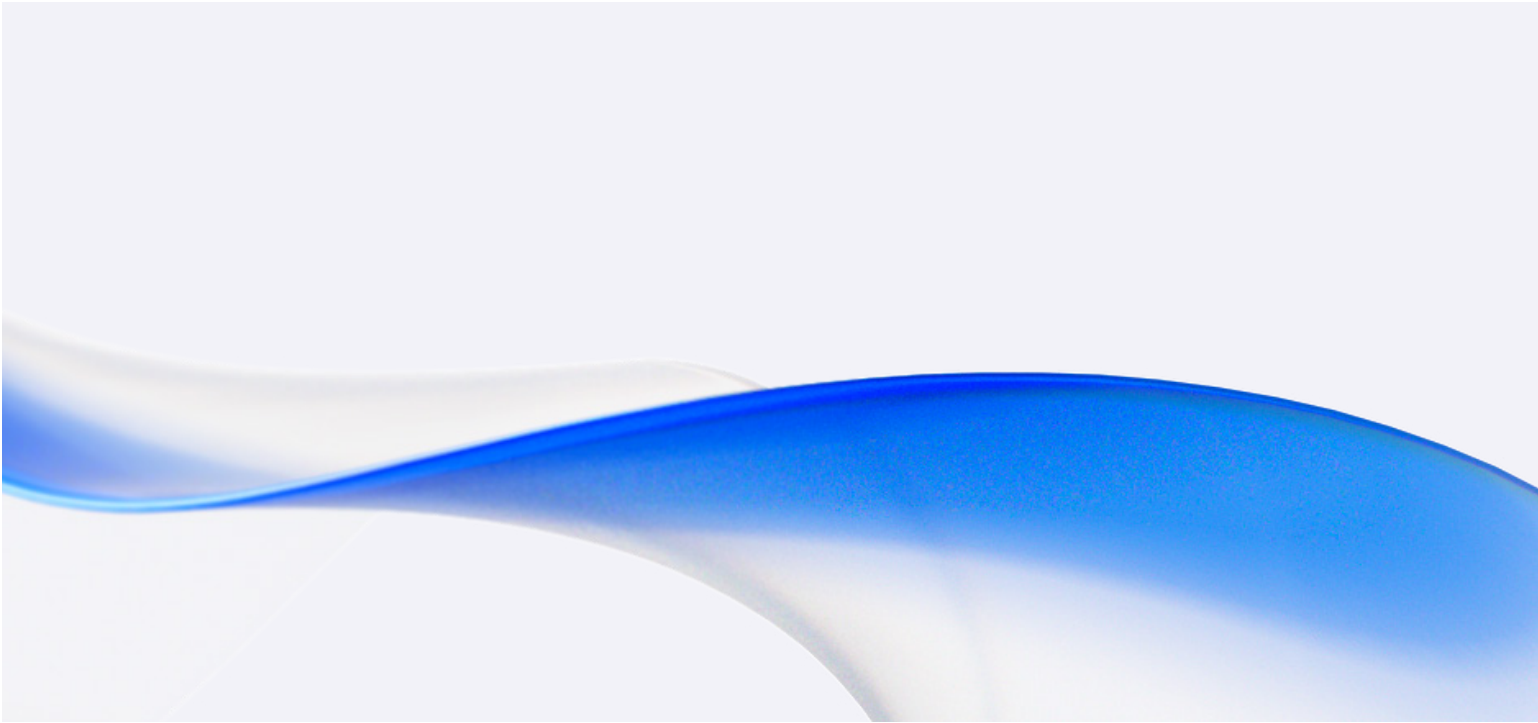
<sup>1</sup> See footnotes within the Performance section for more details.

“ Our approach to helping address the issues facing our planet and its people is rooted in our purpose—  
*Breakthroughs that change patients’ lives.*”

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Dr. Albert Bourla

Pfizer Chairman & Chief Executive Officer



# Performance

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2022 was a year in which we set all-time highs in several financial categories—including Revenue and Adjusted Diluted EPS.

Learn more about our performance on our [Investor site](#).

# Financial Performance

Three-year summary for the years ended December 31

Millions, Except Per Share Data				% Change	
	2022	2021	2020	22/21	21/20
Revenues	\$ 100,330	\$ 81,288	\$ 41,651	23	95
Reported net income <sup>(a)</sup>	\$ 31,372	\$ 21,979	\$ 9,159	43	*
Reported diluted EPS <sup>(a)</sup>	\$ 5.47	\$ 3.85	\$ 1.63	42	*
Adjusted income <sup>(b)</sup>	\$ 37,717	\$ 23,196	\$ 12,601	63	84
Adjusted diluted EPS <sup>(b)</sup>	\$ 6.58	\$ 4.06	\$ 2.24	62	82
Net cash provided by operating activities	\$ 29,267	\$ 32,580	\$ 14,403	(10)	*
Cash dividends paid	\$ 8,983	\$ 8,729	\$ 8,440	3	3

\* Indicates calculation not meaningful.

<sup>(a)</sup> Reported net income is defined as *Net income attributable to Pfizer Inc. common shareholders* in accordance with U.S. GAAP. Reported diluted earnings per share (EPS) is defined as diluted EPS attributable to Pfizer Inc. common shareholders in accordance with U.S. GAAP.

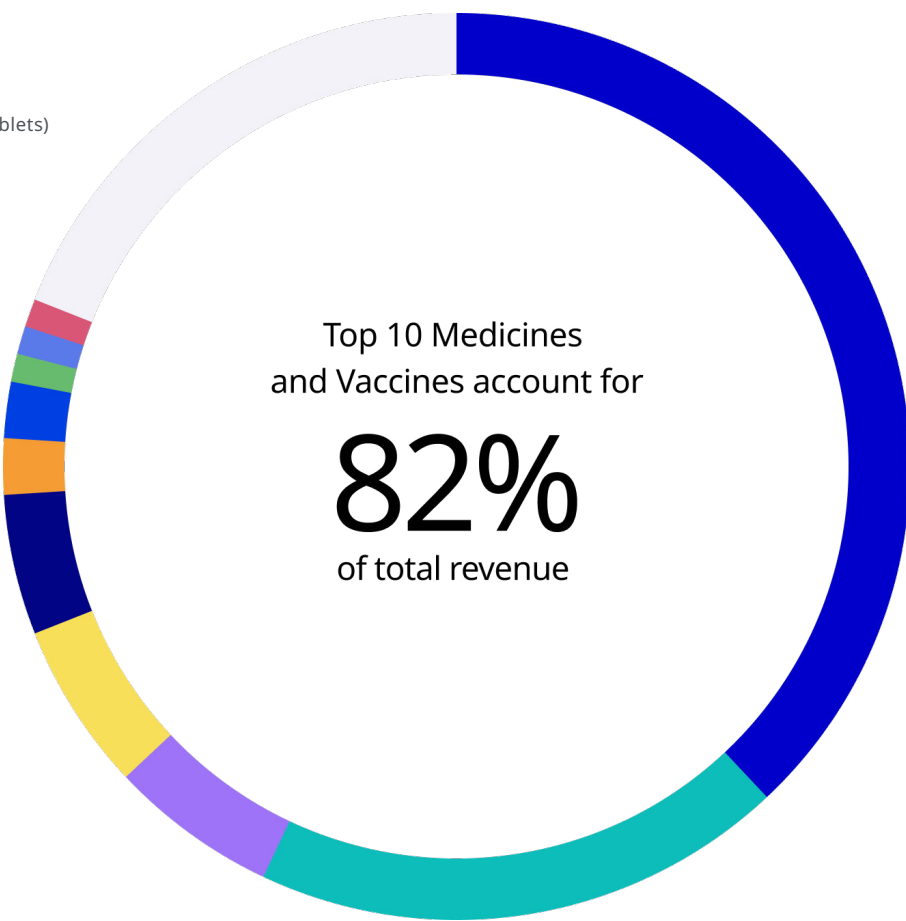
<sup>(b)</sup> Adjusted income and Adjusted diluted EPS are defined as U.S. GAAP *Net income attributable to Pfizer Inc. common shareholders* and reported diluted EPS attributable to Pfizer Inc. common shareholders before the impact of amortization of intangible assets, certain acquisition-related items, discontinued operations and certain significant items. The Adjusted income and Adjusted diluted EPS measures are not, and should not be viewed as, substitutes for U.S. GAAP net income and diluted EPS, have no standardized meaning prescribed by U.S. GAAP and may not be comparable to the calculation of similar measures of other companies. See the *Non-GAAP Financial Measure: Adjusted Income* section of [Management's Discussion and Analysis of Financial Condition and Results of Operations](#) in Pfizer's 2022 Annual Report on Form 10-K for an explanation of how management uses these non-GAAP measures, reconciliations to the most directly comparable U.S. GAAP measures and additional information.

Detailed information on our financial and operational performance can be found in our 2022 Annual Report on Form 10-K.

# Top 10 Medicines and Vaccines

Take a look at our breakdown of the top medicines and vaccines by revenue from 2022.

- **\$37,806 million**  
 (38% of total revenue)  
COMIRNATY<sup>01</sup>
- **\$18,933 million**  
 (19% of total revenue)  
PAXLOVID<sup>®</sup> (nirmatrelvir tablets and ritonavir tablets)
- **\$6,480 million**  
 (6% of total revenue)  
ELIQUIS<sup>®</sup> (apixaban)<sup>2</sup>
- **\$6,337 million**  
 (6% of total revenue)  
PREVNAR<sup>®</sup> Family<sup>3</sup>
- **\$5,120 million**  
 (5% of total revenue)  
IBRANCE<sup>®</sup> (palbociclib)
- **\$2,447 million**  
 (2% of total revenue)  
VYNDAQEL<sup>®</sup> Family<sup>4</sup>
- **\$1,796 million**  
 (2% of total revenue)  
XELJANZ<sup>®</sup> (tofacitinib)
- **\$1,198 million**  
 (1% of total revenue)  
XTANDI<sup>®</sup> (enzalutamide)<sup>5</sup>
- **\$1,003 million**  
 (1% of total revenue)  
ENBREL<sup>®</sup> (etanercept)
- **\$1,003 million**  
 (1% of total revenue)  
INLYTA<sup>®</sup> (axitinib)



[View the interactive graph on the Annual Review site.](#)

<sup>1</sup> COMIRNATY refers to, as applicable, and as authorized or approved, the Pfizer-BioNTech COVID-19 Vaccine, the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), the COMIRNATY Original/Omicron BA.1 Vaccine, and COMIRNATY Original/Omicron BA.4/BA.5 Vaccine. COMIRNATY includes direct sales and alliance revenues related to sales of the above-mentioned vaccines.

<sup>2</sup> ELIQUIS includes alliance revenues and direct sales.

<sup>3</sup> PREVNAR Family includes revenues from PREVNAR 13/PREVENAR 13 (pediatric and adult) and PREVNAR 20/APEXXNAR (adult).

<sup>4</sup> VYNDAQEL Family includes global revenues from VYNDAQEL, as well as revenues for VYNDAMAX in the U.S. and VYNNAC in Japan.

<sup>5</sup> XTANDI represents alliance revenues.

# About This Review

This review covers Pfizer's worldwide business and provides information on our activities for the year ending on December 31, 2022. It describes key dimensions of our purpose, strategy, and performance as well as analysis of trends and strategies for addressing Environment, Social, and Governance (ESG) key performance indicators. The ESG Report, in which this information is supplied, is available for download via link in the footer of this report.

## Forward Looking Information

This Annual Review contains forward-looking statements about, among other topics, our anticipated operating and financial performance, reorganizations, business plans, strategy, and prospects, expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, launches, clinical trial results and other developing data, revenue contribution and projections, potential pricing and reimbursement, potential market dynamics and size, growth, performance, timing of exclusivity, potential benefits and breakthroughs, best-in-class, first-in-class or blockbuster status, strategic reviews, capital allocation objectives, dividends and share repurchases, plans for and prospects of our acquisitions, dispositions and other business-development activities and our ability to successfully capitalize on growth opportunities, manufacturing and product supply, our efforts to respond to COVID-19, including our COVID-19 products, our expectations regarding the impact of COVID-19 on our business, operations and financial results and our ESG strategy and goals that are subject to substantial risks and uncertainties. We cannot guarantee that any forward-looking statement

will be realized. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results, future plans and projected future results.

A further list and description of risks, uncertainties and other matters can be found in Pfizer's Annual Report on Form 10-K for the year ended December 31, 2022, and in Pfizer's subsequent reports on Form 10-Q, in each case including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in Pfizer's subsequent reports on Form 8-K. These reports are available on Pfizer's website at [www.pfizer.com](http://www.pfizer.com) and on the U.S. Securities and Exchange Commission's (SEC) website at [www.sec.gov](http://www.sec.gov). The forward-looking statements in this Annual Review speak only as of the original date of this Annual Review, and we undertake no obligation to update or revise any of these statements as the result of new information or future events or developments or otherwise.

Data in this review and associated ESG Report covers the calendar year from January 1 to December 31, 2022, unless otherwise stated.

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COMIRNATY® is a registered trademark of BioNTech SE.

ELIQUIS® is a registered trademark of Bristol-Myers Squibb Company.

MYFEMBREE® is a registered trademark of Myovant Sciences GmbH.

XTANDI® is a registered trademark of Astellas Pharma Inc.

# Corporate Shareholder Information

## Stock Transfer Agent and Registrar

The principal market for our Common Stock is the New York Stock Exchange. Our stock is also traded on various U.S. regional stock exchanges.

Stock Transfer Agent and Registrar

Computershare Investor Services

P.O. Box 43006

Providence, RI 02940-3006

Telephone: (800) 733-9393

Outside the U.S., Canada and Puerto Rico:  
(781) 575-4591

Internet: [www.computershare.com/investor](http://www.computershare.com/investor)

## Shareholder Services and Programs

Please contact our Stock Transfer Agent and Registrar, Computershare, with inquiries concerning shareholder accounts of record and stock transfer matters, and for information:

- Computershare Investment Program
- Direct purchase of Pfizer stock
- Dividend reinvestment
- Automatic monthly or bi-monthly investments
- Book-entry share ownership
- Direct deposit of dividends

## Pfizer Public Policy Engagement for Global Public Health

Learn more about public policy at Pfizer:

[www.pfizer.com/purpose/contributions-partnerships/political-partnerships](http://www.pfizer.com/purpose/contributions-partnerships/political-partnerships)

Useful Links:

<https://investors.pfizer.com/Investors/Overview/>

<https://www.pfizer.com/contact>

<https://www.pfizer.com/Privacy>

<https://www.pfizer.com/about/careers>

<https://www.pfizer.com/general/terms>

## Additional Information

Find more information about Pfizer online:

[www.pfizer.com](http://www.pfizer.com)

[www.twitter.com/Pfizer](https://www.twitter.com/Pfizer)

[www.facebook.com/Pfizer](https://www.facebook.com/Pfizer)

[www.linkedin.com/company/pfizer](https://www.linkedin.com/company/pfizer)

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## Pfizer 2022 Annual Review

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