



Pfizer Presents New Data at IDWeek 2023

Highlighting Advances in Prevention and Treatment of Certain Respiratory Illnesses and Other Infectious Diseases

Thursday, October 05, 2023 - 04:30pm

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Presentations showcase diversity and momentum of Pfizer's growing portfolio of vaccines and anti-infectives

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) will present data across its infectious disease portfolio at the upcoming IDWeek 2023 held in Boston from October 11-15, 2023. Data from 45 abstracts will highlight the advances Pfizer is making in helping prevent and treat certain infectious diseases, particularly respiratory illnesses. This will include research featured in the IDWeek press program assessing the potential public health impact of ABRYSVO™ (Respiratory Syncytial Virus Vaccine), the company's bivalent respiratory syncytial virus prefusion F (RSVpreF) vaccine for maternal immunization to protect infants against RSV illness.

“The data at this year’s IDWeek highlight Pfizer’s commitment to transforming respiratory health, an area where we are proud to have delivered several innovative vaccine and treatment options over the last three years. We also continue to actively investigate infectious diseases more broadly, with a diverse pipeline of innovative vaccine and anti-infective treatment candidates,” said Annaliesa Anderson, Ph.D., Senior Vice President and Head, Vaccine Research and Development, Pfizer. “With our unique scientific capabilities and vaccine technology platforms, we are unwavering in the fight against the world’s most pressing disease challenges. We are excited to present our latest clinical results that support our growing infectious disease portfolio for the purpose of improving global health outcomes.”

"The burden of respiratory illnesses on global public health is significant. It is particularly relevant as we enter the winter respiratory season in the Northern Hemisphere and once again face the threat of a possible tripledemic with influenza, RSV and COVID-19 co-circulating," said Luis Jodar, Ph. D., Chief Medical Affairs Officer, Vaccines/Antivirals and Evidence Generation, Pfizer. "At IDWeek, we are pleased to share real-world data that will help educate healthcare professionals about the role Pfizer’s vaccines and treatments can play in helping mitigate the impact of certain respiratory infections during this critical period."

Pfizer's participation at IDWeek 2023 comprises breakthrough research from across the company’s robust infectious disease portfolio, covering RSV, COVID-19, pneumococcal disease, Lyme disease, meningococcal disease, multidrug-resistant gram-negative bacterial infections and more. Eight abstracts have been selected for oral presentation, including data on the successful coadministration of ABRYSV0 with an influenza vaccine in older adults and results from the Phase 3 REVISIT study of Pfizer’s investigational antibiotic combination aztreonam-avibactam (ATM-AVI) candidate. Data highlighting the real-world effectiveness of Pfizer’s FDA-approved COVID-19 oral treatment for adults, PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets), will also be featured at the meeting.

A complete list of Pfizer-sponsored accepted abstracts is available [here](#).

Details for Pfizer-sponsored oral presentations are below:

Title/ Abstract Number

Presenting Name/Type

Date/ Time

EDT

Location

IDWEEK PRESS PROGRAM

1942 - Potential Public Health Impact of Bivalent Respiratory Syncytial Virus Prefusion F (RSVpreF) Maternal Vaccine for Prevention of RSV Among US Infants

Amy W. Law, PharmD

Oct 13

2:15 - 2:30 PM US ET

104 ABC

ORAL PRESENTATIONS

1019 - Respiratory Syncytial Virus (RSV) Diagnoses in Hospitalized Patients Increases when Additional Specimen Types are Added to Nasopharyngeal Swab: Results from the RSV in Adults Multispecimen Study

Elizabeth Begier, MD, MPH

Oct 12

3:15 - 3:33 PM US ET

104 ABC

1941 - Coadministration of Bivalent Respiratory Syncytial Virus (RSVpreF) Vaccine with Influenza Vaccine in Older Adults

James Baber, MBChB, MPH

Oct 13

2:00 - 2:15 PM US ET

104 ABC

1944 - Tolerability and Safety of 20-Valent Pneumococcal Conjugate Vaccine (PCV20) in Infants and Older Children in Global Studies

Kathleen McElwee, MD, MPH

Oct 13

2:45 - 3:00 PM US ET

104 ABC

1948 - Rise of Candida auris Infections Worldwide and Trends on the Activity of Fosmanogepix and Comparator Agents Against C. auris Causing Invasive Infections

Cecilia G. Carvalhaes, MD, PhD

Oct 13

2:30 - 2:45 PM US ET

102 AB

1949 – Activity of Aztreonam-Avibactam Against Enterobacterales Resistant to Recently Approved Beta-Lactamase Inhibitor Combinations Collected Worldwide (ex-US: 2020-2022)

Helio S. Sader, MD, PhD, FIDSA

Oct 13

2:45 - 3:00 PM US ET

102 AB

2890 - Pharmacokinetics, Safety, and Efficacy of Ceftazidime-Avibactam in Neonates and Young Infants with Bacterial Infections: Results from a Phase 2a, 2-part, Open-label, Non-randomized, Multicenter Trial

Richard D England,

MD

Oct 14

2:05 - 2:15 PM US ET

254 AB

2893 - Efficacy and Safety of Aztreonam-Avibactam for the Treatment of Serious Infections Due to Gram-Negative Bacteria, Including Metallo- β -Lactamase-Producing Pathogens: Phase 3 REVISIT Study

Yehuda Carmeli, MD MPH

Oct 14

2:35 - 2:45 PM US ET

254 AB

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR ABRYSVO

U.S. INDICATIONS

ABRYSVOTM is a vaccine indicated for:

the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people 60 years of age and older pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age

IMPORTANT SAFETY INFORMATION

ABRYSVO should not be given to anyone with a history of severe allergic reaction (eg, anaphylaxis) to any of its components For pregnant individuals: to avoid the potential

risks of preterm birth, ABRYSV0 should be given during 32 through 36 weeks gestational age. Fainting can happen after getting injectable vaccines, including ABRYSV0. Precautions should be taken to avoid falling and injury during fainting. Adults with weakened immune systems, including those receiving medicines that suppress the immune system, may have a reduced immune response to ABRYSV0. Vaccination with ABRYSV0 may not protect all people. In adults 60 years of age and older, the most common side effects ($\geq 10\%$) were fatigue, headache, pain at the injection site, and muscle pain. In pregnant individuals, the most common side effects ($\geq 10\%$) were pain at the injection site, headache, muscle pain, nausea. In clinical trials where ABRYSV0 was compared to placebo, infants born to pregnant individuals experienced low birth weight (5.1% ABRYSV0 versus 4.4% placebo) and jaundice (7.2% ABRYSV0 versus 6.7% placebo).

View the full Prescribing Information.

INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION FOR PAXLOVID

U.S. Indication

PAXLOVID is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitations of Use

PAXLOVID is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

U.S. FDA Emergency Use Authorization Statement

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of PAXLOVID for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with mild to moderate coronavirus disease 2019 (COVID-19) and who are at high risk for progression to severe COVID-19, including hospitalization or death.

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) 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.

IMPORTANT SAFETY INFORMATION

WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID

PAXLOVID includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life-threatening, or fatal events Prior to prescribing PAXLOVID: 1) Review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like PAXLOVID and 2) Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring Consider the benefit of PAXLOVID treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed

PAXLOVID is contraindicated in patients with a history of clinically significant hypersensitivity reactions (eg, toxic epidermal necrolysis or Stevens-Johnson syndrome) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue PAXLOVID and initiate appropriate medications and/or supportive care.

PAXLOVID is contraindicated with drugs that are primarily metabolized by CYP3A and for which elevated concentrations are associated with serious and/or life-threatening reactions and drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. There are certain other drugs for which concomitant use with PAXLOVID should be avoided and/or dose adjustment, interruption, or therapeutic monitoring is recommended. Drugs listed here are a guide and not considered a comprehensive list of all drugs that may be contraindicated with PAXLOVID. The healthcare provider should consult other appropriate resources such as the prescribing information for the interacting drug for comprehensive information on dosing or monitoring with concomitant use of a strong CYP3A inhibitor like PAXLOVID.

Drugs that are primarily metabolized by CYP3A for which elevated concentrations are associated with serious and/or life-threatening reactions:

Alpha 1-adrenoreceptor antagonist: alfuzosin Antianginal: ranolazine Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine Anti-gout: colchicine (in patients with renal and/or hepatic impairment) Antipsychotics: lurasidone, pimozide

Benign prostatic hyperplasia agents: silodosin Cardiovascular agents: eplerenone, ivabradine Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine HMG-CoA reductase inhibitors: lovastatin, simvastatin (these drugs can be temporarily discontinued to allow PAXLOVID use) Immunosuppressants: voclosporin Microsomal triglyceride transfer protein inhibitor: lomitapide Migraine medications: eletriptan, ubrogepant Mineralocorticoid receptor antagonists: finerenone Opioid antagonists: naloxegol PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension Sedative/hypnotics: triazolam, oral midazolam Serotonin receptor 1A agonist/serotonin receptor 2A antagonist: flibanserin Vasopressin receptor antagonists: tolvaptan

Drugs that are strong CYP3A inducers: PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer:

Anticancer drugs: apalutamide Anticonvulsant: carbamazepine, phenobarbital, primidone, phenytoin Antimycobacterials: rifampin, rifapentine Cystic fibrosis transmembrane conductance regulator potentiators: lumacaftor/ivacaftor Herbal Products: St. John's Wort (hypericum perforatum)

Risk of Serious Adverse Reactions Due to Drug Interactions: Initiation of PAXLOVID, which contains ritonavir, a strong CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving PAXLOVID, may increase plasma concentrations of medications metabolized by CYP3A. Medications that induce CYP3A may decrease concentrations of PAXLOVID. These interactions may lead to:

Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications Loss of therapeutic effect of PAXLOVID and possible development of viral resistance

Severe, life-threatening, and/or fatal adverse reactions due to drug interactions have been reported in patients treated with PAXLOVID. The most commonly reported concomitant medications resulting in serious adverse reactions were calcineurin inhibitors (eg, tacrolimus, cyclosporine), followed by calcium channel blockers.

Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering PAXLOVID to patients with pre-existing liver diseases, liver enzyme abnormalities, or hepatitis.

Because nirmatrelvir is coadministered with ritonavir, there may be a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

The most common adverse reactions in the PAXLOVID group ($\geq 1\%$) that occurred at a greater frequency than in the placebo group were dysgeusia (5% and $<1\%$, respectively) and diarrhea (3% and 2%, respectively).

The following adverse reactions have been identified during use of PAXLOVID under Emergency Use Authorization:

Immune System Disorders: Anaphylaxis, hypersensitivity reactions
Skin and Subcutaneous Tissue Disorders: Toxic epidermal necrolysis, Stevens-Johnson syndrome
Nervous System Disorders: Headache
Vascular Disorders: Hypertension
Gastrointestinal Disorders: Abdominal pain, nausea, vomiting
General Disorders and Administration Site Conditions: Malaise

PAXLOVID is a strong inhibitor of CYP3A, and an inhibitor of CYP2D6, P-gp, and OATP1B1. Coadministration of PAXLOVID with drugs that are primarily metabolized by CYP3A and CYP2D6 or are transported by P-gp or OATP1B1 may result in increased plasma concentrations of such drugs and increase the risk of adverse events. Coadministration with other CYP3A substrates may require a dose adjustment or additional monitoring.

Pregnancy: Available data on the use of nirmatrelvir during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage. There are maternal and fetal risks associated with untreated COVID-19 in pregnancy.

Lactation: There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production. A transient decrease in body weight was observed in the nursing offspring of rats administered nirmatrelvir. Limited published data report that ritonavir is present in human milk. There is no information on the effects of ritonavir on the breastfed infant or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAXLOVID and any potential adverse effects on the breastfed infant from PAXLOVID or from the underlying maternal condition.

Contraception: Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception.

Pediatrics: The optimal dose of PAXLOVID has not been established in pediatric patients.

Systemic exposure of nirmatrelvir increases in renally impaired patients with increase in the severity of renal impairment. No dosage adjustment is recommended in patients with mild renal impairment. Reduce the dose of PAXLOVID in patients with moderate renal impairment (eGFR ≥ 30 to < 60 mL/min). PAXLOVID is not recommended in patients with severe renal impairment (eGFR < 30 mL/min) or in patients with end-stage renal disease (eGFR < 15 mL/min).

PAXLOVID is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C).

Please see Full Prescribing Information , including BOXED WARNING and Patient Information

Click for Fact Sheets:

For Consumers: EUA Fact sheet for Patients, Parents, and Caregivers

For Healthcare Professionals: EUA Fact Sheet for HCPs

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR PREVNAR 20

U.S. INDICATIONS

PREVNAR 20® is a vaccine approved for:

the prevention of invasive disease caused by 20 *Streptococcus pneumoniae* strains (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) in individuals 6 weeks and older. the prevention of otitis media (middle ear infection) caused by 7 of the 20 strains in individuals 6 weeks through 5 years.

IMPORTANT SAFETY INFORMATION

PREVNAR 20 should not be given to anyone who has had a severe allergic reaction to any component of PREVNAR 20 or to diphtheria-toxoid-containing vaccine. Individuals with weakened immune systems may have a lower immune response. Safety data are not available for these groups. A temporary pause in breathing after getting the vaccine has

been observed in some infants who were born prematurely. For premature infants, talk to your doctor about the infant's medical status when deciding to get vaccinated with PREVNAR 20. In individuals 2, 4, 6, and 12 through 15 months of age vaccinated with a 4-dose schedule, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, decreased appetite and injection site redness, injection site swelling, and fever. In individuals 15 months through 17 years of age vaccinated with a single dose, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, fatigue and muscle pain, decreased appetite, injection site swelling and injection site redness, headache, and fever. Ask your doctor about the risks and benefits of PREVNAR 20. Only a doctor can decide if PREVNAR 20 is right for your child.

View the full Prescribing Information.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

Disclosure Notice

The information contained in this release is as of October 5, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's infectious disease pipeline, in-line products and product candidates, including ABRYVO (RSVpreF), Pfizer's aztreonam-avibactam (ATM-AVI) candidate and PAXLOVID, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results

to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 or pre-clinical data for ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates, including the data discussed in this release) in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data; risks associated with interim data, including the risk that final results from the Phase 3 trials for RSVpreF could differ from the interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; the ability to produce comparable clinical or other results for ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates, including efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of ABRYSVO (RSVpreF) and PAXLOVID to be effective against emerging virus variants; the risk that the use of ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications or submissions to request emergency use or conditional marketing authorizations for any potential indications for ABRYSVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates may be filed in any jurisdictions and if obtained, whether or when such emergency use authorization or

licenses will expire or terminate; whether and when any applications that may be pending or filed for ABRYVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates (including any requested amendments to the emergency use or conditional marketing authorizations) may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether ABRYVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates will be commercially successful; intellectual property and other litigation; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of ABRYVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates, including the authorization or approval of products or therapies developed by other companies; the risk that demand for any of our products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel, inventory write-offs or reduced revenues; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for any of Pfizer's infectious disease products or product candidates; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test Pfizer's infectious disease products or product candidates; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines or potential combination respiratory vaccines; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding ABRYVO (RSVpreF) or any of Pfizer's other infectious disease products or product candidates and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges; challenges related to public confidence in, or awareness of ABRYVO (RSVpreF), Pfizer's ATM-AVI candidate, PAXLOVID or any of Pfizer's other infectious disease products or product candidates; uncertainties regarding the impact of COVID-19 on our business, operations and financial

results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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