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U.S. FDA Accepts for Priority Review the Biologics License Application for Pfizer's Investigational 20-valent Pneumococcal Conjugate Vaccine for Adults 18 Years of Age and Older

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If approved, the vaccine will help protect adults against 20 serotypes responsible for the majority of invasive pneumococcal disease and pneumonia

NEW YORK--(BUSINESS WIRE)--

Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) accepted for priority review a Biologics License Application (BLA) for its 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, as submitted for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* serotypes in the vaccine in adults ages 18 years and older.

The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA on the 20vPnC application is in June 2021.

"The FDA's acceptance of our application for 20vPnC is yet another significant milestone in Pfizer's continuing efforts to help protect adults against pneumococcal disease," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research and Development, Pfizer. "If approved, 20vPnC will cover more serotypes responsible for the majority of pneumococcal disease than any other pneumococcal conjugate vaccine currently licensed or currently in late-stage clinical development. Importantly, 20vPnC has shown to induce immune memory, which provides protection and efficacy against non-bacteremic pneumonia, particularly in older adults."

Pfizer's 20vPnC vaccine candidate includes capsular polysaccharide conjugates for the 13 serotypes already included in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine[Diphtheria CRM_{197} Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes that cause invasive pneumococcal disease (IPD),[1,2,3,4,5] and have been associated with high case-fatality rates,[6,7,8,9] antibiotic resistance,[4,10,11] and/or meningitis.[12,13] Globally, pneumococcal pneumonia is estimated to cause about 500,000 deaths and 30 million episodes in adults 70 years and older annually. Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in the U.S. and globally.[14,15,16,17,18,19,20]

The 20vPnC regulatory submission encompasses data from Pfizer's clinical program in adults, which includes Phase 1 and 2 trials and three Phase 3 trials (NCT03760146, NCT03828617, and NCT03835975) describing the

safety and evaluating the immunogenicity of the vaccine candidate to support licensure for an indication to prevent invasive disease and pneumococcal pneumonia caused by *Streptococcus pneumoniae* serotypes in the vaccine in adults 18 years or older. The three Phase 3 trials have enrolled more than 6,000 adult subjects, 18 years and older, including adults 65 years of age and above, and populations of vaccine-naïve adults and adults with prior pneumococcal vaccination.[21,22]

About 20vPnC

On September 20, 2018, Pfizer announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for 20vPnC for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* serotypes in the vaccine candidate in adults age 18 years or older. Breakthrough Therapy Designation is designed to expedite the development and review of drugs and vaccines that are intended to treat or prevent serious conditions and preliminary clinical evidence indicates that the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).[23] Drugs and vaccines that receive Breakthrough Therapy Designation are eligible for all features of the FDA's Fast Track designation, which may include more frequent communication with the FDA about the drug's development plan and eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.[24]

The FDA previously granted Fast Track designation for 20vPnC in September 2017 for use in adults aged 18 years or older.[25] The FDA's Fast Track approach is a process designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address an unmet medical need.[25]

Additionally, in May 2017 the FDA granted Fast Track status and in August 2020 Breakthrough Therapy Designation for a pediatric indication for 20vPnC.[26]

INDICATIONS FOR PREVNAR 13®

- Prevnar 13® is a vaccine approved for adults 18 years and older for the prevention of pneumococcal pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- Prevnar 13® is also approved for children 6 weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by the 13 strains of *Streptococcus pneumoniae* in the vaccine, and for children 6 weeks through 5 years (prior to the 6th birthday) for the prevention of ear infections caused by 7 of the 13 strains in the vaccine
- Prevnar 13® is not 100% effective and will only help protect against the 13 strains in the vaccine

IMPORTANT SAFETY INFORMATION

- Prevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13® or any diphtheria toxoid–containing vaccine
- Children and adults with weakened immune systems (eg, HIV infection, leukemia) may have a reduced immune response
- In adults, the most common side effects were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash
- A temporary pause of breathing following vaccination has been observed in some infants born prematurely
- The most commonly reported serious adverse events in infants and toddlers were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%)

- In children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever
- Ask your healthcare provider about the risks and benefits of Prevnar 13®. Only a healthcare provider can decide if Prevnar 13® is right for you or your child

For the full prescribing information for Prevnar 13®, please visit
http://labeling.pfizer.com/showlabeling.aspx?id=501

Pfizer Inc: 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 150 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.

DISCLOSURE NOTICE:

The information contained in this release is as of December 8, 2020. 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 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, including a BLA filed in the U.S. for the prevention of invasive disease and pneumonia in adults age 18 years or older, expected licensure criteria, a potential pediatric indication and its 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, 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 the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologics license applications may be filed in any other jurisdictions for 20vPnC for the prevention of invasive disease and pneumonia in adults age 18 years or older and in any jurisdictions for any other potential indications; whether and when the BLA pending in the U.S. may be approved and whether and when any such other applications 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 20vPnC will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of 20vPnC; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding 20vPnC and uncertainties regarding the commercial impact of any such recommendations; 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, 2019 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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[1] Baisells E, Guillot L, Nair H, et al. Serotype distribution of Streptococcus pneumoniae causing invasive disease in children in the post-PCV era: A systematic review and meta-analysis. PlosOne. 2017;12(5): e0177113.

[2] Hausdorff W & Hanage W. Interim results of an ecological experiment – Conjugate Vaccination against the pneumococcus and serotype replacement. Hum Vaccin Immunother. 2016;12(2):358-374.

[3] Cohen R, Cohen J, Chalumeau M, et al. Impact of pneumococcal conjugate vaccines for children in high- and non-high income countries. Expert Rev Vaccines. 2017;16(6):625-640.

[4] Moore M, Link-Gelles R, Schaffner W, et al. Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance. Lancet Infect Dis. 2015;15(3):301-309.

[5] Metcalf B, Gertz RE, Gladstone RA, et al. Strain features and distributions in pneumococci from children with invasive disease before and after 13-valent conjugate vaccine implementation in the USA. Clin Microbiol Infect. 2016;22(1):60. e9-60. e29.

[6] Oligbu G, Collins S, Sheppard CL, et al. Childhood Deaths Attributable to Invasive Pneumococcal Disease in England and Wales, 2006–2014. Clin Infect Dis. 2017;65(2):308-314.

[7] van Hoek, Andrews N, Waight PA, et al. Effect of Serotype on Focus and Mortality of Invasive Pneumococcal Disease: Coverage of Different Vaccines and Insight into Non-Vaccine Serotypes. PlosOne. 2012;7(7: e39150.

[8] Stanek R, Norton N, Mufson M. A 32-Years Study of the Impact of Pneumococcal Vaccines on Invasive Streptococcus pneumoniae Disease. Am J Med Sci. 2016;352(6):563-573.

[9] Harboe ZB, Thomsen RW, Riis A, et al. Pneumococcal Serotypes and Mortality following Invasive Pneumococcal Disease: A Population-Based Cohort Study. PlosOne. 2009;6(5): e 1000081.

[10] Tomczyk S, Lynfield R, Schaffner W, et al. Prevention of Antibiotic-Nonsusceptible Invasive Pneumococcal Disease With the 13-Valent Pneumococcal Conjugate Vaccine. Clin Infect Dis. 2016;62(9):1119-1125.

[11] Mendes RE, Hollingsworth RC, Costello A, et al. Noninvasive Streptococcus pneumoniae Serotypes Recovered from Hospitalized Adult Patients in the United States in 2009 to 2012. Antimicrob Agents Chemother. 2015;59(9):5595-5601.

[12] Olarte L, Barson WJ, Lin PL, et al. Impact of the 13-valent pneumococcal conjugate vaccine on pneumococcal meningitis in US children. Clin Infect Dis. 2015;61(5):767-775.

[13] Thigpen MC, Whitney CG, Messonnier NE, et al. Bacterial Meningitis in the United States, 1998–2007. NEJM. 2011;364(21):2016-2025.

[14] Centers for Disease Control and Prevention. Active Bacterial Core (ABCs) surveillance. National Center for Immunization and Respiratory Diseases. Atlanta, GA.

[15] Ladhani, SN, Collins S, Djennad A, et al. Rapid increase in non-vaccine serotypes causing invasive pneumococcal disease in England and Wales, 2000–17: a prospective national observational cohort study. Lancet Infect Dis. 2018;18(4):441-451.

[16] Menéndez R, España PP, Pérez-Trallero E, et al. The burden of PCV13 serotypes in hospitalized pneumococcal pneumonia in Spain using a novel urinary antigen detection test. CAPA study. Vaccine. 2017;35(39):5264-5270.

[17] Azzari C, Cortimiglia M, Nieddu F, et al. Pneumococcal serotype distribution in adults with invasive disease and in carrier children in Italy: Should we expect herd protection of adults through infants' vaccination? Hum Vaccin Immunother. 2016;12(2):344-350.

[18] Pivlishi T. Impact of PCV13 on invasive pneumococcal disease (IPD) burden and the serotype distribution in the U.S. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. October 24th, 2018.

[19] European Centre for Disease Prevention and Control. Invasive pneumococcal disease. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018.

[20] Beall B, Chochua S, Gertz RE Jr, et al. A population-based descriptive atlas of invasive pneumococcal strains recovered within the U.S. during 2015-2016. Front Microbiol. 2018;19(9).

[21] Pfizer Inc. NCT03828617 Study Design. Available at www.clinicaltrials.gov under the identifier NCT03828617.

[22] Pfizer Inc. NCT03835975 Study Design. Available at www.clinicaltrials.gov under the identifier NCT03835975.

[23] U.S. Food and Drug Administration. Breakthrough Therapy
https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm

[24] U.S. Food and Drug Administration. Fast Track
https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm

[25] Data on file. Pfizer Inc., New York, NY

[26] Data on file. Pfizer Inc., New York, NY

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