Pfizer Announces Positive Preliminary Results from a Proof-of-Concept Phase 2 Study (B7471003) of its 20-Valent Pneumococcal Conjugate Vaccine Candidate Being Investigated for the Prevention of Invasive Disease and Otitis Media in Healthy Infants

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Additionally, Pfizer Has Completed Enrollment of its Phase 3 Studies (NCT03828617, NCT03835975 and NCT03760146) for its 20-Valent Pneumococcal Conjugate Vaccine Candidate Being Investigated for the Prevention of Invasive Disease and Pneumonia in Adults Aged 18 Years and Older

Pfizer Inc. (NYSE: PFE) announced today positive preliminary results following administration of three doses in a four-dose series for a Proof-of-Concept Phase 2 study (B7471003) to assess safety and immunogenicity of its 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, PF-06482077, being investigated for the prevention of invasive disease and otitis media caused by Streptococcus pneumoniae serotypes contained in the vaccine in healthy infants. Pfizer’s 20vPnC candidate includes the 13 serotypes contained in Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) plus seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F, and 33F).

“The initial three doses of 20vPnC in this Phase 2 trial provide preliminary evidence that the vaccine candidate in infants has an overall safety profile that is similar to Prevnar 13. 20vPNC induced immune responses for all 20 serotypes in infants. These findings are encouraging and should support the program’s advancement to Phase 3,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. “Once data with the fourth dose are available, we will discuss Phase 3 plans with regulators. If successful in Phase 3 and approved, 20vPnC may help protect infants against seven additional Streptococcus pneumoniae serotypes, which represent prevalent circulating global disease strains today, in addition to those contained within Prevnar 13.”

B7471003 is a randomized, double-blind Phase 2 proof-of concept study to assess the safety and immunogenicity of 20vPnC in approximately 460 healthy infants. Subjects were randomized equally to receive a 4-dose series of either 20vPnC or Prevnar 13 at 2, 4, 6, and 12 months of age. Local reactions and systemic events were collected for 7 days after each vaccination. Adverse events were collected in a similar fashion to the Prevnar 13 infant program. More details on the study can be found on www.clinicaltrials.gov. (NCT03512288)

Pfizer will seek to present and publish outcomes from this clinical trial at a future date once safety and immunogenicity data has been analyzed following the completion of the four-dose regimen.

20vPnC Phase 3 Adult Program Completes Enrollment

Pfizer has completed enrollment in its three Phase 3 pivotal clinical trials (NCT03828617, NCT03835975 and NCT03760146) evaluating 20vPnC for the prevention of invasive disease and pneumonia in adults 18 years and older. Combined, these three trials have enrolled more than 6,000 adult subjects, including populations of vaccine-naïve adults and adults with prior pneumococcal vaccination. Pfizer remains on track to submit the Biologics License Application for the adult 20vPnC indications to the U.S. FDA by the end of 2020, subject to the successful completion of these Phase 3 studies.

About 20vPnC

The seven new serotypes included in 20vPnC are global causes of invasive pneumococcal disease,1,2,3,4,5 and are associated with high case-fatality rates6,7,8,9, antibiotic resistance5,10,11 and/or meningitis.12,13 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

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 in adults age 18 years and 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).21 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.22

The FDA previously granted Fast Track designation for 20vPnC in September 2017 for use in adults aged 18 years and older.23 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.22

Additionally, in May 2017 the FDA granted Fast Track status for a pediatric indication for 20vPnC.

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

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 September 9, 2019. 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, PF-06482077, including potential regulatory submission, timing, potential advancement to Phase 3 trials for 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 jurisdictions for 20vPnC for any indications; whether and when any such 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; 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, 2018 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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22 U.S. Food and Drug Administration. Fast Track https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm

23 Data on file. Pfizer Inc., New York, NY

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