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Pfizer Announces Presentation of Data from a Phase 2 Study of its 20-Valent Pneumococcal Conjugate Vaccine Candidate Being Investigated for the Prevention of Invasive Disease and Pneumonia in Adults Aged 18 Years and Older

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The U.S. FDA awarded Breakthrough Therapy Designation for this potential indication based on these Phase 2 data - - - The Biologics License Application is expected to be submitted to the U.S. FDA by the end of 2020, subject to the successful completion of Phase 3 studies

Pfizer Inc. (NYSE: PFE) announced today the presentation of data from a Phase 2 study of its 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, PF-06482077, being investigated for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae serotypes contained in the vaccine in adults aged 18 years and older. The presentation was delivered at the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam, Netherlands. Pfizer's 20vPnC candidate includes the 13 serotypes contained in Prevnar 13 plus seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F, and 33F).

"The safety and immunogenicity results from this study suggest that our 20vPnC candidate, which initiated Phase 3 development in adults last year, could potentially offer comprehensive coverage of additional serotypes causing pneumococcal disease globally and in the U.S. as substantiated by the receipt of FDA's Breakthrough Therapy Designation," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "We believe the full extent of Prevenar 13 protection of adults has yet to be fulfilled. At the same time, there continues to be a global health need to protect against the potential effects of invasive pneumococcal disease and pneumonia caused by additional serotypes not yet covered by existing conjugate vaccines."

The Phase 2 study was a randomized, active-controlled, double-blinded trial that enrolled 444 adult subjects age 60 to 64. Subjects received a single injection of 20vPnC or Prevnar 13 (Vaccination 1). One month later subjects receiving 20vPnC were given an injection of saline placebo, and subjects receiving Prevnar 13 were given 23-valent polysaccharide vaccine (Vaccination 2). Local reactions and systemic events were recorded for 10 and 7 days respectively after Vaccination 1 and data on adverse events (AEs) were collected for one month following each vaccination. Immunogenicity was assessed by measuring antibody associated with serotype-specific bacterial killing (opsonophagocytic activity [OPA]) prior to vaccination and one month after each vaccination. The study was designed to describe safety and immunogenicity data with 20vPnC in a population of older adults. Given the stage of the study there was no hypothesis testing and data were summarized.

Of the 444 subjects enrolled, 443 received Vaccination 1 and 427 received Vaccination 2. Robust OPA responses were observed for all 20 vaccine serotypes in the 20vPnC group. The OPA geometric mean fold-rises from baseline ranged from 6.1 to 68.6 for the serotypes in common with Prevnar 13, and 9 to 112.2 for the seven additional serotypes not included in Prevnar 13.

Injection site reactions (redness, swelling or pain) and systemic event rates were similar after vaccination with 20vPnC or Prevnar 13, with severe injection site reactions or systemic events reported in less than one percent of 20vPnC recipients. No deaths or serious AEs considered related to vaccine were reported in the study. The overall safety profile of 20vPnC in this study was consistent with historical experience with Prevnar 13.

The safety and immunogenicity findings from this Phase 2 study supported progression to Phase 3 clinical development for the adult indication which started in December 2018.

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 rates,[6,7,8,9] antibiotic resistance[5,10,11] and/or meningitis.[12,13] Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in adults in the U.S. and globally.[14,15,16,17,18,19,20]

About the 20vPnC Phase 3 Program

Pfizer has begun enrollment in three Phase 3 trials (NCT03828617, NCT03835975 and NCT03760146) evaluating 20vPnC in adults. Combined, these three trials will enroll more than 6,000 adult subjects, including populations of vaccine-naïve adults and adults with prior pneumococcal vaccination.

Pfizer's Phase 3 pivotal development program for 20vPnC includes three clinical trials in populations of vaccine-naïve adults and adults with prior pneumococcal vaccination.

The pivotal Phase 3 trial is enrolling an estimated 3,880 adults and is designed to compare immune responses after 20vPnC administration to responses in control subjects ?60 years old receiving 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine; evaluate the immunogenicity of 20vPnC in adults 18-59 years of age; and describe the 20vPnC safety profile in adults ?18 years old. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03760146.

Another Phase 3 trial was initiated on February 12, 2019 and is planned to enroll an estimated 875 adults. It is designed to describe the safety and immunogenicity of 20vPnC in adults 65 years of age or older with prior pneumococcal vaccination. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03835975.

A third Phase 3 trial was initiated on February 14, 2019, and is planned to enroll an estimated 1,610 adults. The study is designed to provide additional safety data and evaluate three different lots of 20vPnC in adults 18 through 49 years of age. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03828617.

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 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 and clinical development is in progress.

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DISCLOSURE NOTICE: The information contained in this release is as of April 13, 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 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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[23] Data on file. Pfizer Inc., New York, NY

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