Pfizer Initiates Phase 3 Program for 20-Valent Pneumococcal Conjugate Vaccine for the Prevention of Invasive Disease and Pneumonia in Adults Aged 18 Years and Older

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Pfizer Inc. (NYSE:PFE) announced today the initiation of a Phase 3 program for its 20-Valent pneumococcal conjugate vaccine (20vPnC) candidate, PF-06482077, for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae serotypes in the vaccine in adults aged 18 years and older.

“While the full extent of Prevenar 13 protection of adults is still being realized, we anticipate our 20vPnC vaccine candidate will be the next important step to help protect adults from a substantial invasive pneumococcal disease and pneumonia burden, including disease caused by serotypes not yet covered by any available conjugate vaccine,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. “As the industry leader in pneumococcal conjugate vaccination, we are proud to start the Phase 3 trials of our third generation pneumococcal vaccine, which received Breakthrough Therapy Designation by the FDA in September 2018.”

About the 20vPnC Phase 3 Program

This first Phase 3 trial will enroll 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.

About 20vPnC

On September 20, 2018, Pfizer announced the 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).1 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.2

The FDA previously granted Fast Track designation for 20vPnC in October 2017 for use in adults aged 18 years and older.3 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.2

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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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 14, 2018. 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, and a potential indication to prevent invasive disease and pneumonia caused by Streptococcus pneumoniae in adults aged 18 years and older, including its potential benefits, and plans to initiate Phase 3 trials in the coming months, 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 trial completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data or additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; 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 the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the immunogenicity and safety information submitted and, if approved, whether 20vPnC will be commercially successful; decisions by regulatory authorities regarding labeling and 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, 2017 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

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

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

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

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