Pfizer Announces Positive Top-Line Results from Phase 2 Study of Investigational Clostridium difficile Vaccine for the Prevention of C. difficile Infection

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Pfizer’s C. difficile Vaccine Candidate to Commence Phase 3 Study in First Half of 2017 C. difficile is an Increasing Worldwide Concern Associated with Approximately 29,000 Annual Deaths in the U.S. Alone

Pfizer Inc. (NYSE:PFE) announced today that the Phase 2 study evaluating the Company’s Clostridium difficile (C. difficile) vaccine candidate, PF-06425090, provided positive data, based on a pre-planned interim analysis. The randomized Phase 2 study (NCT02561195) examined the safety, tolerability, and immunogenicity of the vaccine in healthy adults 65 to 85 years of age. Pfizer’s vaccine candidate is designed to help prevent C. difficile infection (CDI), which can include life-threatening diarrhea and pseudomembranous colitis,1 by inducing a functional antibody response capable of neutralizing the two main disease-causing toxins produced by C. difficile (toxins A and B).2

“Despite improved infection control measures, C. difficile disease continues to rise, further augmenting an already urgent public health threat with particular negative impact on older adults,” said Kathrin Jansen, Ph.D., senior vice president and head of Vaccine Research and Development for Pfizer Inc. “We are very encouraged by these interim immunogenicity and safety results demonstrating robust increases in vaccine-elicited neutralizing antibodies to both toxins, that we believe could provide protection against C. difficile disease.”

Based on findings from the pre-planned interim analysis, Pfizer’s C. difficile vaccine candidate will progress into Phase 3 in the first half of 2017. Pfizer’s C. difficile vaccine candidate was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in August 2014. The FDA’s Fast Track designation is 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.3 About the Phase 2 Study The Phase 2 study (NCT02561195) was a randomized, placebo-controlled, observer-blinded study of more than 850 healthy adults 65-85 years of age, evaluating the safety, tolerability, and immunogenicity of two dose levels (100 µg and 200 µg) of Pfizer’s C. difficile vaccine candidate on two different three-dose vaccination schedules (Days 1/8/30 and Months 0/1/6). More information about the PF-06425090 Phase 2 study can be found at www.clinicaltrials.gov.

About Clostridium difficile

Clostridium difficile (C. difficile) is a spore-forming pathogen that typically causes symptoms in individuals with altered gut microbial flora, releasing toxins that can result in a range of disease manifestations from asymptomatic colonization to diarrhea, pseudomembranous colitis, toxic megacolon, intestinal perforation, or, in the most severe cases, death.4,5 C. difficile, classified by the U.S. Centers for Disease Control and Prevention (CDC) as an urgent public health threat in 2013,6 is the most common cause of antibiotic-associated diarrhea in the healthcare setting and an increasing concern worldwide.7 Responsible for approximately 453,000 U.S. cases (associated with 29,000 deaths) in 2011,8 CDI disproportionately affects older adults, with nearly two-thirds of cases in patients over the age of 65.9 Current treatment options may offer temporary therapeutic improvements, but will not provide long-term protection.10 Up to 25% of patients treated for a first episode of CDI experience a first recurrence of infection, and up to 65% of those patients who experience a first recurrence will experience multiple recurrences.1,11

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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 healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare 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, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, 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 January 26, 2017. 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 a vaccine candidate, PF-06425090, including its potential benefits and the expected timing of commencement of a Phase 3 study, 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 commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; whether and when any biologics license applications may be filed for PF-06425090; 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 efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06425090 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, 2015 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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Media: Sally Beatty, 347-330-7867 sally.beatty@pfizer.com or Investor: Bryan Dunn, 212-733-8917 bryan.dunn@pfizer.com