Pfizer Begins Phase 1 Clinical Trial to Evaluate Investigational Group B Streptococcus Vaccine

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An estimated 10 to 30 percent of pregnant women carry the GBS bacteria;1 the vaccine candidate is being studied to help protect newborns from infection via maternal immunization

“Group B streptococcal disease in infants aged younger than 3 months: systematic review and meta-analysis.”

Pfizer Inc. (NYSE:PFE) today announced that it has started a Phase 1 trial in healthy volunteers of PF-06760805, an investigational vaccine designed to help protect against Group B Streptococcus (GBS) infection. In newborns, GBS manifests as sepsis, pneumonia, and meningitis,2 with potentially fatal outcomes for some, and long-lasting neurological damage in 46 to 50 percent of those infected.3

“Because their immune systems are still immature, GBS can have potentially devastating effects on newborns,” said Carol J. Baker, M.D., Professor of Pediatrics-Infectious Disease at the Baylor College of Medicine in Houston, Texas. “The global health community would welcome a vaccine that could help reduce the impact of GBS everywhere, particularly in areas where the routine administration of antibiotics is not common practice.”

Women who are carriers of the GBS bacteria may pass it on to their newborns during labor and birth. The U.S. and certain developed countries have established recommendations for women to be screened for GBS during their third trimester of pregnancy, and administered prophylactic antibiotics during labor to prevent transmission to their newborns at delivery.4,5 However, this requires a robust health delivery infrastructure that is not widely available globally.

“Pfizer is proud to take this important first step to support our efforts to ultimately develop a GBS vaccine with the potential to immunize a mother to help protect her infant against a devastating disease,” said Kathrin Jansen, Ph.D., senior vice president and head of Vaccine Research and Development for Pfizer Inc.

The risk of developing GBS is highest in the first three months of a newborn’s life.6 While there is variation in the incidence of GBS infant disease among regions of the world, the disease is potentially devastating. A successfully developed, efficacious vaccine could be an important strategy for global disease prevention.

Clinical Development Program

The trial is designed as a Phase 1/2 randomized, placebo-controlled, observer-blinded study in healthy adults 18 to 49 years of age with no history of a GBS infection, and will be conducted in the United States.

Because of the urgent need to help protect newborns in low- and middle-income countries from this devastating condition, and the intent to make a successfully developed vaccine available globally as quickly as possible, Pfizer is pursuing a clinical development strategy in high-, middle- and low-income countries.

In 2016, Pfizer received a grant from the Bill & Melinda Gates Foundation to conduct a Phase 1/2 clinical trial of Pfizer’s vaccine candidate against GBS infection in South Africa, which has one of the highest invasive GBS disease incidences of 2.38 cases per 1,000 live births.7

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DISCLOSURE NOTICE: The information contained in this release is as of June 19, 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 Pfizer's vaccine candidate against Group B Streptococcus (GBS), including their 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 study commencement and completion dates as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; risks associated with preliminary 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 and when drug applications may be filed in any jurisdictions for any potential indications for Pfizer's vaccine candidate against GBS; 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 Pfizer's vaccine candidate against GBS; 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, 2016 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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