



Pfizer Awarded Grant to Evaluate Vaccine to Protect Newborns Against Group B Streptococcus Infection

Wednesday, October 19, 2016 - 04:00am

Grant from the Bill & Melinda Gates Foundation will help advance potential new vaccine that could provide protection from debilitating infections before and shortly after birth. About 1 out of every 4 pregnant women carries group B Streptococcus bacteria which could be passed from mother to baby during labor and birth. A severe, aggressive and potentially deadly infection, group B Streptococcus is a leading cause of life-threatening neonatal sepsis and meningitis.

Pfizer Inc. (NYSE:PFE) today announced an award of a grant from the Bill & Melinda Gates Foundation to conduct a Phase 1/2 clinical trial of Pfizer's vaccine candidate against group B Streptococcus (group B strep or GBS) infection, a leading cause of neonatal sepsis, a serious life-threatening blood infection. The investigational vaccine is designed to protect newborns via maternal immunization.

There is an urgent global health need for a vaccine that could protect pregnant women and their infants against GBS, particularly in developing countries where prophylactic administration of antibiotics is not routine. A pregnant woman has the ability to transfer protective antibodies to her unborn child through the placenta; if successful, the vaccine could help augment this protective effect for the newborn baby.

"The first few days and weeks of a baby's life are the most dangerous by far," said Keith Klugman, Director for Pneumonia at the Bill & Melinda Gates Foundation. "The clinical development of a group B streptococcal vaccine would be an important landmark in the story of vaccine development to protect newborns from this disease through the

immunization of their mothers."

Neonatal GBS infection is a debilitating and often fatal disease with mortality rates of around 6% to 14% of those infected in industrialized countries^{iv} and approximately 14% to 38% of those infected in parts of the developing world.^v The estimated incidence of invasive GBS disease is among the highest in South Africa, with 2.38 cases per 1,000 live births.^{vi}

"The health benefits of maternal immunization to protect pregnant mothers and their babies against flu, tetanus and pertussis are well-documented," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "We are looking to determine whether our investigational vaccine could generate levels of protective antibodies in the mother that, when passed to her unborn baby, will protect the baby against deadly GBS infection during a time when the infant is most vulnerable to infection."

GBS bacteria have the potential to cause severe disease, particularly in newborn infants who have an immature immune system that is still adapting to the environment outside the womb. Some of the most common complications caused by GBS impact the blood, lungs, lining of the brain, and spinal cord in the form of sepsis, pneumonia or meningitis. It is estimated that more than 40% of survivors remain impaired during childhood.^{vii}

Current preventative care in the developed world consists of prophylactic treatment with intravenous antibiotics before delivery of the baby, which is an uncommon practice in the developing world as it presents multiple challenges to implementation in countries lacking a robust health care infrastructure.

Research has shown that a potential conjugate vaccine that incorporates at least five serotypes of GBS could prevent approximately 95% of group B streptococcal disease in infants younger than three months.^{viii}

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The information contained in this release is as of October 19, 2016. 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 an award of a grant from Bill & Melinda Gates Foundation to Pfizer and Pfizer's vaccine candidate against group B Streptococcus (group B strep or 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, 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.

i Centers for Disease Control and Prevention, "Group B Strep (GBS): Fast Facts." Accessed 8 June 2016. Available at <http://www.cdc.gov/groupbstrep/about/fast-facts.html>

ii Thigpen, MC, et al. Bacterial Meningitis in the United States, 1998–2007. *N Engl J Med.* 2011; 364:2016-2025. iii Thigpen MC, et al. Bacterial Meningitis in the United States, 1998–2007. *N Engl J Med.* 2011: 364:2016-2025.

iv Edwards MS, Gonik B, "Preventing the broad spectrum of perinatal morbidity and mortality through group B streptococcal vaccination." Accessed 24 June 2016. Available at <http://www.ncbi.nlm.nih.gov/pubmed/23200934>

v Johri AK, Lata H, et al., "Epidemiology of Group B Streptococcus in developing countries." Accessed 24 June 2016. Available at <http://www.ncbi.nlm.nih.gov/pubmed/23973346>

vi Dangor Z, Lala SG, et al., "Burden of Invasive Group B Streptococcus Disease and Early Neurological Sequelae in South African Infants." Accessed 13 October 2016. Available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123014#sec014>

vii Libster R, Edwards KM, et al., "Long-term outcomes of group B streptococcal meningitis." Accessed 24 June 2016. Available at <http://www.ncbi.nlm.nih.gov/pubmed/22689869>

viii Le Doare K, Heath PT, "An overview of global GBS epidemiology." *Vaccine.* 2013; D7-D12. Accessed October 10 2016. Available at <http://www.sciencedirect.com/science/article/pii/S0264410X13000285>

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