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FDA Grants Breakthrough Therapy Designation to Pfizer's Group B Streptococcus Vaccine Candidate to Help Prevent Infection in Infants Via Immunization of Pregnant Women

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that its investigational Group B *Streptococcus* (GBS) vaccine candidate, GBS6 or PF-06760805, received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of invasive GBS disease due to the vaccine serotypes in newborns and young infants by active immunization of their mothers during pregnancy.

The FDA decision is informed by the interim analysis of a placebo-controlled Phase 2 study (NCT03765073), evaluating the safety and immunogenicity of GBS6 in healthy pregnant women aged 18 to 40 years, who were vaccinated during the second or early third trimester of pregnancy. The study remains ongoing, and Pfizer will publish outcomes from this clinical trial when it is completed.

"GBS infections can have a devastating effect on newborns and their families. While prenatal screening and antibiotics during childbirth help provide protection against GBS in developed countries, this approach is not fully protective in the first week of life; presents multiple challenges in low- and middle-income countries; and has not been shown effective in preventing disease globally in infants beyond the first week of life and through the vulnerable first three months of life," said Annaliesa Anderson, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "If approved for pregnant women, GBS6 could help protect newborns from the serious illnesses caused by this disease like meningitis, pneumonia, and sepsis – fulfilling a critical global public health need. We are encouraged by today's decision and look forward to discussing GBS6 with the FDA and other regulatory agencies to potentially reduce neonatal deaths and positively impact the existing global disease burden of GBS."

The FDA's 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] This decision follows the FDA's March 2017 decision to grant Fast Track status to GBS6. Fast Track status 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]

About GBS6

Hexavalent anti capsular polysaccharide (CPS) / cross reactive material 197 glycoconjugate (GBS6) is an investigational maternal vaccine being developed to help prevent invasive Group B *Streptococcus* (GBS) in newborns. GBS6 is designed to offer protection against the six most prominent GBS serotypes, which account for 98% of disease worldwide.[3] It is being evaluated in an ongoing Phase 2, placebo-controlled study in pregnant

women and their infants in South Africa, U.K., and the U.S. and is assessing the safety and immunogenicity of a single dose administered by intramuscular injection during the second or early third trimester of pregnancy to prevent disease in infants. Pfizer is pursuing a clinical development strategy in high-, middle- and low-income countries with the intent to make a successfully developed vaccine available globally as quickly as possible.

In April 2022, GBS6 was granted PRIME designation by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). This designation provides enhanced support for the development of medicines that target an unmet medical need.[4]

In 2016, Pfizer received a grant from the Bill & Melinda Gates Foundation, which supported the ongoing Phase 2 clinical trial of GBS6 as well as a parallel non-interventional natural history study.

About Group B *Streptococcus* (GBS)

Group B *Streptococcus* (GBS) is a common bacterium that can cause potentially devastating diseases in infants, including sepsis, pneumonia and meningitis, during the first three months of life. About one in four pregnant women carry GBS bacteria in their body and may pass it along to their baby during or prior to birth.[5] Annually, there are an estimated 410,000 GBS cases worldwide, which cause at least 147,000 stillbirths and infant deaths each year.[6]

About Maternal Immunization

During pregnancy, antibodies – special disease-fighting proteins – are actively transferred from the mother's blood across the placenta and to the fetus. This natural process is known as transplacental antibody transfer. Vaccines given to pregnant women (maternal immunization) that are intended to prevent illness in young infants rely on this process of transplacental antibody transfer. When a pregnant woman is vaccinated, her immune response produces vaccine-specific antibodies, which can then be transferred to the fetus.[7] This protection from the mother is called "maternal immunity" and is critical for helping infants fight off potential infections during the most vulnerable first months of life.

About Pfizer: Breakthroughs That Change Patients' Lives

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, including innovative medicines and vaccines. 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 170 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 September 7, 2022. 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 Group B streptococcus (GBS) vaccine candidate, GBS6 , including 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; risks associated with interim 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 biologic license applications may be filed in any jurisdictions for GBS6 for any potential 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 GBS6 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 GBS6; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding GBS6 and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; 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, 2021 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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[1] U.S. Food and Drug Administration (FDA). Breakthrough Therapy. https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm. Updated January 4, 2018. Accessed February 10, 2022.

[2] U.S. Food and Drug Administration. Fast Track https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm. Updated January 4, 2018. Accessed February 10, 2022.

[3] Buurman et al. "A Novel Hexavalent Capsular Polysaccharide Conjugate Vaccine (GBS6) for the Prevention of Neonatal Group B Streptococcal Infections by Maternal Immunization." The Journal of Infectious Diseases 2019. 220(1):105-115. https://academic.oup.com/jid/article/220/1/105/5336091

[4] European Medicines Agency. "PRIME: priority medicines." Accessed 2 May 2022. Page last reviewed 5 April 2022. Available at https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines.

[5]Centers for Disease Control and Prevention. "Group B Strep (GBS): Fast Facts." Accessed 31 January 2022. Page last reviewed 11 June 2020. Available at https://www.cdc.gov/groupbstrep/about/fast-facts.html

[6] World Health Organization. "Group B Streptococcus infection causes an estimated 150,000 preventable stillbirths and infant deaths every year." Accessed 31 January 2022. Page last reviewed 5 November 2017. Available at https://www.who.int/news/item/05-11-2017-group-b-streptococcus-infection-causes-an-estimated-

150-000-preventable-stillbirths-and-infant-deaths-every-year

[7] Faucette et al. “Immunization of pregnant women: Future of early infant protection.” Human Vaccines & Immunotherapeutics 2015. 11(11):2549-2555. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685701/

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