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# Pfizer Announces New England Journal of Medicine Publication on Group B Streptococcus (GBS) Maternal Vaccine Candidate

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- *Results from an ongoing Phase 2 study in pregnant individuals showed the investigational vaccine, GBS6, was generally well-tolerated and generated robust maternal antibody responses that were efficiently transferred to infants*
- *The safety profile between the vaccine and placebo groups was similar in both the mothers and infants*
- *GBS6 maternal vaccination may offer meaningful protection against invasive GBS disease in newborns and young infants, based on a natural history study conducted in parallel to the Phase 2 study*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced data from a Phase 2 study investigating its hexavalent capsular polysaccharide (CPS) conjugate Group B Streptococcus (GBS) vaccine candidate, GBS6, being developed for maternal administration to protect infants against invasive GBS disease. In stage two of the three-part study, which enrolled 360 healthy pregnant individuals, GBS6 generated robust maternal antibody responses against the six GBS CPS serotypes included in the vaccine, and these antibodies were efficiently transferred to infants at ratios of ~0.4-1.3 depending on GBS6 group. Based on a parallel natural history study conducted in South Africa, the Phase 2 study immunogenicity data suggest that GBS6 may offer meaningful protection against invasive GBS disease in newborns and young infants. The results were published in *The New England Journal of Medicine*(NEJM) and will inform a planned Phase 3 clinical development program.

In both the mothers and infants, the safety profile was similar between the vaccine and placebo groups. Local reactions were generally mild or moderate and of short duration with pain at the injection site being the most frequently reported event. Solicited systemic events were similar among the GBS6 groups and the placebo group, with most events being mild or moderate. Overall, 2 to 8% of participants in the GBS6 groups, depending on dose, and 5% of those in the placebo group reported fever. Among pregnant individuals, adverse events (AEs) occurred in 45 to 70% of the participants in the GBS6 groups, depending on dose, and in 61% of those in the placebo group. The most common AEs and serious adverse events (SAEs) were conditions that are related to pregnancy. Among the infants, AEs occurred in 62 to 75% of the participants in the GBS6 groups, depending on dose, and in 74% of those in the placebo group. None of the SAEs were deemed related to the vaccine candidate.

“Group B Streptococcus can cause potentially devastating diseases in infants, including sepsis, pneumonia and meningitis. Annually, there are nearly 400,000 cases of infant disease and approximately 138,000 stillbirths and infant deaths worldwide due to GBS,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “The findings published in *NEJM* provide hope that maternal vaccination with GBS6 may protect infants against GBS, potentially helping to prevent thousands of cases of illness annually, if it is successfully developed and approved. Building on decades of expertise and

knowledge in vaccines, we are committed to helping protect newborns and young infants through maternal immunization."

The Phase 2 placebo-controlled study was divided into three stages.

- **Stage 1:** Evaluated safety and immunogenicity in 66 healthy, nonpregnant individuals in South Africa.
- **Stage 2:** The focus of the NEJM publication, is evaluating safety and immunogenicity in 360 healthy pregnant individuals aged 18 to 40 years and their infants in South Africa. Participants were randomly assigned to receive a single dose of GBS6 formulated at 5, 10 or 20 µg/serotype, with or without an $AlPO_4$ adjuvantor placebo, given from late second trimester. The highest antibody responses were generally observed with the GBS6 20 µg dose, formulated without an aluminum phosphate ($AlPO_4$) adjuvant.
- **Stage 3:** A final formulation is being evaluated in 216 healthy pregnant individuals and their infants in South Africa, the U.S. and U.K.

A parallel natural history study conducted in South Africa is also reported in the same issue of NEJM. This study enrolled approximately 18,000 mother-infant pairs to estimate anti-CPS immunoglobulin (IgG) antibody concentrations in infant sera associated with risk of invasive disease through 89 days of age after delivery. Antibody concentrations associated with protective natural immunity obtained from this second study were compared to maternally transferred GBS6 vaccine-induced antibody levels in infants in the Phase 2 study to determine the percentage of infants that have antibody levels exceeding those associated with protection. Naturally acquired anti-CPS IgG concentrations correlated with reduced risk of disease in the natural history study with similar results for serotypes Ia, III, and an aggregate of all GBS6 serotypes that indicated 75-95% protective titers of 0.184-0.827 µg/mL anti-CPS IgG. The proportion of infants born to immunized mothers in stage two of the Phase 2 study with anti-CPS IgG antibody concentrations >0.184 ug/mL varied by serotype and formulation, with 57% to 97% seroresponder rates achieved for the most immunogenic formulation.

**About GBS6**
Hexavalent anti capsular polysaccharide (CPS) / genetically detoxified diphtheria toxin cross reactive material (CRM) 197 glycoconjugate (GBS6) is being developed as an investigational maternal vaccine to help prevent invasive Group B Streptococcus (GBS) in newborns. Polysaccharides conjugated to CRM have been successfully used by Pfizer in its pneumococcal vaccines, which have a proven track record of safety and effectiveness in millions of infants globally.

GBS6 is designed to offer protection against the six most prominent GBS serotypes, which account for 98% of GBS disease worldwide.[1] GBS6 safety and immunogenicity is being evaluated in an ongoing Phase 2, placebo-controlled study in pregnant women and their infants in South Africa, the U.S. and U.K. following a single intramuscular injection during the second or early third trimester of pregnancy. 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 2016, Pfizer received a grant from the Bill & Melinda Gates Foundation, which supported the ongoing Phase 2 clinical trial of GBS6 as well as the parallel natural history study conducted in South Africa.[2] In May 2022, the Foundation gave Pfizer an additional grant to help support the continued development of GBS6. With these grants from the Bill & Melinda Gates Foundation, Pfizer has committed to support greater access to the vaccine, if approved, in Gavi-supported countries. For more information about the Phase 2 study (NCT03765073), please visit https://www.clinicaltrials.gov.

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.[3] In August 2022, GBS6 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'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 clinically significant endpoints.[4]

**About Group B Streptococcus (GBS)**

Group B Streptococcus (GBS) is a common bacterium that can cause potentially devastating disease in infants, including sepsis, pneumonia and meningitis, primarily during the first three months of life. Up to one in four pregnant individuals 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 394,000 GBS cases worldwide, which cause at least 138,000 stillbirths and infant deaths each year. Invasive GBS disease can also lead to long-term neurodevelopmental impairment in infants who recover, with significant impact on patients, their families and society. Low- and middle-income countries are most heavily affected by GBS: >40% of infant invasive GBS cases and >50% of GBS-related stillbirths and infants deaths occur in sub-Saharan Africa, and another ~35% of cases and deaths arise in Central, South and East/Southeast Asia, regions where access to screening and intrapartum antibiotic prophylaxis as well as delivery by a skilled birth attendant are limited. [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 when their immune system is still developing.

**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 July 19, 2023. 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; 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, 2022 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] 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

[2] Pfizer Inc. "Pfizer Begins Phase 1 Clinical Trial to Evaluate Investigational Group B Streptococcus Vaccine." June 19, 2017. https://www.pfizer.com/news/press-release/press-release-detail/pfizer_begins_phase_1_clinical_trial_to_evaluate_investigational_group_b_streptococcus_vaccine.

[3] 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.

[4] 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.

[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] Goncalves, et al. "Group B streptococcus infection during pregnancy and infancy: estimates of regional and global burden." Lancet Glob Health 2022. 10: e807–19. https://doi.org/10.1016/S2214-109X(22)00093-6.

[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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