U.S. FDA Accepts for Review the Biologics License Application for Pfizer’s Investigational Pentavalent Meningococcal Vaccine Candidate (MenABCWY) in Adolescents

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If approved, the vaccine could help simplify the meningococcal vaccination schedule and provide the broadest serogroup coverage of any meningococcal vaccine

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for its investigational pentavalent meningococcal vaccine candidate (MenABCWY). Pfizer submitted MenABCWY for the prevention of meningococcal disease caused by the most common serogroups in individuals 10 through 25 years of age.

The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA on the pentavalent meningococcal vaccine application is in October 2023.

Pfizer’s MenABCWY vaccine candidate combines the components of two vaccines into one, helping protect against the meningococcal serogroups that cause the majority of invasive meningococcal disease (IMD) globally.1 In the U.S., approximately 55 million adolescents and young adults are in the age range for meningococcal vaccination (11-23 years old), according to ACIP recommendations.2

“The FDA’s acceptance of our application for the pentavalent meningococcal vaccine candidate is an essential step toward helping protect individuals and communities against the most common types of meningococcal disease,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “We believe our investigational MenABCWY vaccine, if approved and recommended, could help simplify the meningococcal vaccination schedule for adolescents and young adults, and in turn improve vaccination rates, and provide the broadest serogroup coverage of any meningococcal vaccine. The pentavalent vaccine candidate was well-tolerated in clinical trials, with a safety profile consistent with currently licensed meningococcal vaccines.”

The regulatory submission is supported by previously announced positive results from a randomized, active-controlled and observer-blinded Phase 3 trial assessing the safety, tolerability, and immunogenicity of the pentavalent vaccine candidate compared to currently licensed meningococcal vaccines, with the goal of determining immunologic noninferiority. The Phase 3 trial (NCT04440163) evaluated more than 2,400 patients from the U.S. and Europe.

Potential U.S. Public Health Impact of a MenABCWY Vaccine

Meningococcal disease is an uncommon but serious illness that can lead to death within 24 hours and, for survivors, can result in life-altering, significant long-term disabilities.3 Together, the five most common meningococcal serogroups account for 95 percent of all IMD cases worldwide, with serogroup B accounting for the majority of disease in adolescents and young adults in the U.S. and Europe.1

In the U.S., the current meningococcal vaccination platform for adolescents and young adults includes a routine recommendation for MenACWY vaccines (two doses) and a separate, shared clinical decision recommendation for MenB-specific vaccines (two doses) in order to achieve the broadest serogroup protection available against meningococcal disease. However, less than a third of U.S. adolescents receive even one dose of a MenB vaccine, and fewer complete the series.4,5 If approved and recommended, Pfizer’s pentavalent vaccine candidate could be another option for the current routine recommendations in place for MenACWY vaccines. Pfizer’s pentavalent vaccine candidate could potentially reduce the total number of doses needed for individuals to be fully vaccinated against the five serogroups, thereby simplifying meningococcal vaccination and increasing the number of adolescents and young adults vaccinated.6 Routine use of a MenABCWY vaccine could reduce IMD cases and associated mortality, the rate of long-term sequelae in survivors, and costs associated with controlling outbreaks.7

About the Pentavalent Meningococcal Vaccine Candidate (MenABCWY)

Pfizer’s pentavalent meningococcal vaccine candidate combines the components from its two licensed meningococcal vaccines, Trumenba® (meningococcal group B vaccine) and Nimenrix® (meningococcal groups A, C, W-135, and Y conjugate vaccine); approvals of Nimenrix® and Trumenba® vary by country. Together, the 5 serogroups included in MenABCWY are responsible for the majority of currently circulating meningococcal disease globally.1 Top line results from a randomized, active-controlled and observer-blinded Phase 3 trial of Pfizer’s pentavalent meningococcal vaccine candidate (NCT04440163) were previously announced in September 2022. Additional information about the trial and results can be found at www.clinicaltrials.gov.

INDICATIONS FOR TRUMENBA® IN THE U.S.

Trumenba® is a vaccine indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by Neisseria meningitidis group B
IMPORTANT SAFETY INFORMATION

Trumenba® should not be given to anyone with a history of a severe allergic reaction to any component of Trumenba® Some individuals with weakened immune systems may have a reduced immune response Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by Neisseria meningitidis group B even with receipt of vaccination with Trumenba® Vaccination with Trumenba® may not protect all vaccine recipients against N meningitidis group B infections Fainting can occur in association with administration of injectable vaccines, including Trumenba® The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain Data are not available on the safety and effectiveness of using Trumenba® and other meningococcal group B vaccines interchangeably to complete the vaccination series Tell your health care provider if you are pregnant, or plan to become pregnant Ask your health care provider about the risks and benefits of Trumenba®. Only a health care provider can decide if Trumenba® is right for you or your child
INDICATION FOR NIMENRIX® IN THE E.U.

Nimenrix® is a vaccine indicated for individuals six weeks of age and older for active immunization to prevent invasive disease caused by Neisseria meningitidis groups A, C, W-135 and Y
IMPORTANT SAFETY INFORMATION

Nimenrix® should not be given to anyone with a history of a severe allergic reaction after

a previous dose of Nimenrix® Some individuals with weakened immune systems may have a reduced immune response Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by Neisseria meningitidis groups A, C, W, and Y, even with receipt of vaccination with Nimenrix® As with any vaccine, vaccination with Nimenrix® may not protect all vaccine recipients against N. meningitidis groups A, C, W and Y Fainting can occur shortly before or after injecting vaccines, including Nimenrix® The most common adverse reactions were loss of appetite, irritability, drowsiness, headache, fatigue, fever, and pain, redness, and swelling at the injection site Tell your healthcare provider if you are pregnant, or plan to become pregnant Ask your healthcare provider about the risks and benefits of Nimenrix®. Only a healthcare provider can decide if Nimenrix® is right for you or your child

Menveo® and Nimenrix® are trademarks of GlaxoSmithKline Biologicals S.A.

Soliris® is a trademark of Alexion Pharmaceuticals, Inc.

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 December 28, 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 MenABCWY vaccine candidate, including its potential benefits, a BLA pending with the FDA and its potential recommendation, 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 any biologic license applications may be filed in particular jurisdictions for Pfizer’s MenABCWY vaccine candidate; whether and when the BLA pending with the FDA or any such other 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 such product candidate 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 Pfizer’s MenABCWY vaccine candidate; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities for Pfizer’s MenABCWY vaccine candidate and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer’s 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.

1 National Library of Medicine. Global estimate of Neisseria meningitidis serogroups proportion in invasive meningococcal disease: A systematic review and meta-analysis. September 2019. Available at: https://doi.org/10.1016/j.micpath.2019.103571. Accessed June 2, 2022. 2 Centers for Disease Control and Prevention. Meningococcal vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States,

2020. September 2020. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm. Accessed December 19, 2022. 3 Borg J, Christie D, Coen PG, Pooy R, Viner RM. Outcomes of Meningococcal disease in adolescence: prospective, matched-cohort study. Pediatrics. 2009;123:e502-e509. Available at: https://pubmed.ncbi.nlm.nih.gov/19254985/. Accessed December 19, 2022. 4 Pingali C et al. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2021. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7135a1-H.pdf. Accessed November 17, 2022. 5 La EM, Garbinsky D, Hunter S, Poston S, Novy P, Ghaswalla P. Meningococcal B vaccination coverage among older adolescents in the United States. Vaccine. 2021;39(19):2660-2667.Available at: https://pubmed.ncbi.nlm.nih.gov/33849722/. Accessed December 19, 2022. 6 National Library of Medicine. Rationale for the Development of a Pentavalent Meningococcal Vaccine: A US-Focused Review. 2022. Available at: https://pubmed.ncbi.nlm.nih.gov/35357651/. Accessed December 19, 2022. 7 National Library of Medicine. Potential Public Health Impact of a Neisseria Meningitidis A, B, C, W, and Y Pentavalent Vaccine in the United States. 2022. Available at: https://pubmed.ncbi.nlm.nih.gov/33615973/. Accessed December 19, 2022. https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htmhttps://pubmed.ncbi.nlm.nih.gov/19254

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