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Pfizer Announces Positive Top-Line Results from Phase 3 Trial of Pentavalent Meningococcal Vaccine Candidate (MenABCWY) in Adolescents

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- *Phase 3 trial demonstrates that the investigational pentavalent meningococcal vaccine (MenABCWY) was well-tolerated with an acceptable safety profile and immunogenicity non-inferior to Trumenba® + Menveo® for all serogroups*
- *Based on these findings, Pfizer plans to submit an application for approval to the U.S. Food and Drug Administration in the fourth quarter of 2022*
- *If approved, MenABCWY 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 positive top-line results from the pivotal Phase 3 trial (NCT04440163) assessing the safety, tolerability, and immunogenicity of its investigational pentavalent meningococcal vaccine (MenABCWY) in healthy individuals 10 through 25 years of age. The trial met all primary and secondary endpoints, with the investigational vaccine demonstrating non-inferiority to licensed vaccines for the five meningococcal serogroups that cause the majority of invasive meningococcal disease: serogroups A, B, C, W and Y.[1] Currently, MenACWY and MenB vaccines are licensed separately, and no single vaccine is available to help protect against the five serogroups.

Participants in the trial were randomly assigned to receive either two doses of MenABCWY or licensed vaccines (two doses of Trumenba® + one dose of Menveo®). Non-inferiority was demonstrated for all five serogroups following two doses of MenABCWY compared to two doses of Trumenba®and one dose of Menveo®.

Additionally, a single dose of MenABCWY met the non-inferiority criteria for serogroups A, C, W and Y compared to one dose of Menveo®. Furthermore, in individuals who had not previously received a meningococcal vaccine, the proportion of subjects with ?4-fold increases in immune responses was observed to be higher following either one or two doses of MenABCWY for serogroups A, C, W and Y compared to one dose of Menveo®. Finally, the proportion of subjects with ?4-fold increases in immune responses was also observed to be higher against all four serogroup B strains following two doses of MenABCWY compared to two doses of Trumenba®. The pentavalent vaccine candidate was well-tolerated, with a safety profile consistent with licensed vaccines.

“We are very pleased with these positive Phase 3 data, which are the first for a MenABCWY vaccine candidate,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “A pentavalent vaccine has the potential to help simplify what is currently a complex meningococcal vaccination schedule in the U.S. and improve vaccine coverage. Our goal is to help ensure as many adolescents and young adults as possible are protected against this devastating disease.”

Based on these Phase 3 results, which meet pre-determined criteria for licensure, Pfizer intends to submit a Biologics License Application to the U.S. Food and Drug Administration in the fourth quarter of this year. Submissions to additional regulatory authorities outside the U.S. are also planned.

“The potential recommendation of a pentavalent vaccine in the U.S. as an alternative to the existing MenACWY vaccines across both the 11- to 12-year-old and 16-year-old vaccination platforms provides a significant opportunity for Pfizer to enter the U.S. MenACWY vaccine market and help protect more young people across the country. Today, we estimate there are approximately 52 million adolescents and young adults who are in the age range for meningococcal vaccination according to CDC guidance,” said Angela Hwang, President, Global Biopharma Business, Pfizer. “We look forward to the public health impact a pentavalent vaccine may provide, and to strengthening our position as a global leader in the prevention of meningococcal disease.”

Potential 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.[2] Together, five serogroups (A, B, C, W and Y) account for 96 percent of all invasive meningococcal disease cases worldwide, with serogroup B accounting for the majority of disease in adolescents and young adults in the U.S. and Europe.[3]

In the U.S., the current vaccination recommendations for adolescents and young adults include a MenACWY vaccine and a separate MenB vaccine (total four doses) to help achieve the broadest 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 two-dose series, resulting in many adolescents being unprotected against meningococcal disease caused by serogroups A, B, C, W, and Y.[4,5] If approved and recommended, Pfizer’s pentavalent vaccine candidate could help simplify the meningococcal vaccination schedule by potentially reducing the total number of doses needed for individuals to be fully vaccinated against the five serogroups.[6] Routine use of a MenABCWY vaccine could help improve meningococcal vaccination rates and coverage, thereby reducing cases of invasive meningococcal disease and associated mortality, the rate of long-term sequelae in survivors, and costs associated with controlling outbreaks.[7]

About the Phase 3 Trial

The randomized, active-controlled and observer-blinded Phase 3 trial of Pfizer’s pentavalent meningococcal vaccine candidate (NCT04440163) was initiated in June 2020 and enrolled 2,431 healthy adolescents and young adults (10 through 25 years of age) from the U.S. and Europe. The study was designed to compare immune responses in individuals after MenABCWY administration to responses in control groups receiving licensed vaccines Trumenba® (meningococcal group B vaccine) and Menveo® (meningococcal group A, C, W-135, and Y conjugate vaccine), as well as to describe the safety profile of the MenABCWY vaccine. Immune responses were assessed by human serum bactericidal assay (hSBA). The study enrolled both individuals who had previously received a MenACWY vaccine and those who had not. All participants had not received any meningococcal group B vaccine prior to enrollment.

Additional information about the trial can be found at www.clinicaltrials.gov. Pfizer plans to present the detailed results from this trial at a future medical congress and submit the results for peer review in a scientific journal.

Pfizer’s pentavalent meningococcal vaccine candidate combines its two licensed meningococcal vaccines, Trumenba® and Nimenrix® (meningococcal group A, C, W-135, and Y conjugate vaccine). Approvals of Nimenrix® and Trumenba® vary by country.

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 September 15, 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, its potential recommendation and planned regulatory submissions, 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 any jurisdictions for Pfizer's MenABCWY vaccine candidate; whether and when any such applications may be approved by regulatory authorities, which will depend on a 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 .

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