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Pfizer Receives Positive CHMP Opinion for TRUMENBA® for Prevention of Meningococcal Group B Disease

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TRUMENBA Has Been Studied in a Global Clinical Development Program Evaluating the Vaccine in Adolescents and Adults1 The Majority of Meningococcal Disease Cases in Europe are Caused by Meningococcal Group B (MenB), with Adolescents and Young Adults at Increased Risk2

“This decision further affirms the effectiveness and robust safety profile of TRUMENBA.”

Pfizer Inc. (NYSE:PFE) today announced that the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending that TRUMENBA® (Meningococcal Group B Vaccine) be granted marketing authorization in the European Union (EU) for active immunization of individuals 10 years and older to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B (MenB).[3] The CHMP’s opinion will now be sent to the European Commission (EC) for final decision.

“This positive opinion by the CHMP to recommend marketing authorization of TRUMENBA in the EU is an additional step toward the fight to help protect individuals over 10 years of age from meningococcal disease caused by serogroup B, an uncommon yet devastating and life-threatening disease,” said Kathrin Jansen, Ph.D., senior vice president and head of Vaccine Research and Development for Pfizer Inc. “This decision further affirms the effectiveness and robust safety profile of TRUMENBA.”

Pfizer conducted a global clinical development program for TRUMENBA, evaluating more than 20,000 adolescents and adults, approximately 15,000 of whom received TRUMENBA. These data, which were reviewed by the CHMP, demonstrate that the benefits of TRUMENBA are its ability to induce protective serum bactericidal antibody responses to diverse meningococcal serogroup B strains expressing fHBP variants that are representative of MenB strains causing invasive disease, and that TRUMENBA is a well-tolerated vaccine.[1]

Meningococcal disease is an uncommon, yet devastating condition that can strike quickly without warning at any age. The most common clinical presentations of meningococcal disease are meningitis and meningococcal septicaemia (also known as meningococcemia), a bloodstream infection.[4] Despite appropriate care, as many as 10 percent of those who develop the disease die from it[2] and of those who survive, up to 20 percent may experience significant medical disabilities including limb amputation, vision or hearing impairment, mental and motor skill impairment and poorer quality of life.[5,6,7] Adolescents and young adults are at an increased risk of meningococcal disease due to inherent environmental and behavioral factors such as living in close quarters and sharing drinks, cups or utensils.[8,9]

The majority of meningococcal disease cases worldwide can be attributed to six Neisseria meningitidis serogroups (A, B, C, W, X and Y).[10,11] In Europe, the majority of cases are caused by serogroup B strains.[2]

Vaccines are one of the greatest public health advances, resulting in the control, elimination or near-elimination of numerous vaccine-preventable infectious diseases. Pfizer's Meningococcal Vaccines portfolio is built with vaccines that help protect against five of the most common disease-causing serogroups – A, C, W, Y and B (approvals varying by country) – which can threaten the health of people at various points in their lives.[1]

About TRUMENBA

TRUMENBA was first introduced in the United States in October 2014 for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B in individuals 10 through 25 years of age.[12]

TRUMENBA is a sterile suspension composed of two recombinant lipidated factor H binding protein (fHBP) variants from N. meningitidis serogroup B, one from fHBP subfamily A and one from subfamily B (A05 and B01, respectively). fHBP is one of many proteins found on the surface of meningococci and contributes to the ability of the bacterium to avoid host defenses. fHBPs can be categorized into two immunologically distinct subfamilies, A and B.[13] The susceptibility of serogroup B meningococci to complement-mediated, antibody-dependent killing following vaccination with TRUMENBA is dependent on both the antigenic similarity of the bacterial and vaccine fHBPs, as well as the amount of fHBP expressed on the surface of the invading meningococci.[14]

As with any vaccine, TRUMENBA may not prevent disease in all vaccinated individuals. The frequency of meningococcal disease caused by serogroup B varies geographically, and could influence the ability to evaluate effectiveness of the vaccine in any given country. Based on the low incidence of meningococcal disease, placebo-controlled clinical trials for TRUMENBA were considered unfeasible due to the size of the study that would be required and were not performed. Licensure of TRUMENBA was based on demonstration of immune responses measured using a serum bactericidal assay with human complement (hSBA).

U.S. Indication for TRUMENBA

TRUMENBA® (Meningococcal Group B Vaccine) is indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by Neisseria meningitidis group B. The effectiveness of the two-dose schedule of Trumenba against diverse Neisseria meningitidis serogroup B strains has not been confirmed.

Important Safety Information

TRUMENBA® (Meningococcal Group B Vaccine) should not be given to anyone with a history of a severe allergic reaction after a previous dose of TRUMENBA.

Individuals with weakened immune systems may have a reduced immune response.

The most common adverse reactions in adolescents and young adults were pain at the 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 healthcare provider if you are pregnant, or plan to become pregnant.

Ask your healthcare provider about the risks and benefits of TRUMENBA.

Only a healthcare provider can decide if TRUMENBA is right for you or your child.

You are encouraged to report negative side effects of vaccines to the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

Visit www.vaers.hhs.gov or call 1-800-822-7967. For the full prescribing information for TRUMENBA, please visit www.trumenba.com.

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DISCLOSURE NOTICE: The information contained in this release is as of March 24, 2017. 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 TRUMENBA® (Meningococcal Group B Vaccine) and the opinion of the CHMP of the EMA regarding the filed marketing authorization application for TRUMENBA, 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, uncertainties regarding the commercial success of TRUMENBA; the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results; whether and when any biologics license applications may be filed in any other jurisdictions for TRUMENBA; whether and when the EMA or regulatory authorities in any other jurisdictions where applications for TRUMENBA may be pending or filed may approve any such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the immunogenicity and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of TRUMENBA; 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, 2016 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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