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Pfizer Announces European Medicines Agency Acceptance for Review of Marketing Authorization Application for TRUMENBA® (Meningococcal Group B Vaccine)

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“At Pfizer we are committed to providing innovative vaccines that help people live the longest, healthiest lives possible.”

Pfizer Inc. (NYSE:PFE) today announced the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for TRUMENBA® (Meningococcal Group B Vaccine) for review. TRUMENBA has been developed for the prevention of invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* serogroup B (MnB) in individuals aged 10 years and older. The acceptance marks the beginning of the regulatory review process for this vaccine in the EU.

"The EMA’s acceptance of TRUMENBA’s Marketing Authorization Application brings us one step closer to fighting this uncommon yet life-threatening disease worldwide, by helping to protect adolescents and adults who are at risk to contract meningococcal disease caused by serogroup B,” said Kathrin Jansen, Ph.D., senior vice president and head of Vaccine Research and Development for Pfizer Inc. “At Pfizer we are committed to providing innovative vaccines that help people live the longest, healthiest lives possible.”

The MAA for TRUMENBA is based upon a clinical trial dataset of approximately 20,800 adolescents and adults aged 10 years and older, studied globally. This dataset demonstrates the consistency of vaccine-induced immune responses to diverse disease-causing MnB strains and the well-studied safety and tolerability profile.[1]

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

TRUMENBA is currently approved in the U.S.

Indication for TRUMENBA in the U.S.

TRUMENBA (Meningococcal Group B Vaccine) is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals aged 10 through 25 years of age.

Approval of TRUMENBA is based on the demonstration of immune response, as measured by serum bactericidal activity against four serogroup B strains representative of prevalent strains in the United States. The effectiveness of TRUMENBA against diverse serogroup B strains has not been confirmed.

Important Safety Information

TRUMENBA® 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 were pain at the injection site, fatigue, headache, muscle pain, and chills.

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.

For the full prescribing information for TRUMENBA, please visit www.trumenba.com.

About TRUMENBA® (Meningococcal Group B Vaccine)

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. 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.[2]

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).

In 2014, TRUMENBA was reviewed and received Accelerated Approval under the FDA's Breakthrough Therapy designation and Priority Review programs.

About Meningococcal Disease

Meningococcal disease can affect any one, at any age.[3] The reported incidence of invasive meningococcal disease (IMD) varies by region, ranging from less than 0.5 cases per 100,000 in North America and just under 1 case per 100,000 in Europe, and up to 10-1,000 cases per 100,000 during epidemic years in Africa.[4] The majority of invasive meningococcal disease cases worldwide can be attributed to six *Neisseria meningitidis* serogroups (A, B, C, W, X and Y).[4,5]

Meningococcal serogroup B disease affects all ages. In Europe, the majority of meningococcal disease cases are caused by serogroup B strains.[6] Global serogroup distribution patterns vary between countries, and change over time.[4]

Serogroup B meningococcal disease may result in life-altering, significant long-term and permanent medical disabilities.[7,8,9] Despite the availability of antibiotic treatment, 1 in 10 adolescents and young adults who contract MnB die and many of those who survive are afflicted with long-term disabilities, such as brain damage, hearing loss, learning disabilities or limb amputations.[10]

Pfizer Inc.: Working together for a healthier world™

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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, 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 May 20, 2016. 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 a marketing authorization application for TRUMENBA filed with the EMA, 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, 2015 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] Pfizer Data on File

[2] TRUMENBA® (Meningococcal Group B Vaccine) Prescribing Information. Philadelphia, PA: Pfizer, Inc. 2015.

[3] World Health Organization. Epidemics of meningococcal disease, African meningitis belt, 2001. *Wkly Epidemiol Rec.* 2001; 76(37); 281-288. http://www.who.int/docstore/wer/pdf/2001/wer7637.pdf. Published

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[10] Granoff D.M. (2013). Meningococcal vaccines. In *Vaccine* (pp. 388-418). Philadelphia, PA: Saunders.

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