Pfizer Granted FDA Breakthrough Therapy Designation for TRUMENBA® (Meningococcal Group B Vaccine) for the Prevention of Invasive Meningococcal B Disease in Children Ages 1 to 9 Years

Monday, April 23, 2018 - 04:00am

Pfizer Inc. (NYSE: PFE) today announced that TRUMENBA® (Meningococcal Group B Vaccine) received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for active immunization to prevent invasive disease caused by Neisseria meningitidis group B (MenB) in children ages 1 through 9 years. This is the first Breakthrough Therapy designation for a MenB vaccine to help protect children as young as 1 year of age. TRUMENBA previously received Breakthrough Therapy designation in 2014 for the prevention of MenB in adolescents and young adults ages 10 through 25 years, and later the same year received FDA approval as the first MenB vaccine approved in the U.S.

As noted in the October 2014 Approval Letter, Pfizer was required to assess the safety and effectiveness of TRUMENBA in children down to 1 year of age. Pfizer has successfully completed Phase 2 studies in this investigational age group and these data have been submitted to the FDA. These data supported Pfizer’s request for Breakthrough Therapy designation.

“Despite the occurrence of invasive serogroup B disease in children ages 1 through 9 years, and the potential life-altering and long-term consequences that may result from this uncommon disease, there is no MenB vaccine licensed in the U.S. for this age group,” said Dr. Luis Jodar, Chief Medical and Scientific Affairs Officer, Vaccines Medical Development, Scientific and Clinical Affairs, Pfizer Inc. “We look forward to working closely with the FDA toward our goal to extend the range of individuals who may benefit from immunization with TRUMENBA.”

In April 2017, TRUMENBA received traditional approval from the FDA in individuals 10 to 25 years of age for the three-dose schedule based on Phase 3 data, making it the only MenB vaccine in the U.S. with this full approval. TRUMENBA can be administered as a two- or three-dose schedule to adolescents and young adults 10 through 25 years of age depending on an individual’s risk of exposure and susceptibility to MenB. A study to confirm the effectiveness of the two-dose schedule is ongoing.

The majority of invasive meningococcal disease cases worldwide can be attributed to six Neisseria meningitidis serogroups (A, B, C, W, X, and Y). Together, serogroups A, B, C, W, and Y account for 90% of all invasive meningococcal disease (IMD)1, with MenB accounting for the majority of disease in adolescents and young adults in the U.S. and Europe.2 As of 2016, the burden of MenB is highest in adolescents/young adults (32%) and infants (20%), followed by children ages 1 to 4 years (12%) and children ages 5 to 10 years (4%).3

Breakthrough Therapy designation was initiated as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) signed in 2012. As defined by the FDA, a breakthrough therapy is a drug intended to be used alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as a breakthrough therapy, the FDA may expedite the development and review of such drug.4

U.S. Indication for TRUMENBA® (Meningococcal Group B Vaccine)

TRUMENBA is a vaccine indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by Neisseria meningitidis (N meningitidis) group B. The effectiveness of the two-dose schedule of TRUMENBA against diverse N meningitidis group 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. Some individuals with weakened immune systems may have a reduced immune response.

As with any vaccine, vaccination with TRUMENBA may not protect all vaccine recipients against N meningitidis group B infections.

The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain. Nausea was reported in adolescents in early phase studies.

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.

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 http://labeling.pfizer.com/ShowLabeling.aspx?id=1796.

About TRUMENBA® (Meningococcal Group B Vaccine)

TRUMENBA® (Meningococcal Group B Vaccine) 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.5

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).

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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, 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 April 23, 2018. 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 potential expanded indication to prevent invasive disease caused by MenB in children ages 1 through 9 years, 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, uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding TRUMENBA and uncertainties regarding the commercial impact of any such recommendations;

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, including unfavorable new clinical data or additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any supplemental biologics license applications may be filed in any jurisdictions for the potential expanded indication for TRUMENBA or in any other jurisdictions for any other potential indications for TRUMENBA; whether and when any such applications may be approved by regulatory authorities, 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 and, if approved, whether TRUMENBA will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of TRUMENBA, including the potential expanded indication; 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, 2017 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 Kieny MP, Excier J, Girard M. Research and development of new vaccines against infectious diseases. Am J Public Health. 2004;94(11):1931-1935. 2 Soeters HM, McNamara LA, Whaley M, Wang X, Alexander-Scott N, Kanadanian, KV, et al. Serogroup B meningococcal disease outbreak and carriage evaluation at a college – Rhode Island, 2015. MMWR Morb Mortal Wkly Rep. 2015;64(22):606-607. 3 US CDC Enhanced Meningococcal Disease Surveillance Report, 2016. Available at: https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf 4 Food and Drug Administration Fact Sheet Breakthrough Therapies at https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstothe 5 TRUMENBA (meningococcal group B vaccine) prescribing information. Philadelphia, PA: Pfizer, Inc. 2017.

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