Pfizer Logo

TRUMENBA® (Meningococcal Group B Vaccine) is Now Available

Tuesday, November 18, 2014 - 03:30am

Pfizer Inc. (NYSE:PFE) announced today that TRUMENBA® (Meningococcal Group B Vaccine), the first and only FDA-approved vaccine for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age, is now available for order by healthcare providers in the United States.

Serogroup B meningococcal meningitis is characterized by high fatality rates and rapid onset, often within 24 hours. For individuals 11-24 years of age, approximately 30 percent of meningococcal disease is serogroup B in the U.S., and 10 percent of these cases result in death.[1] As many as 60 percent of adolescent survivors of meningococcal disease, 15-19 years of age, suffer from permanent life altering consequences such as hearing loss, neurologic damage, or loss of a limb.[2]

“We have been working around the clock since TRUMENBA was approved by the U.S. Food and Drug Administration on October 29 to supply TRUMENBA in the U.S., as the most frequent question we have been asked following approval is when the vaccine would be available here,” said Susan Silbermann, president and general manager, Pfizer Vaccines. “As of November 18, TRUMENBA is available for order by healthcare providers, retail pharmacies, hospitals and college health centers who may be interested in stocking and administering the vaccine. We continue to work very closely with the CDC’s Advisory Committee on Immunization Practices to help inform discussions and potential recommendations regarding prevention of meningococcal group B disease through vaccination, an important step to improve access to TRUMENBA and help in the prevention of such a devastating disease.”

Orders for TRUMENBA may be placed by contacting Pfizer Customer Service at 1-800-666-7248. Stock is currently available to begin shipping to retail pharmacies, hospitals, physician’s offices, college health centers and other medical practices. Availability for those who seek vaccination will vary by provider stocking.

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

U.S. Indication for TRUMENBA® (meningococcal group B vaccine)

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.

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.

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.[3]

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).

TRUMENBA was reviewed and approved under the FDA's Breakthrough Therapy designation and Priority Review programs.

TRUMENBA is to be administered as a 3-dose series at months 0, 2 and 6 in the 10 through 25 year old age group.[3]

About Meningococcal B Disease

The majority of invasive meningococcal disease cases worldwide can be attributed to five *Neisseria meningitidis* serogroups (A, B, C, W and Y).[4]In 2012, approximately 40 percent of all meningococcal disease cases in the U.S. were caused by serogroup B.[5] Meningococcal disease affects all age groups in the U.S., but incidence is highest among infants younger than one year, adolescents and young adults, and the elderly.[6]

Meningococcal disease can be unpredictable and occur quickly and without warning in otherwise healthy individuals.[7,8] Outbreaks and cases of meningococcal group B disease occurred in the U.S. in 2013 and 2014.[9,10,11,12]

Meningococcal disease may result in life-altering, significant long-term and permanent medical disabilities.[2,13,14] Despite the availability of antibiotic treatment, between 10 and 15 percent of patients with meningococcal disease die and 11 to 19 percent of those who survive are afflicted with long-term disabilities, such as brain damage, hearing loss, learning disabilities or limb amputations.[15]

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. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: *The information contained in this release is as of November 18, 2014. 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), 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 commercial success of TRUMENBA; uncertainties regarding whether and when the CDC's Advisory Committee on Immunization Practices will make any potential recommendations regarding meningococcal group B vaccination; 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 jurisdictions other than the United States for TRUMENBA; whether and when any such other 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 efficacy 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, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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