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# Pfizer Receives FDA Accelerated Approval for TRUMENBA® (Meningococcal Group B Vaccine) for the Prevention of Invasive Meningococcal B Disease in Adolescents and Young Adults

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TRUMENBA is the First and Only Approved Vaccine in the U.S. for the Prevention of Meningococcal Meningitis B

Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of TRUMENBA® (meningococcal group B vaccine) for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age. Approval of TRUMENBA is based on 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. As part of the accelerated approval process, Pfizer will complete its ongoing studies to confirm the effectiveness of TRUMENBA against diverse serogroup B strains.

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

"The approval of TRUMENBA is an important public health advance in helping to protect adolescents and young adults from invasive meningococcal serogroup B disease, also known as meningitis B," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer Inc. "Pfizer is proud to have developed the first and only FDA-approved vaccine that addresses an existing and urgent need in the efforts to help prevent this uncommon but life-threatening and devastating disease in the U.S. As a next step, we look forward to participating in discussions with the CDC regarding potential meningococcal group B vaccination recommendations."

Meningococcal disease can be unpredictable and occur quickly and without warning in otherwise healthy individuals.[1,2] Outbreaks and cases of meningococcal group B disease occurred in the U.S. in 2013 and 2014.[3,4,5,6]

"Meningococcal meningitis B is a devastating disease, which though rare, significantly impacts affected individuals and families," said Frankie Milley, Meningitis Angels, Founder/National Executive Director and mother to an only child who died from meningitis. "Vaccines have been available and recommended since 2005

to help protect against four other serogroups of meningococcal disease, and we hope that TRUMENBA will become a recommended vaccine in routine adolescent immunization programs to help prevent meningococcal B disease."

"Meningococcal disease can progress from initial symptoms to death within 24 hours, and is often challenging to diagnose and distinguish from diseases that are more common and less serious, making preventative vaccination critically important," said study investigator Stanley L. Block, MD, pediatrician at Kentucky Pediatric/Adult Research. "In clinical trials, TRUMENBA demonstrated the ability to induce functional immune responses to four serogroup B strains representative of prevalent strains in the United States. As a physician, I am pleased that a meningococcal meningitis B vaccine is now available to help protect adolescents and young adults."

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.[7]

For the full prescribing information for TRUMENBA, please visit www.pfizer.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.[7]

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).

**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).[8] In 2012, approximately 40 percent of all meningococcal disease cases in the U.S. were caused by serogroup B.[9] 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.[10]

Meningococcal disease may result in life-altering, significant long-term and permanent medical disabilities.[11,12,13] 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.[14]

**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.

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

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***DISCLOSURE NOTICE:*** *The information contained in this release is as of October 29, 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 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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[1] Sáfadi MAP, McIntosh EDG. Epidemiology and prevention of meningococcal disease: a critical appraisal of vaccine policies. *Expert Rev Vaccines*. 2011; 10: 1717-1730.

[2] Poland GA. Prevention of meningococcal disease: current use of polysaccharide and conjugate vaccines. *Clin Infect Dis.* 2010; 50: S45-S53.

[3] Jaslow, R. CBS News. Seventh possible meningitis case reported at Princeton University. November 11, 2013. http://www.cbsnews.com/news/seventh-possible-meningitis-case-reported-at-princeton-university/. Accessed October 27, 2014.

[4] Landau, E. CNN.com. 3 meningococcal disease cases at Calif. college. http://www.cnn.com/2013/11/21/health/california-students-illness/. Updated November 21, 2013. Accessed October 27, 2014.

[5] Hayes, A. CNN.com. Philadelphia meningitis death tied to Princeton outbreak. http://www.cnn.com/2014/03/18/health/drexel-meningitis-death/. Updated March 18, 2014. Accessed October 27, 2014.

[6] Zauzmer, J. *The Washington Post*. Georgetown offering preventive antibiotics to close friends of meningitis victim. September 18, 2014.http://www.washingtonpost.com/local/education/georgetown-offering-preventive-antibiotics-to-close-friends-of-meningitis-victim/2014/09/18/d6831604-3fa7-11e4-b0ea-8141703bbf6f_story.html. Accessed October 27, 2014.

[7] TRUMENBA® (meningococcal group B vaccine Prescribing Information, Pfizer, Inc. October 2014.

[8] Pinto VB, Burden R, Wagner A, Moran EE, Lee C. The Development of an Experimental Multiple Serogroups Vaccine for *Neisseria meningitidis. PLoS ONE*. 2013; 8(11): 1-10.

[9] Centers for Disease Control and Prevention. Active Bacterial Core Surveillance (ABCs) Report Emerging Infections Program Network - *Neisseria meningitidis*, 2012. http://www.cdc.gov/abcs/reports-findings/survreports/mening12.html. Accessed October 27, 2014.

[10] Cohn A, MacNeil JR, Harrison LH, et al. Changes in *Neisseria meningitidis* disease epidemiology in the United States, 1998-2007: implications for prevention of meningococcal disease. *Clin Infect Dis*. 2010; 50: 184-191.

[11] Borg J, Christie D, Coen PG, Pooy R, Viner RM. Outcomes of Meningococcal Disease in Adolescence: prospective, matched-cohort study. *Pediatrics*. 2009; 123: e502-e509.

[12] Sabatini C, Bosis S, Semino M, Senatore L, Principi N, Esposito S. Clinical Presentation of Meningococcal Disease in Childhood. *J Prev Med Hyg.* 2012; 53: 116-119.

[13] Brigham KS, Sandora TJ. *Neisseria meningitidis*: epidemiology, treatment and prevention in adolescents. *Curr Opin Pediatr.* 2009; 21: 437-443.

[14] Centers for Disease Control and Prevention. Help Protect Your Preteen and Teen Against Meningococcal Disease.http://www.cdc.gov/features/meningococcal/. Last updated April 21, 2014. Accessed October 27, 2014.

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