Pfizer Announces Positive Topline Results Of Two Phase 3 Studies Of TRUMENBA® (Meningococcal Group B Vaccine)

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Data Consistent with Immunogenicity and Safety Data from Previous Studies

The Phase 3 data extend the body of evidence that supports vaccination of adolescents and young adults with TRUMENBA to help prevent serogroup B meningococcal disease

Pfizer Inc. (NYSE:PFE) announced today positive topline results of two Phase 3 studies of TRUMENBA® (Meningococcal Group B Vaccine). One study included approximately 3,600 healthy individuals 10 through 18 years of age, and the other study included approximately 3,300 healthy individuals 18 through 25 years of age. Both studies met all primary immunogenicity endpoints, demonstrating robust immune responses against certain invasive meningococcal B strains after the vaccine dose series. Safety and tolerability data from both studies were also consistent with data from previous studies.

“We are very pleased with these Phase 3 data that show immunogenicity and safety data consistent with findings that formed the basis for the accelerated FDA approval of TRUMENBA,” said Kathrin Jansen, Ph.D., senior vice president of Vaccine Research and Development for Pfizer Inc. “The Phase 3 data extend the body of evidence that supports vaccination of adolescents and young adults with TRUMENBA to help prevent serogroup B meningococcal disease.”

In October 2014, Pfizer’s TRUMENBA® (Meningococcal Group B Vaccine) was granted accelerated approval by the U.S. Food and Drug Administration (FDA) for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B

in individuals 10 through 25 years of age.

Pfizer plans to present the full results of both studies at an upcoming scientific congress.

Phase 3 Study Designs

Vaccine safety and immunogenicity were evaluated in these two Phase 3 studies.

One Phase 3 study was a randomized, active-controlled, observer-blinded study that included approximately 3,600 healthy individuals 10 through 18 years of age in the United States and Europe. Individuals were randomized to receive one of three different lots of TRUMENBA® in a 0, 2, 6 month schedule or a control. The control group received a licensed hepatitis A (HAV) vaccine at 0 and 6 months and saline at 2 months. The primary endpoints assessed immunogenicity, lot consistency and safety.

Immunogenicity: Demonstration of an immune response measured by serum bactericidal assays with human complement (hSBA) for 4 primary test strains 1 month after the third vaccination with TRUMENBA Lot consistency: hSBA geometric mean titers (GMTs) for 2 primary test strains (A22 and B24) measured 1 month after the third vaccination for individuals receiving one of three different lots of TRUMENBA Safety: Proportion of subjects who reported local and systemic reactions, adverse events (AE), serious adverse events (SAE), newly diagnosed chronic medical conditions (NDCMC), medically-attended adverse events (MAE), autoimmune diseases and neuroinflammatory conditions following vaccination with TRUMENBA or a control
A second Phase 3 study was a randomized, placebo-controlled, observer-blinded study that included approximately 3,300 healthy individuals 18 through 25 years of age in the United States and Europe. Individuals were randomized to receive TRUMENBA® or a saline control in a 0, 2, 6 month schedule. The primary endpoints assessed immunogenicity and safety.

Immunogenicity: Demonstration of an immune response measured by hSBA for 4 primary test strains 1 month after the third vaccination with TRUMENBA Safety: Proportion of subjects who reported local and systemic reactions, AEs, SAEs, NDCMCs, MAEs, autoimmune diseases and neuroinflammatory conditions following vaccination with TRUMENBA or placebo
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 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.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.1

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 Serogroup B Meningococcal Disease

The majority of invasive meningococcal disease cases worldwide can be attributed to five Neisseria meningitidisserogroups (A, B, C, W and Y).2 Meningococcal serogroup B disease affects all age groups in the U.S., but incidence is highest among infants younger than one year, adolescents and young adults.3 In 2013, approximately 500 cases of meningococcal disease occurred in the United States, more than 30 percent of which were caused by serogroup B.4

Serogroup B meningococcal disease may result in life-altering, significant long-term and permanent medical disabilities.5,6,7 Despite the availability of antibiotic treatment, 12.5 percent of patients with meningococcal serogroup B disease die and many of those who survive are afflicted with long-term disabilities, such as brain damage, hearing loss, learning disabilities or limb amputations.8,9

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DISCLOSURE NOTICE: The information contained in this release is as of August 21, 2015. 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 impact of the ACIP's recommendation regarding TRUMENBA; 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 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 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, 2014 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 SEC and available at www.sec.gov andwww.pfizer.com.

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

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3 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.

4 Centers for Disease Control and Prevention. Active Bacterial Core Surveillance (ABCs) Report: emerging infections program network, Neisseria meningitidis, 2013. http://www.cdc.gov/abcs/reports-findings/survreports/mening13.pdf. Accessed August 6, 2015.

5 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.

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

7 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.

8 MacNeil J. Epidemiology of Serogroup B Meningococcal Disease, United States. Presented at the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention. October 30, 2014. Centers for Disease Control and Prevention website: http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2014-10/mening-02-MacNeil.pdf. Accessed August 6, 2015.

9 Centers for Disease Control and Prevention. Preteens, Teens Need Meningococcal Vaccine.http://www.cdc.gov/features/meningococcal/. Last updated April 30, 2015. Accessed August 6, 2015.

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