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Pfizer’s Phase 2 Study Demonstrates Safety, Tolerability and Immunogenicity of TRUMENBA® When Coadministered with Meningococcal A, C, Y and W-135 Polysaccharide Conjugate (MCV4) and Tetanus, Diphtheria and Pertussis (Tdap) Vaccines in Adolescents

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Data presented for the first time at IDWeek 2015™ in San Diego

Pfizer Inc. (NYSE:PFE) announced today that researchers presented for the first time data from a randomized, controlled Phase 2 study of its meningococcal serogroup B vaccine, TRUMENBA®, coadministered with routine meningococcal (groups A, C, Y and W) (MCV4) and tetanus, diphtheria and pertussis (Tdap) vaccines in adolescents. The data, which were released today in an oral presentation at IDWeek 2015™ in San Diego, are based on a study conducted in more than 2,600 healthy individuals 10 through 12 years of age that evaluated the safety, tolerability and immunogenicity of TRUMENBA when coadministered with MCV4 and Tdap. Data demonstrated that immune responses following TRUMENBA, MCV4 and Tdap vaccines given concomitantly were noninferior to immune responses to MCV4 and Tdap alone or TRUMENBA alone.

“These Phase 2 data, which are part of a substantial global clinical development program for TRUMENBA, demonstrated that two important routine adolescent vaccines can be coadministrated with TRUMENBA,” said Kathrin Jansen, Ph.D., senior vice president of Vaccine Research and Development at Pfizer Inc. “In particular, the convenience associated with coadministration of these recommended vaccines – including allowing for vaccination against five of the most common meningococcal serogroups – is an important factor in helping to protect as many adolescents and young adults as possible from vaccine-preventable diseases.”

Pfizer's TRUMENBA (Meningococcal Group B Vaccine) is FDA-approved for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age.

Individuals participating in the study were assigned to one of three groups. Group 1 received TRUMENBA coadministered with MCV4 and Tdap vaccines; Group 2 received MCV4 and Tdap vaccines only; and Group 3 received TRUMENBA only. TRUMENBA immunogenicity was assessed by serum bactericidal assay using human complement (hSBA) with 2 meningococcal serogroup B (MenB) test strains expressing vaccine-heterologous factor H binding protein (fHBP) variants. The immunogenicity of MCV4 and Tdap antigens was assessed utilizing multiplexed Luminex assays and/or serum bactericidal assay using rabbit complement (rSBA).

Immune responses following TRUMENBA, MCV4 and Tdap vaccines given concomitantly were noninferior to immune responses to MCV4 and Tdap alone or TRUMENBA alone. Participants in the concomitant control group had hSBA responses to the 2 MenB test strains of 62.3 to 68 percent and 87.5 to 90 percent after 2 and 3 TRUMENBA doses, respectively. The administration of TRUMENBA alone induced similar responses. Coadministration of TRUMENBA, MCV4 and Tdap did not significantly increase local reactions or systemic events compared to TRUMENBA alone.

About the Phase 2 Study Design

Vaccine safety, tolerability and immunogenicity were evaluated in this Phase 2, randomized, controlled, observer-blinded study of TRUMENBA® in the United States. The study included more than 2,600 healthy individuals 10 through 12 years of age. Group 1 received TRUMENBA coadministered with MCV4 and Tdap vaccines; Group 2 received MCV4 and Tdap vaccines only; and Group 3 received TRUMENBA only. Co-primary objectives included:

- Demonstration that the immune response induced by MCV4 and Tdap vaccines given with TRUMENBA was noninferior to the immune response induced by MCV4 and Tdap vaccines alone when measured one month after the first vaccination; and
- Demonstration that the immune response induced by TRUMENBA given with MCV4 and Tdap vaccines was noninferior to the immune response induced by TRUMENBA alone, when measured one month after the third vaccination with TRUMENBA.

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 meningitidis* serogroups (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]

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 October 9, 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 recommendation of the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices 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 and www.pfizer.com.

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

[2] 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.

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[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 September 14, 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 September 14, 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 September 14, 2015.

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