# Pfizer Announces FDA Acceptance Of And Priority Review Designation For Biologics License Application For Investigational Meningococcal B Vaccine

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Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for bivalent recombinant LP2086 (rLP2086), the company's vaccine candidate for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroup B in 10 through 25 year olds. The FDA has also granted Priority Review designation for the BLA, providing an anticipated Prescription Drug User Fee Act (PDUFA) action date of February 14, 2015.

"Pfizer has closely collaborated with the FDA since 2008 to develop our meningococcal B vaccine candidate with the intent to help prevent this devastating disease," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer. "Both the acceptance of Pfizer's Biologics License Application today, and its Priority Review designation, are significant regulatory milestones that underscore the importance of our efforts to expedite the approval and subsequent availability of our meningococcal B vaccine for U.S. adolescents."

About rLP2086

Pfizer's investigational meningococcal B vaccine is composed of two recombinant LP2086 antigens, or factor H binding proteins (fHBP).1 The vaccine includes antigens from both types of fHBP, subfamily A and subfamily B, as our preclinical research has shown that

this approach has the potential to provide coverage against the majority of meningococcal B strains.2

Pfizer is conducting a global clinical development program for bivalent rLP2086, which includes both Phase 2 and Phase 3 trials evaluating more than 20,000 participants, approximately 14,000 of whom will receive the investigational vaccine.3,4,5,6,7,8,9,10 The Phase 3 program began in November 2012 with the initiation of a large scale safety study. Additional immunogenicity and safety studies are also ongoing.

The FDA granted Breakthrough Therapy designation for bivalent rLP2086 in March 2014 based, in part, on data from clinical trials studying the safety and immunogenicity of bivalent rLP2086.

Clinical data from a Phase 2 study published in the Lancet Infectious Diseases in 2012 showed the investigational bivalent rLP2086 vaccine induced bactericidal antibodies in healthy adolescents aged 11 to 18 years that were broadly active against meningococcal B bacteria.11 Safety data from the study also showed the vaccine had an acceptable safety profile in this healthy adolescent study population and supported the further evaluation of the vaccine in Phase 3 studies.11

Additionally, in two Phase 2 studies presented at the Annual Meeting of the European Society for Paediatric Diseases (ESPID) in May 2014, bivalent rLP2086 was found to elicit bactericidal responses against diverse meningococcal serogroup B test strains.12,13

For more information on ongoing clinical trials of bivalent rLP2086, visit www.clinicaltrials.gov.

About Meningococcal Disease

Each year, approximately 500,000 cases of meningococcal disease occur worldwide due to Neisseria meningitidis.14 The majority of invasive meningococcal disease cases worldwide can be attributed to five N. meningitidis serogroups (A, B, C, W and Y).15 Disease caused by N. meningitidis serogroup B has been estimated at between 20,000 and 80,000 cases per year globally.16 In 2012, approximately 40 percent of cases in the U.S. were due to meningococcal disease caused by serogroup B.17 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.18 There is currently no meningococcal B vaccine approved for use in the

United States.15,19

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DISCLOSURE NOTICE: The information contained in this release is as of August 14, 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 a product candidate, bivalent rLP2086, 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, 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 other jurisdictions for bivalent rLP2086; whether and when the BLA or any such other applications may be approved by the FDA or other 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 the FDA and other regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of rLP2086; 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 our 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 andwww.pfizer.com.

1 Murphy E, et al. Sequence diversity of the Factor H binding protein vaccine candidate in epidemiologically relevant strains of serogroup B Neisseria meningitidis. J Infect Dis. 2009; 200: 379-389.

2 McNeil LK, Zagursky RJ, Lin SL, et al. Role of Factor H Binding Protein in Neisseria meningitidis Virulence and Its Potential as a Vaccine Candidate to Broadly Protect Against Meningococcal Disease. Microbiol. Mol. Biol. Rev. 2013; 77(2): 234- 252.

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4 ClinicalTrials.gov. A Global Phase 3 Safety Study of 120 mcg rLP2086 Vaccine in Adolescents and Young Adults Aged 10 to 25 Years. http://clinicaltrials.gov/ct2/show/NCT01352793?term=B1971014&rank=1. Accessed July 8, 2014.

5 ClinicalTrials.gov. A Clinical Trial to Study the Safety, Tolerance and Immunogenic Response to MCV4, Tdap and Bivalent rLP2086 Vaccine When Given at the Same Time to Children Between the Ages of 10 Through 12 Years of Age. http://clinicaltrials.gov/ct2/show/NCT01461980?term=B1971015&rank=1. Accessed July 8, 2014.

6 ClinicalTrials.gov. A Trial To Assess The Safety, Tolerability, And Immunogenicity Of Rlp2086 Vaccine When Administered In Either 2- Or 3-Dose Regimens In Healthy Subjects Aged ≥11 To <19 Years. http://clinicaltrials.gov/ct2/show/NCT01299480?term=B1971012&rank=1. Accessed July 8, 2014.

7 ClinicalTrials.gov. A Trial to Assess the Safety, Tolerability and Immunogenicity of Repevax® and rLP2086 Vaccine When Given Together in Healthy Subjects Aged >=11 to <19 Years.http://clinicaltrials.gov/ct2/show/NCT01323270?term=B1971010&rank=1. Accessed July 8, 2014.

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10 ClinicalTrials.gov. A Trial to Assess the Safety, Tolerability, and Immunogenicity of Bivalent rLP2086 Vaccine When Given to Healthy Young Adults Aged >=18 to <26 Years. (B1971016).http://clinicaltrials.gov/ct2/show/NCT01352845?term=B1971016&rank=1. Accessed July 8, 2014.

11 Richmond PC, Marshall HS, Nissen MD, et al. Safety, immunogenicity, and tolerability of meningococcal serogroup B (MnB) bivalent rLP2086 vaccine in healthy adolescents: a randomised, single-blind, placebo-controlled, phase 2 trial. Lancet Infect Dis. 2012; 12(8): 597-607. Published online ahead of print May 2012.

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