Pfizer Announces Submission of Biologics License Application to the FDA for Investigational Meningococcal B Vaccine

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Pfizer Inc. (NYSE:PFE) announced today that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) 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 to 25 year olds.

Each year, approximately 500,000 cases of meningococcal disease occur worldwide due to N. meningitidis.1 The majority of invasive meningococcal disease cases worldwide can be attributed to five N. meningitidis serogroups (A, B, C, W-135 and Y).2 Disease caused by N. meningitidis serogroup B has been estimated at between 20,000 and 80,000 cases per year globally.3 In 2012, approximately 40 percent of cases in the U.S. were due to meningococcal disease caused by serogroup B.4 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.5 There is currently no meningococcal B vaccine approved for use in the United States.2,6

"The BLA submission for bivalent rLP2086 marks an important step toward our goal of helping to protect adolescents and young adults against this difficult to diagnose and often deadly disease," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer Inc. "There is an urgent public health need to help prevent meningococcal B disease through vaccination, and we will continue to work closely with the FDA in our efforts to advance our vaccine candidate."

The FDA has a 60-day filing review period to determine whether the BLA is complete and acceptable for filing. Pfizer will communicate the agency's decision.

About rLP2086

Pfizer's investigational meningococcal B vaccine targets LP2086, or factor H binding protein, which is found on the surface of the meningococcal B bacterium.7 The gene for factor H binding protein is present in more than 1,800 meningococcal B isolates studied by Pfizer researchers.7,8 The vaccine contains two recombinant versions of the LP2086 antigen, one representative for each of the two known genetic subfamilies of the antigen.9

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.10,11,12,13,14,15,16,17 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.18 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.18

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.19,20

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

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DISCLOSURE NOTICE: The information contained in this release is as of June 17, 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. Such 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 the FDA will accept the BLA submitted for bivalent rLP2086; 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 as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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 and Form 8-K.

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