Pfizer Announces Positive Phase 2 Study Results for Investigational Meningococcal B Vaccine

Friday, May 09, 2014 - 06:30am

Pfizer Inc. (NYSE:PFE) announced today the results from two Phase 2 studies of bivalent rLP2086, Pfizer's recombinant vaccine candidate, currently under development for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroup B in 10 to 25 year olds. In both studies, bivalent rLP2086 was observed to generate bactericidal responses, a measurement of functional immune response, against diverse meningococcal serogroup B test strains following either two or three doses.1,2 Also, in the study evaluating co-administration of bivalent rLP2086 and a diphtheria, tetanus, pertussis and inactivated polio vaccine (dTaP-IPV), no impact was observed on the immune response to the dTaP-IPV vaccine.1 The data were presented at the 32nd Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID 2014).

"Disease caused by meningococcus serogroup B is serious and unpredictable. The disease is difficult to recognize early and progresses rapidly, making preventive vaccination especially important," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer Inc. "We are encouraged by the safety and tolerability data for our investigational vaccine candidate, bivalent rLP2086, and its potential to help prevent this devastating disease. We look forward to continuing the development of this critically-needed vaccine and working with regulatory authorities to make it available to adolescents and young adults."

Each year, approximately 500,000 cases of meningococcal disease occur worldwide due to Neisseria meningitidis.3The majority of invasive meningococcal disease cases worldwide can be attributed to five N. meningitidisserogroups (A, B, C, W-135 and

Y),4 with between 20,000 and 80,000 cases caused by meningococcal B disease globally.5 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.6

Data Presented at European Society for Paediatric Infectious Diseases Annual Meeting

A Phase 2, randomized, placebo-controlled, single-blind study assessed the safety, tolerability and immunogenicity of bivalent rLP2086 in healthy adolescents aged 11 to 18 years in two- and three-dose schedules. The immune responses to bivalent rLP2086 were measured using a serum bactericidal assay with human complement (hSBA). The functional antibodies assessed by the hSBA are an accepted immunological correlate of protection.7 hSBA titers of ≥ 1:4 are typically associated with protection against serogroup B meningococcal disease.7 One month after three doses of bivalent rLP2086, hSBA titers > 1:8 to diverse meningococcal serogroup B strains were observed in 86 to 99 percent of subjects; and 69 to100 percent after two doses.2 The most common local reaction observed was mild-to-moderate injection site pain; headache and fatigue were the most common systemic events.2

Data from the second Phase 2, randomized, placebo-controlled study that evaluated the effects of co-administration of bivalent rLP2086 with a dTaP-IPV vaccine in healthy adolescents aged 11 to 18 years were also presented at the conference. When given with bivalent rLP2086, dTaP-IPV generated immune responses that are consistent with those observed following administration of dTaP-IPV alone.1 Bactericidal responses to four diverse meningococcal serogroup B strains were also observed following co-administration of bivalent rLP2086 and dTaP-IPV.1 The most common local reaction observed was mild-to-moderate injection site pain; headache and fatigue were the most common systemic events.1 These data suggest that it may be possible to administer bivalent rLP2086 at the same time as the dTaP-IPV vaccine.1

About rLP2086

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.8,9,10,11,12,13,14,15 In March 2014, Pfizer announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for bivalent rLP2086. Pfizer plans to submit a Biologics License Application to the FDA for bivalent

rLP2086 by mid-2014.

Pfizer’s investigational meningococcal B vaccine targets LP2086, or factor H binding protein, which is found on the surface of the meningococcal B bacterium.16 The gene for factor H binding protein is present in more than 1,800 meningococcal B isolates studied by Pfizer researchers.16,17

The Breakthrough Therapy designation received in the U.S. in March 2014 was 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 to18 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

In November 2012, the Phase 3 program began with the initiation of a large scale safety study. Additional immunogenicity and safety studies are also ongoing.

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 May 9, 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 any biologics license applications may be filed in any jurisdictions for bivalent rLP2086; whether and when any such applications may be approved by 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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Pfizer Inc.Media:Sally Beatty, +1 347-330-7867sally.beatty@pfizer.comorInvestors:Ryan Crowe, +1 212-733-8160ryan.crowe@pfizer.com