Pfizer’s Investigational Vaccine Candidate Bivalent rLP2086 Receives U.S. Food and Drug Administration Breakthrough Therapy Designation for Potential Prevention of Meningococcal B Disease

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Pfizer Intends to Submit Biologics License Application for Bivalent rLP2086 to U.S. Food and Drug Administration by Mid-2014

Pfizer Inc. (NYSE:PFE) announced today that the United States Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to Pfizer’s vaccine candidate, bivalent rLP2086, currently under investigation for the prevention of invasive meningococcal disease due to Neisseria meningitidis serogroup B in persons 10 – 25 years of age. Disease caused by Neisseria meningitidis serogroup B has been estimated at between 20,000 and 80,000 cases per year globally, and can result in death or significant long-term disabilities, including brain damage and hearing loss.1,2

Enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), Breakthrough Therapy designation is intended to expedite the development and review of potential new medicines for serious and life-threatening diseases.3 A Breakthrough Therapy designation conveys FDA's existing fast track development program features, as well as more intensive FDA guidance on an efficient drug development program.4

“Pfizer is developing this meningococcal B vaccine candidate to help protect adolescents and young adults against a difficult to diagnose and often deadly disease,” said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer Inc. “We are encouraged by the FDA’s recognition of the need to prevent meningococcal B disease, and the Breakthrough Therapy designation highlights the urgent need for prevention of meningococcal B disease.”

Pfizer is conducting a global clinical development program for rLP2086, which includes both Phase 2 and Phase 3 trials evaluating more than 20,000 participants, about 14,000 of whom will receive the investigational vaccine.5,6,7,8,9,10,11,12 Following interactions that we have had with the FDA, Pfizer intends to submit a Biologics License Application (BLA) to the FDA for bivalent rLP2086 by mid-2014.

Invasive meningococcal disease is a rapidly progressing disease that can lead to serious disabilities and can be life-threatening for those infected.2 Of the five meningococcal serogroups (A, B, C, W-135 and Y) that historically have been responsible for the majority of meningococcal disease,13 serogroup B is the only one for which no broadly-protective vaccine is currently approved in the U.S. 13,14

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. The gene for factor H-binding protein is present in the more than 1,800 meningococcal B isolates Pfizer researchers have studied.15

The Breakthrough Therapy designation was based, in part, on data from two clinical trials studying the safety and immunogenicity of rLP2086. Clinical data from a Phase 2 study published in the Lancet Infectious Diseases showed the investigational rLP2086 vaccine induced bactericidal antibodies in healthy adolescents (aged 11-18 years) that were broadly active against meningococcal B bacteria.16 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.16

In addition, data from another Phase 2, randomized, placebo-controlled, single-blind study of two- and three-dose schedules of rLP2086 in healthy adolescents (aged 11-18 years), showed that the investigational vaccine had an acceptable safety profile.17 Injection site pain was the most common adverse event.17 This study, presented at the Meningitis Research Foundation 2013 meeting, also showed that one month after the last vaccine dose in the two- and three-dose groups, 86-99% (after 3 doses) of subjects and

69-100% (after 2 doses) of subjects had hSBA titers (functional antibodies) greater than or equal to 1:8 to each meningococcal B test strain.17 The study results supported further evaluation of a three dose regimen in the Phase 3 program.

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 rLP2086, visit www.clinicaltrials.gov.

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DISCLOSURE NOTICE: The information contained in this release is as of March 20, 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, 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 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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