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Pfizer To Present Safety And Immunogenicity Data From A Phase 2 Study Of Its Investigational Meningococcal Group B Vaccine, Bivalent rLP2086, Co-Administered With A Licensed Human Papillomavirus Vaccine

Wednesday, October 08, 2014 - 04:00am

Data From This Study Will Be Presented At IDWeek 2014™ In Philadelphia

Pfizer Inc. (NYSE:PFE) announced today it will present the results of a Phase 2, randomized study to evaluate co-administration of the company's investigational meningococcal group B vaccine, bivalent recombinant LP2086 (rLP2086), with a licensed quadrivalent human papillomavirus vaccine (HPV4), at IDWeek 2014™ in Philadelphia. Data demonstrated immune responses to both vaccines were generated after concomitant administration of bivalent rLP2086 and HPV4. Prespecified noninferiority criteria were met for the bivalent rLP2086 antigens studied and three of the four antigens for HPV4.

"We are pleased to present data on our investigational meningococcal group B vaccine at IDWeek 2014," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer Inc. "We look forward to sharing additional data from the ongoing Phase 2 and Phase 3 clinical studies of our vaccine candidate."

Overview of Bivalent rLP2086 Data at IDWeek 2014™ Annual Meeting

Immunogenicity of Human Papillomavirus Vaccine Coadministered with an Investigational Bivalent rLP2086 Vaccine Against Meningococcal Serogroup B in Healthy Adolescents

Friday, October 10, 2014, 12:30 – 2:00 p.m., The Pennsylvania Convention Center: IDExpo Hall BC

This Phase 2, randomized study evaluated co-administration of a licensed quadrivalent human papillomavirus vaccine (HPV4) with bivalent rLP2086, an investigational vaccine against meningococcal disease caused by *Neisseria meningitidis* serogroup B in healthy individuals 11 through 17 years of age at multiple sites across the United States. Subjects were divided into three groups. Group 1 received HPV4 and bivalent rLP2086, Group 2 received bivalent rLP2086 plus saline, and Group 3 received saline and HPV4. The study used a 0, 2 and 6 month vaccination schedule.

Primary immunogenicity endpoints, measured after the third dose, included geometric mean titers (GMTs) against HPV antigens in Groups 1 and 3 and human complement serum bactericidal assay (hSBA) GMTs against meningococcal group B disease test strains in Groups 1 and 2. Secondary immunogenicity endpoints included

the rate of seroconversion to HPV antigens. Safety of bivalent rLP2086 was assessed after concomitant administration with HPV4 or saline. The prespecified noninferiority criteria were met for three of four HPV antigens (GMT) and both meningococcal group B disease test strains. Seroconversion for all four HPV antigens was achieved by 99 percent or more of the subjects for the groups that received HPV4 concomitantly with bivalent rLP2086 or with saline. More local reactions occurred following administration of bivalent rLP2086 compared with saline but the incidence of these reactions did not increase with subsequent vaccine administration. The rates of local and systemic reactions were comparable when bivalent rLP2086 was given with HPV4 to bivalent rLP2086 given alone.

About Bivalent rLP2086

Pfizer's investigational meningococcal group 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 Pfizer's preclinical research has shown that this approach has the potential to provide coverage against the majority of meningococcal group B strains.[2]

Pfizer has been 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. The FDA accepted Pfizer's Biologics License Application (BLA) for bivalent rLP2086 and granted Priority Review designation, with an anticipated PDUFA date of February 14, 2015.

Results of another Pfizer Phase 2 study to assess immunogenicity, safety and tolerability of bivalent rLP2086, in healthy individuals aged 11 through 18 years were published in the *Lancet Infectious Diseases* in 2012. Findings from this study showed that the vaccine induced bactericidal activity against diverse meningococcal group B bacteria strains in healthy individuals and had an acceptable safety profile, supporting further study in Phase 3.[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 group B disease test strains.[12,13]

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

About Meningococcal Disease

The majority of invasive meningococcal disease cases worldwide can be attributed to five *Neisseria meningitidis* serogroups (A, B, C, W and Y).[14] In 2012, approximately 40 percent of all meningococcal disease cases in the U.S. were caused by serogroup B.[15] Meningococcal disease affects all age groups in the U.S., but incidence is highest among infants younger than one year, adolescents and young adults, and the elderly.[16]

Meningococcal disease can result in life-altering, significant long-term and permanent medical disabilities.[17,18,19] 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.[20]

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About IDWeek 2014™

IDWeek 2014™ is an annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA) and the Pediatric Infectious Diseases Society (PIDS). With the theme “Advancing Science, Improving Care,” IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan. IDWeek 2014 takes place October 8-12 at the Pennsylvania Convention Center in Philadelphia, Pennsylvania. The full name of the meeting is IDWeek 2014™. For more information, visit www.idweek.org.

DISCLOSURE NOTICE: *The information contained in this release is as of October 8, 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 and anticipated PDUFA date, 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 jurisdictions other than the United States 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 bivalent 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 its 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 *and* www.pfizer.com.

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Media: Sally Beatty, 347-330-7867 sally.beatty@pfizer.com or Investors: Ryan Crowe, 212-733-8160 ryan.crowe@pfizer.com