Pfizer Announces Start of Four Phase 3 Clinical Trials for Investigational Vaccines

Monday, June 22, 2020 - 08:00am

.q4default .bwalignc { text-align: center; list-style-position:inside; }.q4default .bwlistdisc { list-style-type: disc; }.q4default .bwuline { text-decoration: underline; }

First subjects recently administered immunizations in two studies of 20-valent pneumococcal conjugate vaccine candidate in infants; a pentavalent meningococcal vaccine candidate in adolescents; and a respiratory syncytial virus vaccine candidate in pregnant women

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced the initiation of four Phase 3 clinical trials within its current pipeline of investigational vaccines:

Two studies (NCT04382326 and NCT04379713) of the 20-valent pneumococcal polysaccharide conjugate vaccine candidate, 20vPnC, evaluating a four-dose series in infants starting at 2 months of age. Both studies will expand the data on the safety and tolerability of the investigational vaccine in infants and include a control group of Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). Study NCT04382326 has the goal of determining immunologic noninferiority between 20vPnC and Prevnar 13®, a critical requirement for vaccine licensure. One study (NCT04424316) of the respiratory syncytial virus (RSV) vaccine candidate, RSVpreF, in pregnant women to evaluate the safety and efficacy of RSVpreF in infants born to immunized pregnant women as compared to placebo. One study (NCT04440163) of the pentavalent meningococcal vaccine candidate, MenABCWY, in adolescents and young adults to assess the safety, tolerability, and immunogenicity of the MenABCWY vaccine candidate compared to licensed meningococcal vaccines, with the goal of determining immunologic noninferiority.

“The start of four Phase 3 studies across our portfolio of investigational vaccines is a testament to the talented and dedicated colleagues working throughout Pfizer, and the continued commitment to unlock the potential promise and value that vaccines hold for our world,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer Inc. “If approved, all three vaccine candidates could help prevent serious, possibly deadly infectious diseases that negatively impact millions of people of all ages globally.”

About 20vPnC Pediatric Approximately 3,500 infants will be enrolled in total for these two studies. In both studies, infants will be vaccinated with either 20vPnC or Prevnar 13® (13vPnC) at 2, 4, 6, and 12-15 months of age, along with other routine infant vaccines according to the current CDC recommended schedule. Additional information can be found at www.clinicaltrials.gov under the identifiers NCT04382326 and NCT04379713. The results of the descriptive Phase 2 infant study with 20vPnC (NCT03512288) have been submitted for presentation at ID Week 2020.

In May 2017 the FDA granted Fast Track status for a pediatric indication for 20vPnC.1

Global Burden of Pneumococcal Disease Pfizer’s 20vPnC vaccine candidate includes 13 serotypes already included in Prevnar 13® (13vPnC). Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in the U.S. and globally.2,3,4,5,6,7,8

About RSVpreF The Phase 3 trial of RSVpreF is a global, double-blind, placebo-controlled study that will enroll 6,900 pregnant women ages 18 through 49 and their infants. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT04424316.

In April 2020, positive top-line results were achieved for a Phase 2b proof-of-concept study of RSVpreF, which evaluated the safety, tolerability and immunogenicity of RSVpreF in vaccinated pregnant women ages 18 through 49 and their infants. Detailed results from the study will be shared at a future medical conference. In November 2018, the FDA granted Fast Track status to RSVpreF for prevention of RSV-associated lower respiratory tract illness in infants by active immunization of pregnant women.

Global Burden of RSV RSV is a virus that can cause severe respiratory disease in infants and older adults.9,10 Globally, there are an estimated 33 million cases of RSV annually in children less than 5 years of age, with about 3 million hospitalized and approximately 120,000 dying each year from complications associated with the infection. Nearly half of these pediatric hospitalizations and deaths occur in infants less than 6 months of age.11

The medical community is limited to offering only supportive care for those with the illness.

About MenABCWY The Phase 3 trial will enroll approximately 2,413 adolescents and young adults (10 through 25 years of age) from the United States and Europe. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT04440163.

Initiation of the Phase 3 trial is based on positive results from a proof-of-concept study (NCT03135834) in 543 adolescents and young adults. Detailed results from the proof-of-concept study have been submitted for presentation at ID Week 2020.

Pfizer’s pentavalent meningococcal vaccine candidate combines its two approved meningococcal vaccines, Nimenrix™ (meningococcal group A, C, W-135, and Y conjugate vaccine) and Trumenba® (meningococcal group B vaccine). Approvals of Nimenrix™ and Trumenba® vary by country.

Global Burden of Meningococcal Disease Meningococcal disease is an uncommon but serious disease that can attack without warning12,13 and lead to meningitis and serious blood infections.14,15 The majority of invasive meningococcal disease cases worldwide can be attributed to five Neisseria meningitidis groups (A, B, C, W and Y).16 Together, these meningococcal groups account for 96% of all invasive meningococcal disease (IMD), with group B accounting for the majority of disease in adolescents and young adults in the U.S. and Europe.17,18,19

INDICATIONS FOR PREVNAR 13®

Prevnar 13® is a vaccine approved for adults 18 years and older for the prevention of pneumococcal pneumonia and invasive disease caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F Prevnar 13® is also approved for children 6 weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by the 13 strains of Streptococcus pneumoniae in the vaccine, and for children 6 weeks through 5 years (prior to the 6th birthday) for the prevention of ear infections caused by 7 of the 13 strains in the vaccine Prevnar 13® is not 100% effective and will only help protect against the 13 strains in the vaccine
IMPORTANT SAFETY INFORMATION

Prevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13® or any diphtheria toxoid–containing vaccine Children and adults with weakened immune systems (eg, HIV infection, leukemia) may have a reduced immune response In adults, the most common side effects were pain, redness, and

swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in infants and toddlers were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%) In children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever Ask your healthcare provider about the risks and benefits of Prevnar 13®. Only a healthcare provider can decide if Prevnar 13® is right for you or your child

INDICATION FOR TRUMENBA® IN THE U.S.

Trumenba® is a vaccine indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by Neisseria meningitidis group B The effectiveness of the two-dose schedule of Trumenba® against diverse N. meningitidis group B strains has not been confirmed

IMPORTANT SAFETY INFORMATION

Trumenba® should not be given to anyone with a history of a severe allergic reaction after a previous dose of Trumenba Some individuals with weakened immune systems may have a reduced immune response Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by Neisseria meningitidis group B even with receipt of vaccination with Trumenba® As with any vaccine, vaccination with Trumenba® may not protect all vaccine recipients against N. meningitidis group B infections Fainting can occur in association with administration of injectable vaccines, including Trumenba The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain. Nausea was reported in adolescents in early phase studies Data are not available on the safety and effectiveness of using Trumenba® and other meningococcal group B vaccines interchangeably to complete the vaccination series Tell your health care provider if you are pregnant, or plan to become pregnant Ask your health care provider about the risks and benefits of Trumenba®. Only a health care provider can decide if Trumenba® is right for you or your child

INDICATION FOR NIMENRIX™ IN THE E.U.

Nimenrix™ is a vaccine indicated for individuals six weeks of age and older for active immunization to prevent invasive disease caused by Neisseria meningitidis groups A, C, W-135 and Y

IMPORTANT SAFETY INFORMATION

Nimenrix™ should not be given to anyone with a history of a severe allergic reaction after a previous dose of Nimenrix™ Some individuals with weakened immune systems may have a reduced immune response Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by Neisseria meningitidis groups A, C, W, and Y, even with receipt of vaccination with Nimenrix™ As with any vaccine, vaccination with Nimenrix™ may not protect all vaccine recipients against N. meningitidis groups A, C, W and Y Fainting can occur shortly before or after injecting vaccines, including Nimenrix™ The most common adverse reactions were loss of appetite, irritability, drowsiness, headache, fatigue, fever, and pain, redness, and swelling at the injection site Tell your healthcare provider if you are pregnant, or plan to become pregnant Ask your healthcare provider about the risks and benefits of Nimenrix™. Only a healthcare provider can decide if Nimenrix™ is right for you or your child
Pfizer Inc: Breakthroughs that change patients' lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE:

The information contained in this release is as of June 22, 2020. 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 Pfizer's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, respiratory syncytial virus vaccine (RSVpreF)

candidate and pentavalent meningococcal vaccine (MenABCWY) candidate, including their 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 endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any of Pfizer's 20vPnC, RSVpreF or MenABCWY vaccine candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such vaccine candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer's 20vPnC, RSVpreF or MenABCWY vaccine candidates; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; the impact of COVID-19 on our business, operations and financial results; 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, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

1 Data on file. Pfizer Inc., New York, NY 2 Centers for Disease Control and Prevention. Active Bacterial Core (ABCs) surveillance. National Center for Immunization and Respiratory Diseases. Atlanta, GA. 3 Ladhani, SN, Collins S, Djennad A, et al. Rapid increase in non-vaccine serotypes causing invasive pneumococcal disease in England and Wales, 2000–17: a prospective national observational cohort study. Lancet Infect Dis. 2018;18(4):441-451. 4 Menéndez R, España PP, Pérez-Trallero E, et al. The burden of

PCV13 serotypes in hospitalized pneumococcal pneumonia in Spain using a novel urinary antigen detection test. CAPA study. Vaccine. 2017;35(39):5264-5270. 5 Azzari C, Cortimiglia M, Nieddu F, et al. Pneumococcal serotype distribution in adults with invasive disease and in carrier children in Italy: Should we expect herd protection of adults through infants' vaccination? Hum Vaccin Immunother. 2016;12(2):344-350. 6 Pivlishi T. Impact of PCV13 on invasive pneumococcal disease (IPD) burden and the serotype distribution in the U.S. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. October 24th, 2018. 7 European Centre for Disease Prevention and Control. Invasive pneumococcal disease. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018. 8 Beall B, Chochua S, Gertz RE Jr, et al. A population-based descriptive atlas of invasive pneumococcal strains recovered within the U.S. during 2015-2016. Front Microbiol. 2018;19(9). 9 Centers for Disease Control and Prevention. "Respiratory Syncytial Virus Infection (RSV)." Accessed 2 June 2020. Available at https://www.cdc.gov/rsv/index.html 10 Centers for Disease Control and Prevention. "Symptoms and Care." Accessed 2 June 2020. Available at https://www.cdc.gov/rsv/about/symptoms.html 11 Shi et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. Lancet 2017 Sep 2; 390(10098): 946–958: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5592248/ 12 Poland GA. Prevention of meningococcal disease: current use of polysaccharide and conjugate vaccines. Clin Infect Dis. 2010;50:S45-S53. 13 Serogroup B Meningococcal (MenB) VIS. Centers for Disease Control and Prevention (CDC) Website. https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.html. Updated August 15, 2019. Accessed March 11, 2020. 14 Meningococcal meningitis: signs and symptoms. Centers for Disease Control and Prevention. http://www.cdc.gov/meningococcal/about/symptoms.html. Updated June 7, 2017. Accessed March 11, 2020. 15 Meningococcal disease. Centers for Disease Control and Prevention. http://www.cdc.gov/meningococcal/index.html. Updated January 21, 2020. Accessed March 11, 2020. 16 Microb Pathog. 2019 Sep;134:103571. doi: 10.1016/j.micpath.2019.103571. Epub 2019 Jun 1. 17 Purmohamad A et al. Microbial Pathogenesis 134 (2019) 103571 18https://www.ecdc.europa.eu/sites/default/files/documents/AER_for_2017-invasive-meningococcal-disease.pdf. 19 Soeters HM et al Emerging Infectious Diseases 2019: 25(3); 434-440

View source version on businesswire.com: https://www.businesswire.com/news/home/20200622005177/en/

Pfizer Media Contact: Jessica Smith (212) 733-6213 jessica.m.smith@pfizer.com

Pfizer Investor Contact: Ryan Crowe (212) 733-8160 Ryan.Crowe@pfizer.com

Source: Pfizer Inc.