Pfizer Initiates Phase 3 Study of mRNA-Based Influenza Vaccine

Wednesday, September 14, 2022 - 06:45am

First Phase 3 efficacy study to be conducted using an mRNA-based influenza vaccine; study will enroll 25,000 U.S. adults 18 years and older Influenza causes 140,000 to 710,000 hospitalizations and 12,000 to 52,000 deaths in the U.S. every year1 mRNA-based vaccines require only the genetic sequences of the viruses, enabling more flexible, rapid manufacturing which may lead to improved strain match, and the potential opportunity to improve upon the efficacy of current flu vaccines

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the first participants have been dosed in a pivotal Phase 3 clinical trial to evaluate the efficacy, safety, tolerability and immunogenicity of the company's quadrivalent modified RNA (modRNA) influenza vaccine candidate in approximately 25,000 healthy U.S. adults.

"For years, there has been a need to better address the burden of influenza, despite the use of existing seasonal flu vaccines. Our experience with RNA viruses and mRNA technology has given us an even deeper understanding of the opportunity to potentially provide more efficacious vaccines that could further reduce the yearly rates of the severe outcomes of viral disease like flu, including hospitalization and death," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. "We are excited to start the first Phase 3 efficacy study of an mRNA-based influenza vaccine that could potentially deliver an improved flu vaccine to help address the significant burden of this disease."

Each year, even when currently available vaccine strains match circulating influenza virus strains well, those vaccines typically confer only 40% to 60% protection, with even lower protection in years with poor matching of strains.2 With circulating influenza strains continually changing, predicting the best match for the next season's vaccine is difficult

for global health experts as those strains are chosen more than six months before the start of the influenza season that they target. The flexibility of mRNA technology and its rapid manufacturing could potentially allow better strain matches in future years, and in a pandemic influenza situation, mRNA technology could allow rapid, large-scale manufacturing of vaccines. mRNA-based influenza vaccines require only the genetic sequence of the virus.

Influenza annually causes 140,000 to 710,000 hospitalizations, 12,000 to 52,000 deaths3 and about $25 billion in economic loss in the U.S.4 The impact of flu on racial and ethnic minority groups in the U.S. is even larger. Black Americans are 1.8 times more likely than their white counterparts to be hospitalized for flu while Latino and Indigenous Americans are 1.2 and 1.3 times more likely, respectively.5 Although vaccination remains one of the best ways to help prevent infection and serious illness, racial and ethnic minority communities in the U.S. continue to be vaccinated at lower rates,6 and clinical trial enrollment for new or improved vaccines tend to lack diversity.7 Pfizer made a public commitment to help reduce health disparities through its clinical trials and ensure that Pfizer's clinical study populations fully represent the racial and ethnic diversity of the countries where trials are conducted.

About Pfizer's mRNA-based Flu Vaccine Program

The quadrivalent modRNA vaccine candidate will encode World Health Organization recommended strains for the Northern Hemisphere 2022-23 cell culture- or recombinant-based influenza vaccines.8 Additional information about the study can be found at www.clinicaltrials.gov.

This Phase 3 study is informed by previously shared data from the ongoing Phase 2 trial which demonstrates a safety and immunogenicity profile supportive of program advancement and is part of Pfizer's broader influenza vaccine program, focused on leveraging mRNA technology in a vaccine to help protect against the flu. Beyond the modRNA vaccine candidate, Pfizer has ongoing studies exploring more novel mRNA technology like self-amplifying RNA (saRNA), which has the potential to provide added benefit in the future.

In 2018, Pfizer entered into a worldwide collaboration and license agreement with BioNTech under which Pfizer has the exclusive right to carry out the clinical development and commercialization of mRNA-based influenza vaccines. Upon potential approval and commercialization, BioNTech would receive a royalty on Pfizer's sales.

About Pfizer: 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.

Pfizer Disclosure Notice

The information contained in this release is as of September 14, 2022. 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 single dose quadrivalent modified RNA influenza vaccine candidate, mRNA technology, Pfizer’s broader influenza vaccine program, including studies exploring self-amplifying RNA, our commitment to helping reduce health disparities, and manufacturing, 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; risks associated with interim data, including the risk that final results from the ongoing Phase 2 study could differ from the data discussed in this release; 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 biologic license applications may be filed in any jurisdictions for Pfizer’s modified RNA influenza vaccine candidate for any potential indications or for any other potential vaccine candidates in Pfizer’s influenza vaccine program; 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 Pfizer’s modified RNA influenza vaccine candidate or any such other potential 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 modified RNA influenza vaccine candidate or any such other potential vaccine candidates; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding Pfizer’s modified RNA influenza vaccine candidate or any such other potential 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, 2021 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 Disease Burden of Flu. CDC. Available at https://www.cdc.gov/flu/about/burden/index.html 2 Vaccine Effectiveness: How Well do the Flu Vaccines Work? CDC. Available at https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm. 3 Disease Burden of Flu. CDC. Available at https://www.cdc.gov/flu/about/burden/index.html 4 Putri et al, Vaccine. 2018 Jun 22;36(27):3960-3966. doi: 10.1016/j.vaccine.2018.05.057 5 Flu Disparities Among Racial and Ethnic Minority Groups. CDC. Available at https://www.cdc.gov/flu/highrisk/disparities-racial-ethnic-minority-groups.html 6 Flu Disparities Among Racial and Ethnic Minority Groups. CDC. Available at https://www.cdc.gov/flu/highrisk/disparities-racial-ethnic-minority-groups.html 7 Assessment of the inclusion of racial/ethnic minority, female, and older individuals in vaccine clinical trials. JAMA Netw Open. 2021;4(2):e2037640. doi:10.1001/jamanetworkopen.2020.37640 8 Recommended composition of influenza virus vaccines for use in the 2021-2022 northern hemisphere influenza season. World Health Organization. Available at https://www.who.int/publications/i/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2021-2022-northern-hemisphere-influenza-season.

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Source: Pfizer Inc.