Pfizer Logo

Pfizer Starts Study of mRNA-Based Next Generation Flu Vaccine Program

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- *Influenza results in approximately 5 million cases of severe illness and 290,000 to up to 650,000 deaths worldwide every year,[1] with current seasonal vaccines preventing 40% to 60% of the disease in the best-matched seasons [2]*
- *mRNA-based vaccine design requires only the genetic sequences of the viruses, enabling more flexible, rapid manufacturing 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 Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of a single dose quadrivalent mRNA vaccine against influenza in healthy adults. Pfizer's mRNA influenza vaccine program is the first in a planned wave of programs leveraging mRNA technology for influenza. Beyond influenza, the company plans to explore mRNA in other respiratory viruses, including medically appropriate vaccines combinations that could provide protection against more than one respiratory virus, as well as expand to develop mRNA technology in oncology, and genetic diseases.

"Since 2018, we have been working to develop a potential mRNA influenza vaccine, driven by our deep understanding of infectious diseases and our extensive experience in researching, developing and implementing new vaccine technologies to help prevent them," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer. "The COVID-19 pandemic allowed us to deliver on the immense scientific opportunity of mRNA. Influenza remains an area where we see a need for vaccines which could result in improved efficacy in any given season, and we believe mRNA is the ideal technology to take on this challenge to transform global health outcomes."

Conventional seasonal influenza vaccines are generally developed by growing the virus in chicken eggs or mammalian cells, which are inactivated and processed to be made into a vaccine. This process faces multiple challenges, including producing immunogenic antigens, keeping up with virus strain changes, and alterations in the vaccine antigens during production. 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 in the Northern Hemisphere.

Even when the vaccine strains match circulating influenza virus strains well, current seasonal vaccines typically confer 40% to 60% protection against circulating strains, with even lower protection in years with poor matching of strains.[3] Influenza causes approximately 5 million cases of severe illness and up to 650,000 deaths worldwide every year.[4]

mRNA-based influenza vaccine design requires only the genetic sequence of the virus. The flexibility of mRNA technology and its rapid manufacturing could potentially allow better strain match, greater reliability of supply, and the potential opportunity to improve upon the efficacy of current flu vaccines. Furthermore, in a pandemic

influenza situation, mRNA technology could allow rapid, large-scale manufacturing of effective vaccines.

About the Phase 1 Study

The Phase 1 randomized study will take place in the United States and will start by evaluating the safety, tolerability, and immunogenicity of a single dose of an influenza mRNA vaccine in healthy adults 65-85 years of age, with an FDA-approved standard quadrivalent influenza vaccine as a control.

The mRNA vaccine candidates will encode World Health Organization recommended strains. [5] After initial testing of vaccine candidates encoding individual strains, multivalent combinations are planned to be tested. As the program progresses, strains may be updated based on the recommendations for subsequent influenza seasons.

Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05052697.

In 2018, Pfizer entered into a worldwide collaboration agreement with BioNTech under which Pfizer will 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 27, 2021. 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 mRNA influenza vaccine candidate, mRNA technology and plans to expand to develop mRNA technology in other respiratory viruses, oncology, and genetic diseases and to explore medically appropriate combinations to potentially develop vaccines that could provide protection against more than one respiratory virus, 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 biologic license applications may be filed in any jurisdictions for Pfizer's

mRNA influenza vaccine for any potential indications or for any other potential vaccine or product 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 Pfizer's mRNA influenza vaccine or any such other potential vaccine or product 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 mRNA influenza vaccine or any such other potential vaccine or product candidates; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding Pfizer's mRNA influenza vaccine or any such other potential vaccine or product 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, 2020 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] Influenza (Seasonal). World Health Organization. Available at https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal).

[2] Vaccine Effectiveness: How Well do the Flu Vaccines Work? CDC. Available at https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.

[3] Vaccine Effectiveness: How Well do the Flu Vaccines Work? CDC. Available at https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.

[4] Influenza (Seasonal). World Health Organization. Available at https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal).

[5] 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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Media Relations
Jerica Pitts
+1 (347) 224-9084
Jerica.Pitts@pfizer.com

Investor Relations
Bryan Dunn
+1 (212) 733-8917
Bryan.Dunn@pfizer.com

Source: Pfizer Inc.