



NEWS RELEASE

Moderna Announces First Participants Dosed in Phase 3 Study of Seasonal Influenza Vaccine Candidate (mRNA-1010)

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mRNA-1010 is Moderna's first seasonal influenza vaccine candidate to enter a Phase 3 trial

mRNA-1010 is one of several influenza vaccine candidates being developed in Moderna's respiratory portfolio

Moderna now has four programs in Phase 3 studies: Omicron-containing bivalent COVID booster, influenza, RSV, CMV

CAMBRIDGE, MA / ACCESSWIRE / June 7, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced the first participants have been dosed in a Phase 3 study of the Company's seasonal influenza vaccine candidate (mRNA-1010). The trial is expected to enroll approximately 6,000 adults in Southern Hemisphere countries.

"We are pleased to begin this Phase 3 study of our seasonal influenza vaccine candidate, mRNA-1010, our fourth mRNA vaccine candidate to begin a pivotal Phase 3 study. mRNA-1010 is the first of several influenza vaccine candidates we are developing with the aim of iteratively improving traditional vaccines by inducing broad and robust immune responses. We believe our mRNA platform, with the flexibility and speed of our manufacturing process, is well-positioned to address the significant unmet need in seasonal flu, said Stéphane Bancel, Chief Executive Officer of Moderna. "Influenza vaccines are a key pillar in our respiratory vaccine strategy that includes the development of combination candidates targeting multiple viruses in a single vaccine, including influenza with SARS-CoV-2 and respiratory syncytial virus. With the start of dosing for its mRNA-1010 program, Moderna now has four programs in late stage Phase 3 studies, including its SARS-CoV-2 booster, RSV, seasonal flu and CMV vaccine



candidates. Beginning in the fall of 2022, the Company's Phase 3 pipeline could lead to three respiratory commercial launches over the next two to three years."

This Phase 3 randomized, observer-blind study is designed to evaluate the safety and immunological non-inferiority of mRNA-1010 to a licensed seasonal influenza vaccine in adults 18 years and older. Participants will be randomly assigned on a 1:1 ratio to receive either a single dose of mRNA-1010 or a single dose of a licensed seasonal influenza vaccine as a comparator.

About mRNA-1010 & Seasonal Influenza

mRNA-1010 is a vaccine candidate that encodes for hemagglutinin (HA) glycoproteins of the four influenza strains recommended by the World Health Organization (WHO) for the prevention of influenza, including influenza A/H1N1, A/H3N2, and influenza B/Yamagata- and B/Victoria-lineages. HA is a major influenza surface glycoprotein that is considered an important target to generate broad protection against influenza and is the primary target of currently available influenza vaccines. Moderna is proactively preparing for a confirmatory efficacy study for mRNA-1010 as early as the 2022/2023 Northern Hemisphere influenza season, if needed.

Influenza (influenza A and influenza B) epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing a substantial burden on healthcare systems. Worldwide, influenza leads to 3-5 million severe cases of influenza and 290,000-650,000 influenza-related respiratory deaths annually, despite the availability of current influenza vaccines. Although both influenza A and B cause seasonal epidemics, it is the influenza A viruses that lead to >95% of influenza-related hospitalization in adults.

Moderna's Respiratory Vaccine Program

Moderna is advancing a portfolio of respiratory candidates, including five influenza mRNA vaccine candidates. In addition to mRNA-1010, Moderna is developing influenza vaccine candidates that include additional HA antigens for broader coverage of circulating influenza A strains (mRNA-1011 and mRNA-1012), and vaccine candidates that incorporate both HA and neuraminidase (NA) antigens to target multiple proteins involved in the influenza virus lifecycle to reduce the potential of viral antigenic escape (mRNA-1020 and mRNA-1030).

Moderna is also developing two combination vaccine candidates, including a vaccine candidate against influenza and SARS-CoV-2 (mRNA-1073), and another candidate against influenza, SARS-CoV-2, and RSV (mRNA-1230). The goal of Moderna's combination vaccine candidates is to provide protection against multiple respiratory pathogens in a single vaccine.

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past seven years. To learn more, visit www.modernatx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including expected enrollment in the Phase 3 trial of mRNA-1010; the potential for Moderna's influenza vaccine candidates to improve upon traditional influenza vaccines; Moderna's plans regarding a potential confirmatory efficacy study for mRNA-1010; and the potential to provide protection against multiple respiratory pathogens in a single vaccine. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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