Moderna Announces First Participant Dosed in Phase 3 Study of mRNA-1083, a Combination Vaccine Against Influenza and COVID-19

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mRNA-1083 is Moderna's first respiratory combination vaccine candidate to enter a Phase 3 trial.

Phase 3 initiation follows data from a Phase 1/2 trial where mRNA-1083 showed strong immunogenicity against influenza and COVID-19, with an acceptable reactogenicity and safety profile, compared to licensed standalone vaccines.

Company has multiple programs in Phase 3 development across several areas, including respiratory diseases, latent viruses, and oncology.

CAMBRIDGE, MA / ACCESSWIRE / October 24, 2023 / Moderna, Inc. (NASDAQ:MRNA) today announced that the first participant has been dosed in a Phase 3 study of the Company's combination vaccine candidate against influenza and COVID-19 (mRNA-1083) in the U.S. The trial is expected to enroll approximately 8,000 adults in the Northern Hemisphere.

The Phase 3 study will evaluate the immunogenicity, safety, and reactogenicity of mRNA-1083 as compared with active control, co-administered licensed influenza and SAR-CoV-2 vaccines in two independent age-group sub-study cohorts involving 4,000 adults 65 years and older and 4,000 adults 50 to <65 years of age.

The mRNA-1083 candidate selected to advance to Phase 3 achieved hemagglutination inhibition antibody titers similar to or greater than both licensed quadrivalent influenza vaccines and achieved SARS-CoV-2 neutralizing
antibody titers similar to the Spikevax bivalent booster in the **Phase 1/2 study.**

mRNA-1083 has the potential to efficiently reduce the overall burden of acute viral respiratory diseases by providing simultaneous protection against influenza and SARS-CoV-2 viruses in a single injection. mRNA-1083 offers greater convenience and has the potential to lead to increased compliance with vaccine recommendations. This approach could benefit public health by synergistically increasing coverage rates against influenza and SARS-CoV-2 viruses.

The Company continues to target a potential initial regulatory approval for the combination vaccine in 2025.

**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 and integrated manufacturing facilities that allow 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 eight years. To learn more, visit [www.modernatx.com](http://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 regarding: Moderna's development of a combination vaccine candidate against seasonal influenza and COVID-19, mRNA-1083; the initiation of a Phase 3 trial evaluating the immunogenicity, safety, and reactogenicity of mRNA-1083 as compared with active control, co-administered licensed influenza and SAR-CoV-2 vaccines, the potential benefits of combination vaccines; the ability of mRNA-1083 to protect against respiratory disease, and protection compared to licensed comparators; and the potential timeline for testing and approval of mRNA-1083. 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 Annual Report on Form 10-K for the year ended December 31, 2022, 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 of this press release.

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