NEWS RELEASE

Moderna Announces Interim Phase 3 Safety and Immunogenicity Results for mRNA-1010, a Seasonal Influenza Vaccine Candidate

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mRNA-1010 demonstrated superiority on seroconversion rates for A/H3N2 and A/H1N1, superiority on geometric mean titer ratios for A/H3N2, and non-inferiority on geometric mean titer ratios for A/H1N1

Non-inferiority was not met for seroconversion rates and geometric mean titer ratios for the influenza B/Victoria- and B/Yamagata-lineage strains

mRNA-1010 showed an acceptable safety and tolerability profile

Separate parallel pivotal Phase 3 efficacy study has now accrued over 200 PCR-confirmed cases, almost all influenza A consistent with the burden of disease in older adults; an independent DSMB is expected to review the first interim analysis of efficacy by the end of 1Q

mRNA-1010 is one of five influenza vaccine candidates being evaluated by Moderna

CAMBRIDGE, MA / ACCESSWIRE / February 16, 2023 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced interim results from its pivotal Phase 3 safety and immunogenicity trial of mRNA-1010 (P301), an mRNA-based seasonal influenza (flu) vaccine candidate, in adults. The Phase 3 randomized trial was designed to evaluate the safety and immunogenicity of mRNA-1010 in adults 18 years and older in the Southern Hemisphere. mRNA-1010 encodes for hemagglutinin (HA) glycoproteins of the four influenza strains recommended by the World Health Organization (WHO) to prevent

influenza, including influenza A/H1N1, A/H3N2, and influenza B/Yamagata- and B/Victoria-lineages. Interim results indicate that mRNA-1010 achieved superiority on seroconversion rates for A/H3N2 and A/H1N1, as well as superiority on geometric mean titer ratios for A/H3N2 and non-inferiority on geometric mean titer ratios for A/H1N1. Non-inferiority was not met for either endpoints for the influenza B/Victoria- and B/Yamagata-lineage strains.

"Today's results represent an important step forward in the development of mRNA-based influenza vaccines to address the substantial burden of disease caused by influenza. We are encouraged by the safety and tolerability profile, and by the strong immunogenicity results against Influenza A viruses which cause the overwhelming majority of flu-related disease in older adults. We now look forward to the efficacy results from the ongoing pivotal Phase 3 efficacy study being conducted in parallel," said Stephen Hoge, M.D., Moderna's President. "While we did not achieve non-inferiority for the Influenza B strains which are more frequent in younger populations, we have already updated the vaccine that we believe could improve immune responses against Influenza B and will seek to quickly confirm those improvements in an upcoming clinical study thanks to the agility of our mRNA platform."

This Phase 3 randomized, observer-blind study was designed to evaluate the safety and immunological non-inferiority of mRNA-1010 to a licensed seasonal influenza vaccine in adults 18 years and older. The trial enrolled 6,102 adults across Argentina, Australia, Colombia, Panama, and the Philippines during the Southern Hemisphere influenza season. Participants were randomly assigned to receive either a single dose of mRNA-1010 or a single dose of a licensed seasonal influenza vaccine as a comparator. mRNA-1010 encodes for hemagglutinin (HA), a major influenza surface glycoprotein considered an important target to generate protection against influenza and is the primary target of currently available influenza vaccines.

mRNA-1010 was found to be generally well-tolerated. 70% of mRNA-1010 recipients reported solicited adverse reactions (SARs) compared to 48% of participants in the active comparator group. A lower rate of SARs was observed in older age groups compared to the younger adult groups. The majority of SARs were grade 1. Pain and axillary swelling were the most common local SARs, and headache, myalgia, and fatigue were the most common systemic SARs reported. No significant differences in unsolicited adverse events, serious adverse events, or adverse events of special interest were observed between the mRNA-1010 and comparator groups.

The ongoing mRNA-1010 Phase 3 efficacy study (P302) conducted in Northern Hemisphere countries has accrued more than 200 PCR-confirmed cases. Consistent with the predominant circulation of A/H3N2 and A/H1N1 viruses during this influenza season, more than 99% of confirmed cases in the study are caused by influenza A viruses. The first per protocol interim analysis of efficacy is now expected to be reviewed by an independent Data and Safety Monitoring Board (DSMB) before the end of the first quarter. Based on these results the DSMB will notify the Company whether the primary efficacy endpoint has been met or whether the study should continue accruing

further cases towards the final analysis.

Seasonal Influenza

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. Influenza affects people of all ages, but older adults are disproportionately affected by influenza and its complications.

Although both influenza A and B cause seasonal epidemics, influenza A viruses lead to the majority (>95%) of influenza-related hospitalization in adults. The influenza A/H3N2 subtype, in particular, is a significant cause of illness in older adults and is responsible for most of the recent influenza outbreaks and excess morbidity caused by the virus.

Moderna's Influenza Vaccine Program

Moderna is advancing a portfolio of five influenza vaccine candidates that include additional HA antigens for broader coverage of circulating influenza A strains (mRNA-1011 and mRNA-1012) and 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 combination vaccine candidates, including vaccine candidates against influenza and SARS-CoV-2, influenza and RSV, and influenza, SARS-CoV-2, and RSV. 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 eight years. To learn more, visit **www.modernatx.com**.

Moderna 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 statements regarding: the Company's development of vaccine candidates against seasonal flu, including mRNA-1010, mRNA-1020, mRNA-1030, mRNA-1011 and mRNA-1012; the ability of mRNA-1010 to demonstrate seroconversion against A/H3N2 and A/H1N1 flu strains; the vulnerability of older adults to influenza A strains; the safety and tolerability of mRNA-1010; the launch and timing of vaccine candidates with modified influenza B strains; the ability of mRNA vaccines to address limitations of existing influenza vaccines; the timing for readouts from the P302 study of mRNA-1010; and Moderna's plans for additional influenza vaccine candidates. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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, among others, those risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022, each 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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