NEWS RELEASE

Moderna Announces mRNA-1345, an Investigational Respiratory Syncytial Virus (RSV) Vaccine, Has Met Primary Efficacy Endpoints in Phase 3 Trial in Older Adults

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mRNA-1345 demonstrated vaccine efficacy of 83.7% against RSV lower respiratory tract disease, defined by 2 or more symptoms in older adults

mRNA-1345 was generally well-tolerated, with no safety concerns identified by the DSMB

Based on these results, Moderna intends to submit mRNA-1345 for regulatory approval

CAMBRIDGE, MA, ACCESSWIRE / January 17, 2023 / Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced positive topline data from its ConquerRSV Phase 3 pivotal efficacy trial of mRNA-1345, an investigational mRNA vaccine targeting respiratory syncytial virus (RSV) in older adults. Following review by an independent Data and Safety Monitoring Board (DSMB), the primary efficacy endpoints have been met, including vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; $p<0.0001$) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. Based on these results, Moderna intends to submit for regulatory approval in the first half of 2023.

"Today's results represent an important step forward in preventing lower respiratory disease due to RSV in adults 60 years of age and older. These data are encouraging, and represent the second demonstration of positive phase 3 trial results from our mRNA infectious disease vaccine platform after, Spikevax, our COVID-19 vaccine. We look

forward to publishing the full data set and sharing the results at an upcoming infectious disease medical conference," said Stéphane Bancel, Moderna's Chief Executive Officer. "Respiratory diseases are a major public health priority given they have a significant health impact and are a leading cause of hospitalization. For these reasons, in addition to our mRNA-1345 RSV vaccine candidate, we are committed to developing a portfolio of respiratory mRNA vaccines to target the most significant viruses causing respiratory disease, including COVID-19, influenza, and human metapneumovirus."

"RSV significantly affects the health of older and high-risk adults, particularly those with comorbidities," said Abdullah Baqui, a principal investigator for the study sites in Bangladesh and Professor, Department of International Health, Director, International Center for Maternal and Newborn Health, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University. "This trial will help to understand the role of severe acute respiratory infections in older adult populations and inform the future implementation of vaccines in adults in lower-resource areas."

The ConquerRSV trial is a randomized, double-blind, placebo-controlled study of approximately 37,000 adults 60 years or older in 22 countries, including the US (**NCT05127434**). The primary efficacy endpoints were based on two definitions of RSV-LRTD defined as either two or more symptoms, or three or more symptoms of disease. The interim analysis was based on 64 cases of RSV-LRTD with two or more symptoms, of which 55 occurred in the placebo group and 9 occurred in the mRNA-1345 group, and 20 cases of RSV-LRTD with three or more symptoms, of which 17 cases were observed in the placebo group compared with three cases observed in the mRNA-1345 group. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078). The trial is ongoing, and additional efficacy analyses are planned as cases accrue, including for severe RSV.

A concurrent review of available safety data was also conducted by the DSMB. mRNA-1345 was well tolerated with no safety concerns identified. Safety and tolerability will continue to be followed in this ongoing study. To date most solicited adverse reactions were mild or moderate and the most commonly reported solicited adverse reactions in the mRNA-1345 group were injection site pain, fatigue, headache, myalgia, and arthralgia. The overall rate of severe (Grade 3 or greater) solicited systemic adverse reactions was 4.0% for mRNA-1345 and 2.8% for placebo. The overall rate of Grade 3 or greater solicited local adverse reactions was 3.2% for mRNA-1345 and 1.7% for placebo. The study is ongoing, and an updated analysis of safety and tolerability will be provided at the time of regulatory submission.

Moderna will submit the data for peer-reviewed publication and present it at an upcoming scientific meeting.

About RSV

RSV, a highly contagious seasonal respiratory virus and a leading cause of lower respiratory tract infections and pneumonia, causes a particularly large burden of disease in infants and older adults. RSV can cause severe disease with an estimated 5.2 million cases and nearly half a million hospitalizations in adults 60 years or older reported across high-income countries in 2019. Each year in the US, approximately 60,000-120,000 older adults are hospitalized, and 6,000-10,000 of them die due to RSV infection.

Complications in adults include respiratory distress, pneumonia, bronchitis, hospitalization, and death. In addition to acute infection, RSV can exacerbate underlying medical conditions such as asthma and COPD and can result in acute myocardial infarction, stroke, and long-term decline of respiratory functions.

About mRNA-1345

mRNA-1345 is an investigational RSV vaccine that consists of a single mRNA sequence encoding for a stabilized prefusion F glycoprotein. The vaccine uses the same lipid nanoparticles (LNPs) as in the Moderna COVID-19 vaccines. The F glycoprotein is on the surface of the virus and is required for infection by helping the virus to enter host cells. It exists in two states, prefusion and postfusion. The prefusion conformation is a significant target of potent neutralizing antibodies and is highly conserved across both RSV-A and RSV-B subtypes.

Moderna's RSV Clinical Trials

The Phase 3 trial is part of a comprehensive clinical development program investigating the immunogenicity and safety of mRNA-1345. Moderna is advancing a broad respiratory portfolio, and the Phase 3 ConquerRSV trial is one of five ongoing RSV trials, including pediatric and combination clinical trials.

Since RSV causes a significant disease burden in children, mRNA-1345 is being tested in an ongoing Phase 1 trial in pediatric populations; the clinical trial is fully enrolled.

Moderna has developed a respiratory combination vaccine program to target the most significant viruses causing respiratory disease in older adults, including combinations against RSV, COVID-19, influenza, and human metapneumovirus (hMPV). Moderna recently started a Phase 1 study of mRNA-1230 targeting SARS-CoV-2, influenza, and RSV, and mRNA-1045 targeting influenza and RSV. In an ongoing Phase 3 trial, Moderna is evaluating the coadministration of mRNA-1345 and a licensed influenza vaccine, and coadministration of mRNA-1345 with mRNA-1273.214.

Moderna plans to initiate a Phase 1 pediatric trial of mRNA-1365, targeting RSV and hMPV. Like RSV, hMPV is a major cause of lower respiratory tract infection in the pediatric population and a common cause of morbidity and mortality in immunocompromised patients and older adults.

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 a vaccine against RSV (mRNA-1345); the vaccine efficacy of mRNA-1345; the development of additional respiratory vaccines by the Company; the potential for mRNA-1345 to reduce disease burden from RSV; future efficacy readouts from the Phase 3 trial of mRNA-1345; the safety profile and tolerability of mRNA-1345; the mechanism of action for mRNA-1345; the conduct of additional trials targeting RSV; and the anticipated timing for submissions for regulatory approval of mRNA-1345. 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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