NEWS RELEASE

Moderna Granted FDA Breakthrough Therapy Designation for mRNA-1345, An Investigational Respiratory Syncytial Virus (RSV) Vaccine Candidate

1/30/2023

Designation based on positive topline data from the ConquerRSV Phase 3 pivotal efficacy trial, which demonstrated vaccine efficacy of 83.7% against RSV lower respiratory tract disease, defined by 2 or more symptoms in older adults

CAMBRIDGE, MA / ACCESSWIRE / January 30, 2023 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced mRNA-1345, an investigational mRNA vaccine candidate for respiratory syncytial virus (RSV), has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) in adults aged 60 years or older. The designation was based on **positive topline data** from the ConquerRSV Phase 3 pivotal efficacy trial.

"The FDA's Breakthrough Designation for mRNA-1345 further emphasizes the significant health impact of RSV in older adults and the high unmet need," said Stéphane Bancel, Chief Executive Officer of Moderna. "With this designation, we look forward to productive conversations with the FDA in the hopes of bringing our RSV vaccine candidate for older adults to the market safely and quickly. Moderna's mRNA platform has now demonstrated two positive Phase 3 infectious disease trial results and we continue to advance a portfolio of respiratory mRNA vaccines targeting the most serious diseases. We are grateful to the FDA for this designation."

The FDA's Breakthrough Therapy Designation is granted to expedite the development and review of drugs that are

intended to treat a serious condition, and when preliminary clinical evidence indicates the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).1

mRNA-1345 was previously granted **Fast Track designation** by the FDA in August 2021. Moderna intends to submit a license application for regulatory approval in the first half of 2023.

The ConquerRSV study, a randomized, double-blind, placebo-controlled study evaluating the efficacy of mRNA-1345 against RSV-LRTD as defined by two or more symptoms. The study met its primary efficacy endpoints, including vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; $p<0.0001$) against RSV-LRTD as defined by two or more symptoms and VE of 82.4% (96.36% CI: 34.8%, 95.3%; $p=0.0078$) in RSV-LRTD as defined by three or more symptoms.

mRNA-1345 was generally well tolerated with no clinically significant safety signals identified. 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 study is ongoing, and an updated analysis of safety and tolerability will be provided at the time of regulatory submission.

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.

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 potential timing for submission for regulatory approval of mRNA-1345; the potential for mRNA-1345 to reduce disease burden from RSV; the safety profile and tolerability of mRNA-1345; and the mechanism of action for 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.

1U.S. Food and Drug Administration (FDA). Breakthrough Therapy. **https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm** . Updated January 4, 2018. Accessed January 26, 2023.

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