NEWS RELEASE

# Moderna Initiates Phase 3 Portion of Pivotal Trial for mRNA Respiratory Syncytial Virus (RSV) Vaccine Candidate, Following Independent Safety Review of Interim Data

2/22/2022

Endorsement to proceed given by the independent Data and Safety Monitoring Board based on preliminary Phase 2 safety and tolerability data

Moderna expects to enroll approximately 34,000 participants in multiple countries

RSV causes severe disease burden among older adults and young children; there is no approved vaccine to prevent RSV

CAMBRIDGE, MA / ACCESSWIRE / February 22, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the Data and Safety Monitoring Board (DSMB) for the RSV program has endorsed the start of the Phase 3 portion of the pivotal clinical study of mRNA-1345, the Company's Respiratory Syncytial Virus (RSV) vaccine candidate, in adults 60 years and older. The DSMB's endorsement comes after independent review of preliminary Phase 2 data, which suggest that the vaccine has an acceptable safety profile in older adults at the selected dose. This study is known as ConquerRSV.

"RSV is one of the most widespread respiratory viruses, causing severe disease and hospitalization in older adults, and yet there is no vaccine available on the market," said Stéphane Bancel, Chief Executive Officer of Moderna. "We

believe that our vaccine candidate against RSV has the potential to protect against over 1 million infections globally each year[1], improving quality of life for those at high-risk of becoming infected and reducing the burden on health care systems. An mRNA vaccine against RSV could have a positive impact on individuals, communities, and global public health. Our ultimate goal is to combine our RSV vaccine with our COVID-19 and flu boosters into a single dose booster."

RSV is a common respiratory virus that generally causes cold-like symptoms. While most people who contract RSV recover in approximately one to two weeks, the virus can be serious for young children and older adults. For these higher-risk groups, RSV is a leading cause of severe respiratory illness, including pneumonia and respiratory distress.

The burden of illness caused by RSV is substantial; each year in the United States, RSV causes approximately 177,000 hospitalizations and 14,000 deaths in adults 65 and older, resulting in an estimated $3 billion in annual medical costs.

RSV tends to be a seasonal illness, with infections in the United States and countries with similar climates primarily occurring during fall, winter and spring. In the past year, however, the COVID-19 pandemic has impacted normal transmission patterns, leading to unusual levels of infection. In June 2021, the **CDC issued a health alert** flagging increased interseasonal RSV infection in certain parts of the United States, and similar trends have **been seen globally**. There is currently no approved vaccine for RSV.

mRNA-1345 is a vaccine against RSV encoding for a prefusion F glycoprotein, which elicits a higher neutralizing antibody response compared to the postfusion state. mRNA-1345 uses the same lipid nanoparticle (LNP) as Moderna's COVID-19 vaccine and contains optimized protein and codon sequences. The FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age. The primary purpose of the Phase 3 segment of the study is to establish the safety and efficacy of mRNA-1345 vaccine in adults older than 60 years of age in support of licensure. Moderna expects to enroll approximately 34,000 participants. To learn more about eligibility, please **click here.**

Moderna is advancing mRNA vaccines against additional respiratory viruses including **COVID-19 booster vaccine candidates** and a **seasonal flu vaccine candidate** (mRNA-1010). The Company also recently announced that it is developing a single dose vaccine that combines a booster against COVID-19 and a booster against flu. In preclinical studies, Moderna has observed that its seasonal flu, RSV and COVID-19 booster vaccines can be combined into one dose that produces an immune response to all six antigens. Moderna intends to explore vaccine combinations including RSV, flu and COVID-19.

About Moderna

In 10 years since its inception, Moderna has transformed from a science 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 both clinical and commercial production at scale and at unprecedented speed. 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 autoimmune 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 regarding: the Company's development of a vaccine candidate against respiratory syncytial virus (RSV) (mRNA-1345); the ability of mRNA-1345 to induce neutralizing antibodies against RSV in older adults; the safety profile and tolerability of mRNA-1345; the ability of mRNA-1345 to reduce RSV infections in older adults; the conduct of Phase 2/3 clinical trials for mRNA-1345; the potential for the Company to produce and commercialize combination vaccines; the disease burden and costs associated with RSV infection; and the Company's development of vaccine candidates against other respiratory diseases, including seasonal flu and COVID-19. 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.

[1] Shi, Ting, et al. J Infect Dis. (07 Oct 2020), **https://pubmed.ncbi.nlm.nih.gov/30880339/**

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