NEWS RELEASE

Moderna Announces Clinical and Program Updates at 4th Vaccines Day

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Next-generation, refrigerator-stable COVID-19 vaccine candidate, mRNA-1283, has dosed first participant in its Phase 3 trial

Company expects to file for approval of its investigational RSV vaccine candidate, mRNA-1345, this quarter

Company's first influenza candidate, mRNA-1010, did not accrue sufficient cases at the interim efficacy analysis to declare early success in the Phase 3 Northern Hemisphere efficacy trial and the independent DSMB recommended continuation of efficacy follow-up

Preliminary immunogenicity analysis from the Northern Hemisphere trial showed mRNA-1010 demonstrated titers consistent with superiority against influenza A strains (H1N1, H3N2) and non-inferiority against influenza B strains (B/Victoria, B/Yamagata) versus the licensed comparator

Moderna announces new development candidates against Lyme disease, the Company's first bacterial vaccine, and norovirus, an enteric virus

Company establishes 2027 financial framework for the Respiratory Franchise

CAMBRIDGE, MA / ACCESSWIRE / April 11, 2023 / **Moderna, Inc.** (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced clinical and program updates demonstrating expansion and advancement of its mRNA pipeline. The updates include advancements in the

Company's respiratory and latent virus portfolios, new vaccine candidates, and commercial and financial framework announcements for the respiratory vaccines business.

"Our mRNA platform has changed medicine and will continue to have a major impact on global health. Today we are excited to announce multiple new vaccine candidates, including for enteric viruses, such as norovirus, and targeting Lyme disease, our first bacterial vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna. "With mRNA-1010, our first investigational vaccine against seasonal flu, we are encouraged by the consistently strong immunogenicity results against influenza A, and titers consistent with non-inferiority against influenza B strains in the most recent Phase 3 trial. With our mRNA platform and technology, as well as our agile manufacturing capabilities, we are confident that we can quickly develop safe and effective vaccines to address critical unmet needs."

Portfolio Overview

The vaccine portfolio seeks to address infectious diseases that cause considerable health burdens, including those due to respiratory viruses, latent viruses, global health threats, and now norovirus and Lyme disease.

Respiratory Portfolio

Moderna's approach to ease the global burden of respiratory infections includes vaccine candidates against major causative pathogens, including SARS-CoV-2, influenza virus, and respiratory syncytial virus (RSV). Respiratory infections are a top cause of death globally and are particularly harmful to the young, immunocompromised, and older adults who experience more severe illness, greater incidence of hospitalization, and greater mortality than younger adults.

Moderna's respiratory pipeline includes Phase 3 trials against RSV and influenza, and a next-generation COVID-19 candidate. The pipeline includes four additional influenza vaccines with expanded antigens (Phase 1 - Phase 2), vaccines against other respiratory pathogens (e.g., hMPV, PIV3), and five combination vaccine programs (preclinical - Phase 2).

COVID-19

Despite the success of vaccination in reducing the burden of SARS-CoV-2, COVID-19 remains a leading cause of severe illness and mortality throughout the world.

Moderna expects to continue to meet the evolving needs of the endemic COVID-19 market including through multi-valent boosters and by advancing next-generation vaccines. The Company's mRNA platform can produce variant-

matched vaccines on an accelerated time horizon, consistent with recent U.S. Food and Drug Administration (FDA) comments on the timing of potential strain selection for the fall booster season.

Moderna's next-generation, refrigerator-stable COVID-19 vaccine, mRNA-1283, has demonstrated encouraging results in multiple clinical studies and recently began dosing participants in a Phase 3 trial.

Influenza (Flu)

Worldwide, influenza leads to 3-5 million severe cases of flu and 290,000-650,000 flu-related respiratory deaths annually. Three main types of influenza viruses (A, B, and C) infect humans. Although influenza A and B viruses cause seasonal flu epidemics, the influenza A viruses lead to most flu-related hospitalization in older adults, including more than 95% of hospitalizations in the most recent flu season.

The Company has five influenza vaccine candidates in clinical development.

- mRNA-1010 a seasonal quadrivalent vaccine using strains recommended by the World Health Organization (WHO)
- mRNA-1011/1012, aseasonal penta-/hexa-valent vaccine candidate that includes more hemagglutinin antigens (e.g. H3, H1) to expand strain matching
- mRNA-1020/1030, a seasonal vaccine candidate that includes neuraminidase antigens to target more conserved regions of the virus

mRNA-1010

The Company's first vaccine candidate against influenza is mRNA-1010, which is being developed in adults. mRNA-1010 is currently being evaluated in two Phase 3 trials. The first Phase 3 trial (P301) was conducted in the Southern Hemisphere to evaluate safety and non-inferior immunogenicity compared to a licensed flu vaccine. The previously **announced** interim results from the P301 trial indicated that mRNA-1010 demonstrated superiority in geometric mean titers (GMT) for A/H3N2 and non-inferiority in GMT for A/H1N1. mRNA-1010 did not meet non-inferiority for both influenza B/Victoria- and B/Yamagata-lineage strains. mRNA-1010 demonstrated an acceptable safety and tolerability profile in the trial, and the independent Data and Safety Monitoring Board (DSMB) for P301 did not identify any safety concerns.

The second Phase 3 trial (P302) is being conducted in the Northern Hemisphere to evaluate safety and non-inferior efficacy compared to a licensed flu vaccine. The independent DSMB has completed the first interim analysis of efficacy and informed the Company that mRNA-1010 did not meet the statistical threshold necessary to declare early success and recommended that the trial continue with efficacy follow-up towards the next analysis. The DSMB did not identify any safety concerns. Blinded follow-up for safety and efficacy is ongoing in this trial.

A preliminary analysis of immunogenicity from a subset of participants in the P302 trial has also been completed. In this analysis, mRNA-1010 demonstrated geometric mean titer ratios consistent with superiority against both influenza A strains (A/H1N1, A/H3N2) and consistent with non-inferiority against both influenza B strains (B/Victoria, B/Yamagata) relative to the licensed comparator. The P302 study did not pre-specify success criteria for immunogenicity endpoints.

The Company has developed an update to mRNA-1010 that is expected to have improved immunogenicity against influenza B strains and announced plans to initiate a confirmatory Phase 3 trial this month.

Respiratory Syncytial Virus

RSV is the leading cause of respiratory illness in young children, and older adults are at high risk for severe infections. In addition to acute mortality and morbidity, RSV infection is associated with long-term sequelae such as asthma and impaired lung function in pediatric populations, and exacerbation of chronic obstructive pulmonary disease in older adults. Annually, there are approximately two million medically attended RSV infections and 58,000 to 80,000 hospitalizations in children younger than 5 years old in the U.S. And in the U.S., each year there are up to 160,000 hospitalizations and 10,000 RSV-related deaths in adults aged 65 and older due to RSV. Across high-income countries in 2019, RSV caused an estimated ~5.2 million cases, 470,000 hospitalizations and 33,000 in-hospital deaths in adults 60+ years old.

Moderna is advancing RSV candidates to address the areas of greatest need, including candidates for older adults and pediatric populations, and combination vaccines to target RSV along with flu and COVID-19.

mRNA-1345

mRNA-1345, Moderna's RSV vaccine candidate, is in an ongoing Phase 2/3, randomized, observer-blind, placebo-controlled case-driven trial (ConquerRSV) in adults aged 60 years and older. In this study, 35,541 participants from 22 countries were randomized 1:1 to receive one dose of mRNA-1345 or placebo.

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. Vaccine efficacy was maintained in participants over 70 years of age and participants with comorbidities. mRNA-1345 was well tolerated; solicited adverse reactions were mostly grade 1 or grade 2 in severity. No cases of Guillain-Barre Syndrome (GBS) have been reported.

mRNA-1345 has been granted Breakthrough Therapy Designation (BTD) by the FDA for the prevention of RSV-LRTD in adults aged 60 years or older.

Pediatrics

Pediatric RSV mRNA-1345 and a combination vaccine including RSV and human metapneumovirus (hMPV) mRNA-1365 are enrolling children in a Phase 1 study of children 5 to less than 24 months old.

Combination Respiratory Vaccines

Moderna's combination vaccine candidates cover respiratory viruses associated with the largest disease burden in the category.Phase 1 combination studies with Covid+Flu (mRNA-1073), Flu+RSV (mRNA-1045) and Covid+Flu+RSV (mRNA-1230) have completed enrollment. An investigational new drug (IND) application has been submitted for a next-generation Covid+Flu vaccine candidate (mRNA-1083). The Company intends to have combination vaccines available by 2025 and expects to regularly update combinations with improved next-generation vaccine candidates as appropriate.

Latent Virus Portfolio

Moderna is advancing seven vaccine candidates against five viruses that cause latent infections, five of which are in clinical trials. When latent, a virus is present in the body but exists in a resting state, typically without causing any noticeable symptoms. Latent viruses can reactivate and cause clinical symptoms during times of stress or when immunity is compromised. The capacity for latency is a defining feature of human immunodeficiency virus (HIV) and members of the Herpesviridae family, including Cytomegalovirus (CMV), Epstein-Barr virus (EBV), Varicella-Zoster virus (VZV), and **herpes simplex virus** (HSV).

Cytomegalovirus (CMV)

CMV is the most common cause of congenital infection worldwide and is responsible for more than $1 billion in annual healthcare costs. One in 200 babies in the U.S. are born with a congenital CMV infection, and of those affected, one in five will have severe, life-altering health problems. Possible short- and long-term sequelae of CMV infection include microcephaly, chorioretinitis, seizures, sensorineural hearing loss, cognitive impairment, and cerebral palsy.

CMVictory is in a pivotal Phase 3 trial evaluating mRNA-1647 against primary CMV infection in women ages 16 to 40 years. The trial is a randomized, observer-blind, placebo-controlled study designed to evaluate the efficacy, safety, and immunogenicity of mRNA-1647 to evaluate the prevention of primary infection. The trial is more than 50%

enrolled, with an expectation to enroll up to 7,300 women from approximately 150 clinical sites. The primary efficacy analysis will be triggered based on the accrual of seroconversion cases.

Since the majority of cases of disabling congenital CMV infection could be prevented by a universal vaccination policy, Moderna is testing mRNA-1647 in adolescents. A Phase 1/2 open-label and placebo-controlled study of mRNA-1647 to evaluate safety and immunogenicity in male and female participants at 9 to 15 years of age has begun enrollment.

Human immunodeficiency virus (HIV)

Human immunodeficiency virus (HIV), the cause of AIDS, continues to have devastating health effects globally, resulting in approximately 650,000 deathsworldwide annually. Moderna is advancing three Phase I clinical trials of HIV vaccines with partners (mRNA-1644/IAVI G002; mRNA-1644/IAVI G003; mRNA-1574/NIAID) to expand on proof-of-concept data and evaluate the potential of mRNA technology to successfully deliver immunogens. The goal of these trials is to determine whether this approach is safe and immunogenic, meaning that the immunogens elicit the right type of broadly neutralizing HIV-1 antibodies (bnAbs). The trials are the beginning of an iterative research process with the expectation for multiple Phase 1 trials to converge on a potentially protective vaccine that merits advancement to Phase 2. These trials are conducted in parallel to accelerate the advancement of immunogens into vaccine candidates.

Emerging Programs

Enteric Virus Vaccine: Norovirus

Enteric viruses, including norovirus, are a leading cause of global acute gastroenteritis (AGE), resulting in significant morbidity and mortality worldwide,particularly among young children and older adults. Norovirus is highly contagious and the leading cause of diarrheal disease globally, associated with 18% of all diarrheal diseases worldwide, resulting in approximately 200,000 deaths per year and substantial healthcare costs.

Given the wide genetic and antigenic diversity of noroviruses, a broadly effective norovirus vaccine will require a multivalent vaccine design. Moderna is announcing the development of pentavalent (mRNA-1405) and trivalent (mRNA-1403) candidates for norovirus.

Bacterial Vaccines: Lyme Disease

Moderna is announcing new development candidates to address Lyme disease, mRNA-1982 and mRNA-1975, representing the Company's first application of its mRNA technology to bacterial pathogens.

With approximately 120,000 Lyme disease cases reported per year in the U.S. and Europe, there is a significant quality of life burden created by this pathogen. With rising atmospheric temperatures, Lyme territory continues to increase in the U.S. Lyme disease burden follows a bimodal age distribution, affecting mainly children under 15 and older adults. Patients can develop rash, fever, headaches, fatigue, joint pain, swelling, stiffness, and headaches. Older adults appear to have higher odds of unfavorable treatment response as compared with younger patients and neurologic manifestations are more common at presentation for this older adult population.

To address Lyme's biological complexity, Moderna is advancing a seven-valent approach with two Lyme disease vaccine candidates that will be developed in parallel. mRNA-1982 is designed to elicit antibodies specific for Borrelia burgdorferi, which causes almost all Lyme disease in the U.S. mRNA-1975 is designed to elicit antibodies specific for the four major Borrelia species causing disease in the U.S. and Europe.

Commercial Updates

Moderna expects six major vaccine product launches in the next few years, each with significant addressable markets. The annual global endemic COVID-19 booster market alone is estimated by Moderna to be approximately $15 billon.

2027 Respiratory Franchise Financial Framework

The Company estimates respiratory product sales in 2027 to be in the range of $8 billion to $15 billion with corresponding Respiratory operating profit in the range of $4 billion to $9 billion. This framework is supported by $6 billion to $8 billion of additional research and development investments over the next few years. Of note, these estimates are for the respiratory vaccine business only and do not include forecasts for other Moderna products or investments.

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 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**

INDICATION (U.S.)

SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the vaccine.
- The vaccine may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials following administration of the vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site, and rash.
- The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at **https://vaers.hhs.gov/reportevent.html** or by calling 1-800-822-7967.
- Please see the **SPIKEVAX Full Prescribing Information**. For information regarding authorized emergency uses of the Moderna COVID-19 Vaccine, please see the **EUA Fact Sheet**.

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 potential of Moderna's mRNA platform;

anticipated timing of regulatory action for Moderna's older adults RSV vaccine; Moderna's 2027 financial framework for its Respiratory Franchise, including product sales, operating profit and research and development investments; Moderna's ability to advance multiple generations of single-virus and combination respiratory vaccines, and the potential benefits of combination vaccines; Moderna's intention to have combination vaccines available by 2025; Moderna's ability to meet the evolving needs of the endemic COVID-19 market, including Moderna's ability to serve the fall 2023 market and to rapidly adapt to emerging variants; Moderna's ability to execute on its long-term flu strategy; Moderna's development of an update to mRNA-1010 that is expected to have improved immunogenicity against influenza B strains and Moderna's plans to initiate a confirmatory Phase 3 trial; the potential size of the addressable market for Moderna's CMV vaccine candidate; enrollment in the Phase 3 trial of mRNA-1647 (CMV), including the number of participants to be enrolled; the potential for mRNA vaccines to address enteric viruses and bacterial pathogens; the impact of climate change on human pathogenic diseases; and Moderna's expectations regarding vaccine product launches in the near future, including timing and the size of addressable markets. 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, 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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