NEWS RELEASE

Moderna Announces Advances Across Its Industry-Leading mRNA Pipeline and Provides Business Update

1/10/2022

807 million doses of Moderna's COVID-19 vaccine shipped globally in 2021; approximately 25% of those doses shipped to low- and middle-income countries

Product sales for 2021 approximately $17.5 billion (unaudited)

Increasing APAs for 2022 delivery to approximately $18.5 billion and approximately $3.5 billion in options

Announcing a new collaboration with Carisma Therapeutics for in vivo chimeric antigen receptor monocyte (CAR-M) therapeutics for the treatment of cancer, including solid tumors

Company continues to scale with 40 programs in development, including 23 in ongoing clinical studies

CAMBRIDGE, MA / ACCESSWIRE / January 10, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced recent updates on its industry-leading mRNA pipeline. Moderna continues to scale, now with 40 programs in development including 23 in ongoing clinical studies encompassing mRNA infectious disease vaccines and mRNA therapeutics spanning seven different modalities. Moderna and collaborators have published nearly 100 peer reviewed manuscripts.

"2021 was a year of incredible impact and growth for Moderna. Because of our many years of investment in mRNA technology we were ready to develop and launch our Covid-19 vaccine which helped millions of people around the
world. We have delivered 807 million doses with approximately 25% of those doses going to low- and middle-income countries and we will continue to scale in 2022 to help end the COVID-19 pandemic. While our COVID-19 vaccine is our first medicine to market, we have made significant progress across our pipeline of 40 development programs and now have 23 mRNA programs in clinical trials,” said Stéphane Bancel, Chief Executive Officer of Moderna. "We will continue to advance mRNA vaccines that can have a profound impact on health and quality of life including vaccines against respiratory viruses with the goal of bringing to market a pan-respiratory annual customizable booster vaccine. In parallel, we are advancing first-in-class vaccines against latent viruses, which remain in the body for life and can cause lifelong medical conditions and we are also working to bring to market therapeutics based on mRNA-encoded proteins to help address multiple disease areas. We look forward to further leveraging our mRNA technology and delivery into gene-editing and other ways to impact human health."

Stéphane Bancel will present an update on the Company and its pipeline of mRNA development programs on Monday, January 10, 2022, at 8:15 a.m. ET at the 40th Annual J.P. Morgan Healthcare Conference. A live webcast of both the presentation and question and answer session will be available under "Events & Presentations" in the investors section of Moderna’s website at investors.modernatx.com. A replay of the webcast will be archived on Moderna’s website for 30 days following the presentation.

Recent pipeline progress includes:

COVID-19 Vaccine Development

- Currently authorized 50 µg booster of mRNA-1273 increased neutralizing antibody levels against Omicron approximately 37-fold compared to pre-boost levels and a 100 µg dose of mRNA-1273 increased neutralizing antibody levels approximately 83-fold compared to pre-boost levels
- Moderna is developing an Omicron-containing booster vaccine candidate (mRNA-1273.529)

Respiratory Vaccines

- Seasonal flu vaccine candidate (mRNA-1010) successfully boosted hemagglutination inhibition (HAI) assay geometric mean titers against all strains 29 days after vaccination at all doses tested in younger and older adults in Phase 1 study and no significant safety concerns were observed; Phase 2 study of mRNA-1010 is fully enrolled; preparation for the Phase 3 study is underway

Latent Virus Vaccines

- First participants dosed in Phase 3 study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647)
- First participants dosed in Phase 1 study of EBV vaccine candidate (mRNA-1189)

Therapeutics
Phase 2 study of mRNA therapeutic that encodes for vascular endothelial growth factor-A (VEGF-A) (AZD8601) met the primary endpoint of safety and tolerability.

Initial data from the ongoing Phase 1 study of OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752) in patients with accessible solid tumors and lymphoma showed that mRNA-2752 given in combination with AstraZeneca’s durvalumab (IMFINZI®) was tolerated at all dose levels tested and elicited evidence of anti-tumor activity.

Summary of Program Updates:

Core Modalities

Prophylactic Vaccines: Moderna is developing vaccines against viral diseases where there is an unmet medical need including vaccines against respiratory infections and vaccines against latent viruses.

Vaccines against respiratory infections

- COVID-19 vaccine - addressing the Omicron variant: On December 20, 2021, Moderna announced preliminary neutralizing antibody data against the Omicron variant following the Company’s booster candidates at 50 µg and 100 µg dose levels. The currently authorized 50 µg booster of mRNA-1273 increased neutralizing antibody levels against Omicron approximately 37-fold compared to pre-boost levels and a 100 µg dose of mRNA-1273 increased neutralizing antibody levels approximately 83-fold compared to pre-boost levels. Moderna’s first line of defense against Omicron is a booster dose of mRNA-1273. Given the long-term threat demonstrated by Omicron’s immune escape, Moderna will continue to develop an Omicron-specific variant vaccine (mRNA-1273.529) that it expects to advance into clinical trials in early 2022 and will evaluate including Omicron in its multivalent booster program.

- Seasonal influenza vaccine (mRNA-1010): On December 10, 2021, Moderna announced positive interim data from the Phase 1 study of mRNA-1010. mRNA-1010 successfully boosted hemagglutination inhibition (HAI) assay geometric mean titers against all strains 29 days after vaccination at all doses tested in both younger and older adults and no significant safety concerns were observed. The Phase 2 study of mRNA-1010 is fully enrolled and preparation for the Phase 3 study is underway. mRNA-1010 encodes for hemagglutinin (HA) glycoproteins of four flu strains and targets lineages recommended by the World Health Organization (WHO) for the prevention of influenza, including seasonal influenza A H1N1, H3N2 and influenza B Yamagata and Victoria.

- Seasonal Influenza vaccines with expanded and broader immunologic coverage (mRNA-1011 and mRNA-1012): On December 10, 2021, Moderna announced two development candidates which the Company believes may expand coverage against seasonal influenza strains. mRNA-1011 will have one additional
hemagglutinin (HA) antigen and mRNA-1012 will have two additional HA antigens. Moderna is also developing two next-generation flu candidates that incorporate neuraminidase antigens to potentially improve immunity by increasing immunologic breadth targeting more conserved antigens (mRNA-1020, mRNA-1030).

- **COVID-19 and flu combination vaccine (mRNA-1073):** mRNA-1073 encodes for the COVID-19 spike protein and the Flu HA glycoproteins.

- **Respiratory syncytial virus (RSV) vaccine (mRNA-1345):** The first participants have been dosed in the Phase 2/3 study of mRNA-1345, known as ConquerRSV. Moderna is choosing study locations in the U.S. and internationally based on the ongoing epidemiology of RSV. The primary purpose of the Phase 2 segment of the study is to evaluate the safety of mRNA-1345 vaccine in adults older than 60 years of age for initiation of the large-scale Phase 3 segment of the study. 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 into the study. There is no approved vaccine to prevent RSV.

**Vaccines against latent viruses**

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** The first participants have been dosed in the Phase 3 study, known as CMVictory, which is evaluating the safety and efficacy of mRNA-1647 against primary CMV infection in women ages 16-40 years. The Company will seek to enroll up to approximately 8,000 participants in the study, including 6,900 women of child-bearing age, at approximately 150 sites globally, beginning in the U.S. Moderna has set a goal of enrolling a diverse group of U.S. participants into the study, including approximately 42% of participants who are Persons of Color. Based on the interim analysis of the Phase 2 study, the 100 μg dose has been chosen for the Phase 3 pivotal study. The ClinicalTrials.gov identifier is NCT05085366. To learn more about eligibility, visit www.CMVictory.com.

- **Epstein-Barr virus (EBV) vaccine (mRNA-1189):** The first participant has been dosed in the Phase 1 study of mRNA-1189. EBV is spread through bodily fluids (e.g., saliva) and contracted primarily by young children and adolescents. It is a major cause of infectious mononucleosis (IM), and associated risks to other long-term medical conditions, including an increased risk of developing multiple sclerosis by approximately 4 to 10-fold, certain lymphoproliferative disorders and cancers, and autoimmune diseases. While EBV infection in early childhood is predominantly asymptomatic, primary infection in adolescence can lead to IM, which can debilitate patients for weeks to months, sometimes requiring hospitalization for serious complications. Similar to Moderna’s CMV vaccine (mRNA-1647), mRNA-1189 contains four mRNAs that encode EBV envelope glycoproteins (gH, gL, gp42, gp220). There is currently no approved vaccine for EBV or IM.

**Systemic Secreted & Cell Surface Therapeutics:** In this modality, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface.
• Antibody against the chikungunya virus (mRNA-1944): The Phase 1 study evaluating escalating doses of mRNA-1944 has successfully completed. The full results of the Phase 1 study were published in *Nature* on December 9, 2021.

**Exploratory Modalities**

**Intratumoral Immuno-Oncology**: These programs aim to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors.

• OX40L/IL-23/IL-36y (Triplet) (mRNA-2752): The Phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with advanced solid tumor malignancies and lymphoma is fully enrolled. Enrollment in additional cohorts is ongoing. **Interim data** from the ongoing Phase 1 study of mRNA-2752 in patients with accessible solid tumors and lymphoma showed that mRNA-2752 given in combination with AstraZeneca's durvalumab (IMFINZI®) was tolerated at all dose levels tested and elicited evidence of anti-tumor activity. The recommended dose for expansion (RDE) is up to 8 mg mRNA-2752 + durvalumab.

**Localized Regenerative Therapeutics**: Localized production of proteins has the potential to be used as a regenerative medicine for damaged tissues.

• VEGF-A (AZD8601): On November 15, 2021, Moderna announced positive data from the AstraZeneca-led Phase 2 (EPICCURE) study evaluating the use of an mRNA therapeutic that encodes for vascular endothelial growth factor-A (VEGF-A), AZD8601, in patients undergoing coronary artery bypass grafting (CABG). The Phase 2 study met the primary endpoint of safety and tolerability of AZD8601. In the study of 11 patients, seven were treated with AZD8601 VEGF-A mRNA and four received placebo injections. Numerical trends were observed in endpoints in the heart failure efficacy domains compared with placebo, including increase in left ventricular ejection fraction (LVEF) and patient reported outcomes. In addition, all seven patients treated with AZD8601 had NT-proBNP levels below heart failure (HF) limit at 6 months follow-up compared to one of four patients treated with placebo. Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.

Information about each development candidate in Moderna’s pipeline can be found at [investors.modernatx.com](http://investors.modernatx.com).

**Corporate Social Responsibility**

• **Global Access**: Approximately 807 million doses of the Moderna COVID-19 vaccine were shipped around the world during 2021.[1] Moderna outlined its **strategy** for improving global access on October 8, 2021. Consistent with that strategy, approximately 25% of all doses delivered in 2021 went to low- and middle-income countries through direct sales by Moderna and donations from high-income countries. The more than
200 million doses delivered to low- and middle-income countries in 2021 are more than Moderna delivered to any other country or multinational group last year, other than the United States.

- In 2021, Moderna facilitated the donation of approximately 138 million doses to low- and middle-income countries from other nations and delivered more than 34 million doses to Gavi on behalf of the COVAX facility. Gavi has exercised its option to purchase 254 million doses for delivery in the first half of 2022. Under the agreement, total potential deliveries to Gavi may reach 650 million doses by the end of 2022.
- In 2021, the African Union agreed to purchase 50 million doses of the Moderna COVID-19 vaccine for delivery in the first quarter of 2022. The African Union notified Moderna on January 6, 2022 that it has declined its option to purchase a further 60 million doses for delivery in the second quarter of 2022 given its assessment that it has acquired enough doses to ensure that 70% of the African population can be fully vaccinated.

- mRNA Facility in Africa: Moderna announced that it will build a state-of-the-art mRNA facility in Africa, in part to ensure future access to mRNA vaccines in future pandemics, and is in the final stages of country selection with assistance from the United States government.
- Sustainability: Moderna announced a pledge to achieve net-zero carbon emissions globally by 2030.
- Moderna Science Center: Moderna announced that it is investing in a new science center, known as the Moderna Science Center in Cambridge, MA. This 462,000 square foot state-of-the-art building is targeting LEED Zero certification and is being designed to be the most sustainable commercial lab building in Cambridge.
- AI Academy: Moderna announced the launch of its Artificial Intelligence (AI) Academy in partnership with Carnegie Mellon University. The AI Academy is intended to educate and empower Moderna employees to integrate AI and machine learning solutions into their efforts to advance mRNA medicines.
- Moderna Charitable Foundation: Moderna announced it is establishing a new charitable foundation to promote public health, healthcare and educational opportunities, particularly in underserved populations.
- Moderna Fellowship Program: Moderna announced the launch of the Moderna Fellowship Program to support the next generation of scientists and healthcare professionals as they innovate in the field of mRNA research towards improving patient care and population health.

Financial Updates

- Product Sales: Product sales for 2021 were approximately $17.5 billion (unaudited).
- Capital Allocation Priorities: Moderna's capital allocation priorities include reinvesting in the business and accelerating investment in R&D, manufacturing infrastructure and company buildout, and considering attractive external investment opportunities (licenses and/or M&A) to further expand the reach of Moderna's technology.
- Moderna announced a new strategic collaboration agreement with Carisma Therapeutics, Inc. to discover, develop and commercialize in vivo engineered chimeric antigen receptor monocyte (CAR-M) therapeutics for the treatment of cancer, including solid tumors.

- 2022 Advanced Purchase Agreements (APAs): Moderna has signed 2022 APAs for product sales of approximately $18.5 billion (up from $17 billion announced in November 2021) and approximately $3.5 billion in options including for any potential updated COVID-19 vaccine booster candidates. The Company is currently in active discussions for additional 2022 COVID-19 vaccine contracts.

Corporate Updates

- Continued Growth: Moderna ended 2021 with approximately 2,700 full time employees, an increase from approximately 1,300 full time employees at the end of 2020.
- Company Recognition: Moderna was named a top employer by Science and Science Careers for the seventh consecutive year and was named the number one company on Fast Company’s 2021 Best Workplaces for Innovators list.
- Global Expansion: Moderna is committed to expanding its partnerships with governments to equip countries with access to innovative vaccines against respiratory viruses, and domestic access to rapid pandemic response capabilities. To date, Moderna has announced in principle agreements with Australia and Canada.

Key 2022 Investor and Analyst Event Dates

- Vaccines Day: March 24
- Science Day: May 17
- R&D Day: September 8

About Moderna

In 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 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 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 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 efforts to continue developing vaccines against COVID-19, including efforts to develop vaccines against variant strains of SARS-CoV-2 and for updated booster doses; the ability of the Moderna COVID-19 Vaccine to provide protection against COVID-19 over time and to trigger an antibody response against variants of concern; the potential for booster doses of the Moderna COVID-19 Vaccine and variant-specific vaccine candidates to trigger neutralizing antibodies; the conduct and timing of clinical trials for programs in the Company's pipeline, including its vaccine candidates against seasonal flu, CMV, VEGF-A, OX40L/IL-23/IL-36γ (Triplet) and EBV; expected timing for commencement of clinical trials for the Company's Omicron-specific variant vaccine candidate; the Company's development of next-generation flu vaccine candidates; the construction of manufacturing facilities in Canada, Africa and Australia, and the Company's discussions with other countries regarding in-country mRNA vaccine manufacturing capabilities; the Company's efforts to achieve net-zero carbon emissions; investment in the Company's new Moderna Science Center; the Company's capital allocation priorities, including its intention to reinvest in the business, accelerate investment, and seek external investment opportunities; expected product sales for 2021; anticipated dollar amounts to be received in connection with doses to be delivered under advance purchase agreements and options in 2022, which should not be construed as expected 2022 revenue; and the likelihood that options for purchases of the Company's COVID-19 vaccine will be exercised. 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 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.

Moderna Contacts
[1] Consisting of 50 µg and 100 µg doses, equivalent to approximately 790 million doses at the 100 µg dose level

SOURCE: Moderna, Inc.