



NEWS RELEASE

Moderna Announces First Participant Dosed in Phase 2 Study of Omicron-Specific Booster Candidate and Publication of Data on Booster Durability Against Omicron Variant

1/26/2022

Phase 2 study of Omicron-specific booster candidate (mRNA-1273.529) will include two cohorts: one including participants who received the two-dose primary series of mRNA-1273 and another including participants who received the two-dose primary series and a 50 µg booster dose of mRNA-1273

Omicron neutralization six months after the third 50 µg dose of mRNA-1273 declined, but remained detectable in all participants

CAMBRIDGE, MA / ACCESSWIRE / January 26, 2021 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the first participant has been dosed in the Phase 2 study of the Company's Omicron-specific booster candidate (mRNA-1273.529). Additionally, Moderna announced the publication of neutralizing antibody data against the Omicron variant six months following a booster dose in **The New England Journal of Medicine**. While Omicron neutralization had declined 6.3-fold from peak titers at day 29 post-boost, levels remained detectable in all participants. Neutralizing titers against Omicron declined more rapidly than titers against the ancestral strain of the virus (D614G) which declined 2.3-fold over the same time period.

"We are reassured by the antibody persistence against Omicron at six months after the currently authorized 50 µg booster of mRNA-1273. Nonetheless, given the long-term threat demonstrated by Omicron's immune escape, we



are advancing our Omicron-specific variant vaccine booster candidate and we are pleased to begin this part of our Phase 2 study," said Stéphane Bancel, Chief Executive Officer of Moderna. "We are also evaluating whether to include this Omicron-specific candidate in our multivalent booster program. We will continue to share data with public health authorities to help them make evidence-based decisions on the best booster strategies against SARS-CoV-2."

Phase 2 Study of mRNA-1273.529

This extension of an earlier study will evaluate the immunogenicity, safety, and reactogenicity of mRNA-1273.529 as a single booster dose in adults aged 18 years and older in two cohorts: individuals who previously received the two-dose primary series of mRNA-1273 with the second dose being at least six months ago (cohort 1), or who have received the two-dose primary series and a 50 µg booster dose of mRNA-1273 with the booster dose being at least three months ago (cohort 2). Participants in both cohorts will receive a single booster dose of mRNA-1273.529.

Moderna expects to enroll approximately 300 participants into each cohort of this study, which will be conducted at up to 24 sites in the U.S. Additionally, Moderna is evaluating the inclusion of mRNA-1273.529 in its multivalent booster program.

Data on Booster Durability Against Omicron Variant

Moderna previously 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.

Today's data includes sera from 20 booster recipients each of mRNA-1273 at the 50 µg and 100 µg dose levels, multivalent candidate mRNA-1273.211 at the 50 µg and 100 µg dose levels, and multivalent candidate mRNA-1273.213 at the 100 µg dose level. Neutralizing antibodies against Omicron were assessed in a pseudovirus neutralization titer (ID50) assay (PsVNA) conducted at laboratories established by the National Institute of Allergy and Infectious Diseases' (NIAID) Vaccine Research Center and Duke University Medical Center.

At seven months post-second dose and before the third booster dose, Omicron neutralization was detected in only 55% of participants. A booster dose of mRNA-1273 at the 50 µg dose level increased Omicron GMTs to 20-fold higher than peak Omicron titers post-dose two. At six months after the third booster dose, Omicron neutralization had declined 6.3-fold from peak titers at day 29 post-boost but remained detectable in all participants. Neutralizing titers against Omicron declined faster after the booster than for the wild-type virus (D614G) which declined 2.3-fold

over the same time period.

A 100 µg booster dose of mRNA-1273, mRNA-1273.211 or mRNA-1273.213 resulted in similar Omicron GMTs, with all three boosters leading to neutralizing titers 2.5-2.6-fold higher than neutralizing titers after the 50 µg booster dose of mRNA-1273.

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 development of a vaccine against the SARS-CoV-2 virus (mRNA-1273); the Company's efforts to develop vaccines against variants of the SARS-CoV-2 virus, including the Omicron variant (mRNA-1273.529) and multivalent candidates (mRNA-1273.211 and mRNA-1273.213); the timing for developing and testing in clinical trials of an Omicron variant-specific vaccine candidate (mRNA-1273.529); and the ability of the Company's existing vaccine candidates (including 50 µg and 100 µg boosters of mRNA-1273) to trigger neutralizing antibodies against the Omicron variant. 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.

Moderna Contacts

Media:

Colleen Hussey

Director, Corporate Communications

617-335-1374

Colleen.Hussey@modernatx.com

Investors:

Lavina Talukdar

Senior Vice President & Head of Investor Relations

617-209-5834

Lavina.Talukdar@modernatx.com

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