Modern announces Omicron-Containing Bivalent Booster Candidate mRNA-1273.214 Demonstrates Superior Antibody Response Against Omicron

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Data Show Significantly Higher Geometric Mean Titer Ratios, Meeting Prespecified Endpoints for Superiority Against Omicron Variant

mRNA-1273.214 Exhibited an 8-Fold Boost in Neutralizing Geometric Mean Titers Against Omicron Among Baseline Seronegative Participants

Safety and Tolerability Profile for mRNA-1273.214 is Consistent with Prior Booster Dose of mRNA-1273

Regulatory Submission Planned for Coming Weeks to Enable Use of mRNA-1273.214 For Fall Booster

Conference Call to be Held Today At 8:00 AM ET

CAMBRIDGE, MA / ACCESSWIRE / June 8, 2022 / Moderna, Inc., (NASDAQ:MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced new clinical data on its Omicron-containing bivalent COVID booster candidate, mRNA-1273.214, containing mRNA-1273 (Spikevax) and a vaccine candidate targeting the Omicron variant of concern. A 50 µg booster dose of mRNA-1273.214 met all pre-specified endpoints including superior neutralizing antibody response (geometric mean ratio) against the Omicron variant one month after administration when compared to the original mRNA-1273 vaccine. The booster dose of mRNA-1273.214 was generally well-tolerated, with side effects comparable to a booster dose of mRNA-1273 at the 50 µg dose level.
"We are thrilled to share the preliminary data analysis on mRNA-1273.214, which is the second demonstration of superiority of our bivalent booster platform against variants of concern and represents an innovation in the fight against COVID," said Stéphane Bancel, Chief Executive Officer of Moderna. "Looking at these data alongside the durability we saw with our first bivalent booster candidate, mRNA-1273.211, we anticipate more durable protection against variants of concern with mRNA-1273.214, making it our lead candidate for a Fall 2022 booster. We are submitting our preliminary data and analysis to regulators with the hope that the Omicron-containing bivalent booster will be available in the late summer. Taken together, our bivalent booster candidates demonstrate the power of Moderna's mRNA platform to develop vaccines that meet immediate, global public health threats."

mRNA-1273.214 met all primary endpoints in the Phase 2/3 trial including neutralizing antibody response against Omicron when compared to a 50 µg booster dose of mRNA-1273 in baseline seronegative participants. Pre-specified criteria for superiority as measured by neutralizing geometric mean titer ratio (GMR) with the lower bound of the confidence interval >1 was met. The GMR and corresponding 97.5% confidence interval was 1.75 (1.49, 2.04). A booster dose of mRNA-1273.214 increased neutralizing geometric mean titers (GMT) against Omicron approximately 8-fold above baseline levels. Primary endpoints of non-inferiority against ancestral SARS-CoV-2 were also met, with GMR against ancestral SAR-COV-2 (D614G) of 1.22 (1.08-1.37).

Among seronegative participants one month after administration, the neutralizing GMT against ancestral SARS-CoV-2 for mRNA-1273.214 was 5977 (CI: 5322, 6713), compared to GMT for mRNA-1273 of 5649 (CI: 5057, 6311). The GMT against Omicron for mRNA-1273.214 was 2372 (CI: 2071, 2718), compared to GMT for mRNA-1273 of 1473 (CI: 1271, 1708).

Binding antibody titers (MSD) were also significantly higher (nominal alpha of 0.05) against all other variants of concern (Alpha, Beta, Gamma, Delta, Omicron) for mRNA-1273.214 when compared to mRNA-1273.

The mRNA-1273.214 50 µg booster dose was well-tolerated in the 437 study participants. The safety and reactogenicity profile of the mRNA-1273.214 50 µg booster dose was similar to that of mRNA-1273 50 µg dose when these vaccines were administered as a second booster dose.

In February 2021, Moderna announced its strategy to update booster candidates to address the ongoing evolution of the SARS-CoV-2 virus, including monovalent and bivalent candidates targeting multiple variants of concern. The Company's primary focus has been on the bivalent booster approach, which are boosters that address two viral strains simultaneously.

Results from the Company's Beta-containing bivalent booster candidate, mRNA-1273.211, announced in April 2022, demonstrated superiority against Beta, Delta and Omicron variants of concern one month after administration,
with continued superiority that was durable against Beta and Omicron variants of concern six months after administration. Given the significantly higher antibody titers induced by mRNA-1273.214 compared to mRNA-1273, Moderna anticipates that antibody titers induced by mRNA-1273.214 will be more durable over time against Omicron as compared to mRNA-1273. Moderna will report data from Day 91 after vaccination later in the summer.

Moderna is planning to submit the interim analysis and data to regulators for review in the coming weeks.

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET today, Wednesday, June 8, 2022. To access the live conference call, please dial (866) 922-5184 (domestic) or (409) 937-8950 (international) and refer to conference ID 8138198. A webcast of the call will also be available under "Events and Presentations" in the Investors section of the Moderna website.

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. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators. 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 bivalent vaccine candidate against COVID-19 (mRNA-1273.214); the ability of mRNA-1273.214 to induce higher neutralizing antibody titers against the Omicron variant of concern than the Company’s vaccine candidate against the ancestral strain of SARS-CoV-2 (mRNA-1273) over time and to trigger a strong immune response; the tolerability and safety profile for mRNA-1273.214; the anticipated submission of data for mRNA-1273.214 to regulators for review; and plans to
disclose follow up data on mRNA-1273.214 in the summer. 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.

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