NEWS RELEASE

Moderna's Omicron-Containing Bivalent Booster Candidate, mRNA-1273.214, Demonstrates Significantly Higher Neutralizing Antibody Response Against Omicron Subvariants BA.4/5 Compared To Currently Authorized Booster

7/11/2022

mRNA-1273.214 has now demonstrated significantly higher antibody titers against all tested variants, including Omicron BA.1 and BA.4/5 subvariants, ancestral virus, Alpha, Beta, Delta, and Gamma

Moderna has completed regulatory submissions for mRNA-1273.214 in EU, UK, and Australia, expects to complete most remaining filings this week

Company simultaneously developing mRNA-1273.222, a bivalent candidate based on BA.4/5, consistent with recent FDA guidance

CAMBRIDGE, MA / ACCESSWIRE / July 11, 2022 / Moderna, Inc., (NASDAQ:MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced new clinical data on its bivalent Omicron (BA.1) booster candidate, mRNA-1273.214. One month after administration in previously vaccinated and boosted participants, a 50 µg booster dose of mRNA-1273.214 elicited significantly higher neutralizing antibody responses against the Omicron subvariants BA.4 and BA.5 compared to the currently authorized booster (mRNA-1273) regardless of prior infection status or age (adults over 18, greater or less than 65 years old).

Among participants without prior infection, bivalent mRNA-1273.214 resulted in significantly higher neutralizing

titers against BA.4/5 compared to the currently authorized booster, with a geometric mean ratio of 1.69 (95% CI: 1.51-1.90)1. One month after booster, BA.4/5 neutralizing titers were 776 (95% CI: 719, 838) for mRNA-1273.214 and 458 (95% CI: 421, 499) for the currently authorized booster. The BA.4/5 geometric mean fold rise (GMFR) from pre-booster levels was 6.3-fold (95% CI: 5.7, 6.9) for mRNA-1273.214 recipients, and 3.5-fold (95% CI: 3.2, 3.9) for mRNA-1273 recipients. Consistent results were demonstrated across subgroups, including in those age 65 and older. The complete data has been submitted for peer reviewed publication and shared with regulators.

"We are very pleased that our bivalent platform continues to demonstrate better performance than the current booster. Today's update extends the remarkable performance of mRNA-1273.214, demonstrating significantly higher titers against all tested variants, including the BA.4/5 and BA.1 Omicron subvariants, and adds to the largest body of data confirming the superiority of a bivalent approach. This superior breadth and durability of immune response following a bivalent booster has now been shown in multiple Phase 2/3 studies involving thousands of participants," said Stephane Bancel, Chief Executive Officer of Moderna. "We are working with regulators to advance two bivalent vaccine candidates, mRNA-1273.214 and mRNA-1273.222, based on different market preferences for Omicron subvariants, clinical data requirements, and urgency of starting fall booster campaigns for vulnerable populations."

Today's data add to results shared last month from the Company's ongoing Phase 2/3 study in approximately 800 participants. Previous results showed a 50 µg booster dose of mRNA-1273.214 met all pre-specified primary endpoints and was generally well tolerated, with a reactogenicity and safety profile that was consistent with the currently authorized booster.

Moderna is advancing two bivalent candidates for the fall based on different market preferences for Omicron subvariants. The mRNA-1273.214 bivalent booster is the only candidate expected to have demonstrated significantly higher titers against the BA.4/5 strain in a clinical trial before the fall booster season, when compared to the currently authorized booster. The second bivalent booster candidate, mRNA 1273.222, is based on the BA.4/5 strain and is being developed consistent with recent FDA advice. Both bivalent candidates contain 25 µg of the currently authorized booster (mRNA-1273) and 25 µg of an Omicron subvariant.

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**.

1Based on ANCOVA model

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 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 bivalent vaccine candidates against COVID-19 (mRNA-1273.214 and mRNA-1273.222); the ability of mRNA-1273.214 to induce higher neutralizing antibody titers against Omicron subvariants BA.4 and BA.5 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, regardless of prior infection and across age groups; the tolerability and safety profile for mRNA-1273.214; the Company's bivalent booster strategy and its ability to offer strong protection against anticipated virus surges in the fall; and the submission of data for mRNA-1273.214 to regulators for review and the timing of such submissions and review. 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 of this press release.

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