



NEWS RELEASE

Moderna Announces Clinical Update on Bivalent COVID-19 Booster Platform

4/19/2022

Moderna's first bivalent booster vaccine candidate, mRNA-1273.211, demonstrated superior neutralizing titers compared to mRNA-1273 against all variants of concern, including Omicron; superiority was maintained for six months after booster for the Beta and Omicron variants

Tolerability and safety of the bivalent booster were consistent with authorized 50 µg mRNA-1273 booster

Moderna is evaluating an updated bivalent booster incorporating more Omicron-specific mutations (mRNA-1273.214) in a Phase 2/3 clinical study; initial data on this candidate, expected in the second quarter, will inform selection of fall 2022 booster for Northern Hemisphere

CAMBRIDGE, MA / ACCESSWIRE / April 19, 2022 / Moderna, Inc., (NASDAQ:MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines today announced new clinical data on its bivalent COVID-19 booster platform including data on the Company's first bivalent booster candidate, mRNA-1273.211, which includes mutations found in the Beta variant of concern, several of which have been persistent in more recent variants of concern including Omicron. A 50 µg booster dose of mRNA-1273.211 demonstrated superiority against Beta, Delta and Omicron variants of concern one month after administration. Superiority continued six months after administration for Beta and Omicron variants of concern as well. A 50 µg booster dose of mRNA-1273.211 was generally well tolerated with a reactogenicity profile comparable to a booster dose of mRNA-1273 at the 50 µg dose level. The manuscript is available as a preprint through **Research Square**.

"We are pleased with these data for our first bivalent booster candidate, mRNA-1273.211. We believe that these



results validate our bivalent strategy, which we announced and began pursuing in February 2021. The results indicate that mRNA-1273.211 at the 50 µg dose level induced higher antibody responses than the 50 µg mRNA-1273 booster, even when additional variants of concern were not included in the booster vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna. "Our latest bivalent booster candidate, mRNA-1273.214, which combines the currently authorized Moderna COVID-19 booster with our Omicron-specific booster candidate, remains our lead candidate for the fall 2022 Northern Hemisphere booster. We look forward to sharing initial data on mRNA-1273.214 later in the second quarter. We believe that a bivalent booster vaccine, if authorized, would create a new tool as we continue to respond to emerging variants."

Moderna is developing updated booster candidates to address the continued 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 to maintain high neutralizing antibody titers while improving breadth of immunity to variants. Moderna has multiple bivalent booster candidates that have been evaluated to date, which include mRNA-1273.211 (9 spike protein mutations, based on the Beta variant), and mRNA-1273.214 (32 spike protein mutations, based on the Omicron variant). mRNA-1273.211 includes four mutations and mRNA-1273.214 includes 32 mutations present in the Omicron variant of concern.

A 50 µg booster dose of mRNA-1273.211 met Moderna's objectives for its modified, bivalent booster candidates, including superiority immunogenicity criteria against variants of concern when compared to its currently approved mRNA-1273 booster dose (50 µg). A booster dose of mRNA-1273.211 demonstrated superiority against the ancestral SARS-CoV-2 and the Beta, Delta and Omicron variants one month after the booster dose and superiority against the ancestral SARS-CoV-2, Beta and Omicron 6 months compared to the booster dose of mRNA-1273. There was a 2.20-fold (95% CI: 1.74, 2.79) and 2.15-fold (95% CI: 1.66, 2.78) increase in the neutralizing antibody titers against Omicron with the mRNA-1273.211 booster dose compared to the mRNA-1273 booster dose at 1 month and 6 months, respectively.

The mRNA-1273.211 booster candidate was generally well tolerated in 300 study participants who received the 50 µg dose and 595 participants who received the 100 µg dose of mRNA-1273.211 (895 participants in total). The 50 µg booster dose of mRNA-1273.211 had a similar incidence of solicited adverse reactions and unsolicited adverse events with the authorized mRNA-1273 booster (50 µg).

The results indicate that the bivalent booster vaccine candidate mRNA-1273.211 at the 50 µg dose level induced higher antibody responses than the 50 µg mRNA-1273 booster, even when the variants were not included in the booster vaccine which, if authorized, would create a new tool as Moderna responds to emerging variants.

Moderna's bivalent prototype and Omicron booster vaccine candidate (mRNA-1273.214) is currently being evaluated in a Phase 2/3 study. The Company expects initial data on mRNA-1273.214 in the second quarter of this

year to inform selection of its candidate for the Northern Hemisphere fall 2022 booster.

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-1273.211); the ability of mRNA-1273.211 to induce higher neutralizing antibody titers against variants of concern than the Company's vaccine candidate against the ancestral strain of SARS-CoV-2 (mRNA-1273); the tolerability and safety profile for mRNA-1273.211; the implications for the results of mRNA-1273.211 for the development of other bivalent vaccine candidates, including mRNA-1273.214; and the anticipated timing for results of mRNA-1273.214. 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

Senior 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

SOURCE: Moderna, Inc.

View source version on [accesswire.com](https://www.accesswire.com):

<https://www.accesswire.com/697884/Moderna-Announces-Clinical-Update-on-Bivalent-COVID-19-Booster-Platform>