

Moderna Announces Strategy to Address Omicron (B.1.1.529) SARS-CoV-2 Variant

Company testing three existing COVID-19 vaccine booster candidates against the Omicron variant

Company announcing a new variant-specific vaccine candidate against Omicron (mRNA-1273.529)

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 26, 2021-- [Moderna, Inc.](#), (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced updates to its strategy to address SARS-CoV-2 variants of concern, given the emergence of the B.1.1.529 (Omicron) variant.

The recently described Omicron variant includes mutations seen in the Delta variant that are believed to increase transmissibility and mutations seen in the Beta and Delta variants that are believed to promote immune escape. The combination of mutations represents a significant potential risk to accelerate the waning of natural and vaccine-induced immunity. A booster dose of an authorized vaccine represents the only currently available strategy for boosting waning immunity. The Moderna COVID-19 vaccine (mRNA-1273) is authorized as a booster for many populations at the 50 µg dose level. The Company is working rapidly to test the ability of the current vaccine dose to neutralize the Omicron variant and data is expected in the coming weeks.

Since early 2021, Moderna has advanced a comprehensive strategy to anticipate new variants of concern. This strategy includes three levels of response should the currently authorized 50 µg booster dose of mRNA-1273 prove insufficient to boost waning immunity against the Omicron variant.

First, Moderna has already tested a higher dose booster of mRNA-1273 (100 µg) in healthy adults.

Moderna has completed dosing of 306 participants in a safety and immunogenicity study of this high dose (100 µg) booster. The 100 µg dose of mRNA-1273 has also recently been [studied](#) by the National Institutes of Health (NIH) in the U.S. and has generally resulted in the highest neutralizing titers against prior SARS-CoV-2 strains. Moderna is working to rapidly test sera from its high dose booster recipients in neutralizing assays to determine if the 100 µg dose provides superior neutralizing protection against Omicron.

Second, Moderna is already studying two multi-valent booster candidates in the clinic that were designed to anticipate mutations such as those that have emerged in the Omicron variant. The first candidate (mRNA-1273.211) includes several mutations present in the Omicron variant that were also present in the Beta variant of concern¹. The Company has completed dosing in a potentially pivotal safety and immunogenicity study of mRNA-1273.211 at the 50 µg (N=300) and 100 µg (N=584) dose levels. A second multi-valent candidate (mRNA-1273.213) includes many of the mutations present in the Omicron variant that were also present in the Beta and Delta variants². The Company has completed dosing at the 100 µg (N=584) dose level and also plans to explore the 50 µg dose level in approximately 584 participants. Moderna will rapidly expand testing of sera from completed and ongoing multi-valent booster studies to determine if these multi-valent candidates are able to provide superior neutralizing protection against Omicron.

¹ Identical or similar S mutations (n=4): K417N, E484K/A, N501Y, D614G

² Identical or similar S mutations (n=8): T95I, G142D, K417N, T478K, E484K/A, N501Y, D614G, P681R/H

Third, Moderna will rapidly advance an Omicron-specific booster candidate (mRNA-1273.529). This candidate is part of the Company's strategy to advance variant-specific candidates for a subset of variants of significant concern. During 2021 this has already included Beta- and Delta-specific boosters. The Company has repeatedly demonstrated the ability to advance new candidates to clinical testing in 60-90 days.

"From the beginning, we have said that as we seek to defeat the pandemic, it is imperative that we are proactive as the virus evolves. The mutations in the Omicron variant are concerning and for several days, we have been moving as fast as possible to execute our strategy to address this variant," said Stéphane Bancel, Chief Executive Officer of Moderna. "We have three lines of defense that we are advancing in parallel: we have already evaluated a higher dose booster of mRNA-1273 (100 µg), second, we are already studying two multi-valent booster candidates in the clinic that were designed to anticipate mutations such as those that have emerged in the Omicron variant and data is expected in the coming weeks, and third, we are rapidly advancing a Omicron-specific booster candidate (mRNA-1273.529)."

About Moderna

In 10 years since its inception, Moderna has transformed from a science 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 six 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); the potential timing for developing a variant-specific vaccine candidate; the testing of the Company's existing vaccine candidates (including 100 µg boosters) against the Omicron variant and the timing for assessment of effectiveness of those variant-specific strains; and the mutations in the Omicron variant and their similarity to mutations in other variants and their potential impact on waning immunity. 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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