Moderna And the European Commission (EC) Amend Covid-19 Vaccine Agreement to Supply Omicron-Containing Bivalent Candidates; EC Purchases Additional 15 million Doses

8/9/2022

Contractually remaining doses of Moderna’s COVID-19 vaccine (Spikevax, mRNA-1273) will be converted to Moderna’s next generation Omicron-containing bivalent vaccines.

CAMBRIDGE, MA / ACCESSWIRE / August 9, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced an amendment to its agreement with the European Commission (EC) to convert contractually agreed doses of Moderna’s COVID-19 vaccine (Spikevax, mRNA-1273) to the Company’s Omicron-containing bivalent vaccines for supply in 2022, pending regulatory approval. In addition, the EC has agreed to purchase an additional 15 million doses of Omicron-containing vaccine booster candidates from Moderna.

"The European Commission and Moderna have been steadfast partners in the fight against the COVID-19 pandemic. This agreement highlights the EC's trust in our mRNA platform and next-generation bivalent COVID-19 vaccines," said Stéphane Bancel, Moderna's Chief Executive Officer. "Participating member states will now have access to Omicron-containing vaccine booster candidates, and protection against COVID-19, heading into the winter season."

Under the amendment, contractually scheduled doses in July and August of Moderna’s COVID-19 vaccine (Spikevax, mRNA-1273) will be deferred to later in 2022, with all remaining contractually agreed doses of mRNA-1273...
converted to Omicron-containing bivalent vaccines, pending approval by the European Medicines Agency (EMA).

Moderna is advancing two bivalent candidates for utilization in global vaccination efforts. The mRNA-1273.214 bivalent booster candidate is based on the Omicron subvariant BA.1 and has demonstrated positive clinical data against variants of concern, including Omicron. The second bivalent booster candidate, mRNA 1273.222, is based on the BA.4/5 strain. Both bivalent candidates contain 25 µg of the currently authorized booster (mRNA-1273) and 25 µg of an Omicron-specific subvariant.

Authorized Use

Spikevax (elasomeran mRNA vaccine) has been granted Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency, and is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals six years of age and older. A booster dose may be given at least three months after the second dose for people aged 12 years and older.

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 seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both ground-breaking science and rapid scaling of manufacturing. 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 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 agreement with the European Commission to convert contractually remaining doses of Moderna's COVID-19 vaccine (Spikevax, mRNA-1273) to the Company's
Omicron-containing bivalent vaccines and to purchase an additional 15 million doses of vaccine; the timing for delivery of vaccine doses under agreements with the European Commission; and the potential availability of a bivalent booster vaccine candidates in 2022, pending approval from the European Medicines Agency. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022, each 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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