



NEWS RELEASE

Medicines and Healthcare Products Regulatory Agency (MHRA) Authorizes Moderna's Omicron-Containing Bivalent Booster in the UK

8/15/2022

Study results show mRNA-1273.214 has demonstrated significantly higher antibody titers against Omicron BA.1 and BA.4/5 subvariants when compared with mRNA-1273

CAMBRIDGE, MA / ACCESSWIRE / August 15, 2022 / [Moderna, Inc](#) . (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK has granted conditional authorization for the use of the Omicron-containing bivalent COVID-19 booster vaccine, mRNA-1273.214 (Spikevax Bivalent Original/Omicron▼) as a booster dose for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. Spikevax Bivalent Original/Omicron is a next-generation bivalent vaccine that contains mRNA-1273 (Spikevax) and a vaccine candidate targeting the Omicron variant of concern (BA.1).

"We are delighted with the MHRA's authorization of Spikevax Bivalent Original/Omicron, our next-generation COVID-19 vaccine. This represents the first authorization of an Omicron-containing bivalent vaccine, further highlighting the dedication and leadership of the UK public health authorities in helping to end the COVID-19 pandemic," said Stéphane Bancel, Chief Executive Officer of Moderna. "mRNA-1273.214 has consistently shown superior breadth of immune response over mRNA-1273 in clinical trials. This bivalent vaccine has an important role to play in protecting people in the UK from COVID-19 as we enter the winter months."

The decision from the MHRA is based on clinical trial data from a [phase 2/3 trial](#), in which mRNA-1273.214 met all



primary endpoints, including superior neutralizing antibody response against Omicron (BA.1) when compared to a 50 µg booster dose of mRNA-1273 in baseline seronegative participants. A booster dose of mRNA-1273.214 increased neutralizing geometric mean titers (GMT) against Omicron approximately 8-fold above baseline levels. In addition, mRNA-1273.214 elicited potent 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.

Moderna is working with The Vaccine Taskforce, UK Health Security Agency, and NHS to make Spikevax Bivalent Original/Omicron available to the UK public. Moderna has completed regulatory submissions for mRNA-1273.214 in Australia, Canada, and the EU and expects further authorization decisions in the coming weeks.

Authorized use

Spikevax bivalent Original/Omicron is indicated as a booster dose for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

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 development of the Company's COVID-19 Vaccine (mRNA-1273.214, or Spikevax Bivalent Original/Omicron); the authorization of mRNA-1273.214 in adults ages 18 years and older by the Medicines and Healthcare products Regulatory Agency; 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); the safety, efficacy, and tolerability of mRNA-1273.214 in adults ages 18 and above; and the ability of mRNA-1273.214 to protect against COVID-19. 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 hereof.

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