



NEWS RELEASE

Ministry Of Health, Labour and Welfare in Japan Approves Partial Change to a New Drug Authorization for Moderna's Omicron-Targeting Bivalent Booster COVID-19 Vaccine, mRNA-1273.214

9/12/2022

CAMBRIDGE, MA / ACCESSWIRE / September 12, 2022 / **Moderna, Inc.** (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has received approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for a partial change to a new drug application for its Omicron-targeting bivalent COVID-19 booster, mRNA-1273.214 (Spikevax Bivalent Original/Omicron BA.1). Spikevax Bivalent Original/Omicron contains mRNA-1273 (Spikevax) and a vaccine candidate targeting the Omicron variant BA.1.

"COVID-19 continues to threaten public health in Japan, as infections by Omicron and its subvariants continue. mRNA-1273.214 has demonstrated the ability to trigger significantly higher antibody titers against Omicron BA.1 and BA.4/5 subvariants when compared with mRNA-1273," said Rami Suzuki, President & Representative Director of Moderna Japan. "We will continue to work with the Ministry of Health, Labour and Welfare to bring this important vaccine to people in Japan as soon as possible to help protect against COVID-19."

The approval from the MHLW 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 the currently authorized 50 µg booster dose of Spikevax (mRNA-1273) in previously uninfected participants. A booster dose of Spikevax Bivalent Original/Omicron (mRNA-1273.214) increased neutralizing geometric mean titers (GMT) against Omicron approximately 8-fold above baseline levels. In addition, Spikevax Bivalent Original/Omicron

(mRNA-1273.214) elicited higher neutralizing antibody titers against the Omicron subvariants BA.4 and BA.5 when compared to Spikevax (mRNA-1273) regardless of prior infection status or age, including in those aged 65 and older. mRNA-1273.214 was generally well tolerated, with a reactogenicity and safety profile consistent with the currently authorized booster.

Moderna has received authorization decisions for Omicron-targeting bivalent boosters in the United States, Australia, Canada, Europe, Switzerland, South Korea, Taiwan, and the UK to date and has completed regulatory submissions worldwide. In Japan, Takeda Pharmaceutical Co. Ltd. continues to provide distribution support for Spikevax Bivalent Original/Omicron under the current national vaccination campaign for Moderna's COVID-19 vaccines for a transitional period. Supply is expected to commence during September.

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. One 0.5 mL dose is provided intramuscularly.

About Moderna

In over 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 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 Ministry of Health Labor and Welfare; the ability of mRNA-1273.214 to induce higher neutralizing antibody titers against Omicron subvariants BA.1 and BA.4/5 than mRNA-1273; the safety, efficacy, and tolerability of mRNA-1273.214; the ability of mRNA-1273.214 to protect against COVID-19; the Company's aim to supply Spikevax Bivalent Original/Omicron in Japan during September; and regulatory submissions for mRNA-1273.214 that the Company has submitted worldwide. 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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