



Better Health, Brighter Future

News Release

Takeda and Moderna Announce Plans to Transfer Marketing Authorization for Spikevax™ COVID-19 Vaccine in Japan to Moderna

OSAKA, Japan, May 31, 2022 – Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) (“Takeda”) and Moderna, Inc. ([Nasdaq:MRNA](#)) (“Moderna”) today announced plans to transfer the marketing authorization in Japan for Moderna’s COVID-19 vaccine Spikevax™ (mRNA-1273) from Takeda to Moderna in Japan as of August 1, 2022. Takeda also agreed with Moderna that it will continue to provide distribution support under the current national vaccination campaign for Moderna’s COVID-19 vaccine for a transitional period. Please see the attached press release for details.

There is no change in Takeda’s full year consolidated reported forecast for the fiscal year ending March 31, 2023 (FY2022), as the financial impacts from these agreements have been included in the forecast announced on May 11, 2022.

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- *Moderna to become marketing authorization holder in Japan and be responsible for all import, local regulatory, development, quality assurance and commercial activities for Spikevax™ from 1st August 2022*
- *Companies concluded memorandum of understanding that Takeda will continue to provide distribution support for the Moderna COVID-19 vaccines for a transitional period.*

CAMBRIDGE, MA and OSAKA, Japan, May 31, 2022 -- Moderna, Inc., (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, and [Takeda \(TSE:4502/NYSE:TAK\)](#) announced to transfer the marketing authorization in Japan for Moderna's COVID-19 vaccine Spikevax™ (mRNA-1273) from Takeda to Moderna in Japan as of August 1, 2022.

Moderna will assume responsibility for all Spikevax™ activities, including import, local regulatory, development, quality assurance and commercialization. Takeda has agreed with Moderna that it will continue to provide distribution support under the current national vaccination campaign for Moderna COVID-19 vaccines for a transitional period. Both companies will be responsible for ensuring proper implementation of operations associated with this transfer.

“We thank Takeda for their support and partnership in bringing our COVID-19 vaccine to Japan over the last two years, and for helping to play a key role in addressing the pandemic across the country,” said Stéphane Bancel, Moderna's Chief Executive Officer. “We are happy to take this important step as we continue to build and strengthen our own commercial organization in Japan, and we look forward to continuing our partnership in 2022.”

“We are proud to have been able to support the early public health response to the COVID-19 pandemic by using the Takeda network to provide Moderna's COVID-19 vaccine to the people of Japan,” said Gary Dubin, M.D., President, Global Vaccine Business Unit at Takeda. “Following transfer of the marketing authorization to Moderna, we will continue to provide transitional distribution support to ensure supply continuity.”

Authorized Use

Moderna's COVID-19 vaccine Spikevax™ has been granted authorization for special approval by the Ministry of Health, Labour and Welfare of Japan. In Japan, it is indicated for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. A dose may be given to people aged 12 years or older. A second dose should be given as soon as possible if more than four weeks have passed since the first vaccination. A booster dose may be given at least five months after the second dose for people aged 18 years and older. A fourth dose may be given at least five months after the third dose for the elderly etc. considering the benefits and risks.

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.

About Takeda

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetics and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries and regions. For more information, visit <https://www.takeda.com>.

Takeda's Commitment to Vaccines

Vaccines prevent 2 to 3 million deaths each year and have transformed global public health. For more than 70 years, Takeda has supplied vaccines to protect the health of people in Japan. Today, Takeda's global vaccine business is applying innovation to tackle some of the world's most challenging infectious diseases, such as dengue, COVID-19, Zika and norovirus. Takeda's team brings an outstanding track record and a wealth of knowledge in vaccine development and manufacturing to advance a pipeline of vaccines to address some of the world's most pressing public health needs. For more information, visit www.TakedaVaccines.com.

Moderna Forward-Looking Statements

This post contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the transfer of marketing authorization holder from Takeda to Moderna in Japan for the Spikevax COVID-19 vaccine (mRNA-1273) and the responsibilities undertaken by each company in association with the transfer. 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 post 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.

Takeda Important Notice

For the purposes of this notice, "press release" means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited ("Takeda") regarding this release. This press release (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this press release. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This press release is being given (together with any further information which may be provided to the recipient) on the condition that it is

for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

Takeda Forward-Looking Statements

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda’s future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as “targets”, “plans”, “believes”, “hopes”, “continues”, “expects”, “aims”, “intends”, “ensures”, “will”, “may”, “should”, “would”, “could” “anticipates”, “estimates”, “projects” or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda’s global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda’s operations and the timing of any such divestment(s); and other factors identified in Takeda’s most recent Annual Report on Form 20-F and Takeda’s other reports filed with the U.S. Securities and Exchange Commission, available on Takeda’s website at: <https://www.takeda.com/investors/sec-filings/> or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda’s future results.

Medical information

This press release contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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