Better Health, Brighter Future

News Release

Takeda Announces Approval of Nuvaxovid® COVID-19 Vaccine for Primary and Booster Immunization in Japan

- ***Nuvaxovid Intramuscular Injection, containing Matrix-MTM adjuvant, is the first recombinant protein-based COVID-19 vaccine approved for use in Japan***
- ***Approval for primary and booster immunization is based on efficacy and safety data from Japan and international clinical studies***
- ***Takeda is manufacturing Nuvaxovid at its Hikari facility and will begin distribution in Japan as soon as possible***

OSAKA, Japan and CAMBRIDGE, Massachusetts, April 19, 2022 – Takeda (TSE:4502/NYSE:TAK) today announced that it has received manufacturing and marketing approval from the Japan Ministry of Health, Labour and Welfare (MHLW) for Nuvaxovid® Intramuscular Injection (Nuvaxovid), a novel recombinant protein-based COVID-19 vaccine, for primary and booster immunization in individuals aged 18 and older. Novavax licensed and transferred its manufacturing technologies to enable Takeda to develop and manufacture the vaccine at its facility in Hikari. Takeda will begin distribution of Nuvaxovid doses purchased by the Government of Japan as soon as possible.

"COVID-19 continues to pose a significant threat to the health and well-being of our global community," said Gary Dubin, M.D., President of the Global Vaccine Business Unit, Takeda. "We are proud to contribute to the development of Nuvaxovid and to manufacture the vaccine at our Hikari facilities, continuing our commitment to the COVID-19 public health response in Japan."

The approval is based on Takeda's New Drug Application (NDA) submission which included interim results from a Phase 1/2 study conducted by Takeda in Japan and several studies conducted by Novavax, including two pivotal Phase 3 clinical trials in the U.K., the U.S. and Mexico, and Phase 1/2 studies in Australia and the U.S. Interim results from the Phase 1/2 study in Japan were positive and consistent with previously reported clinical trial results. No serious adverse events were reported in this study and the vaccine candidate was well-tolerated. Additional safety and efficacy data were submitted to support booster immunization, including a Phase 2 study conducted by Novavax in South Africa evaluating a booster dose given 6 months after primary immunization.

Nuvaxovid is stored at a refrigerated temperature of 2 -8°C and will be transported using a conventional vaccine supply chain.

Takeda received funding for the technology transfer and research and development to manufacture Nuvaxovid at its Hikari facility through the MHLW and Japan Agency for Medical Research and Development.

The financial impact of the vaccine on the full year consolidated financials for the fiscal year ending March 31, 2023 (Fiscal Year 2022) will depend on the specific distribution schedule. We will disclose the Fiscal Year 2022 forecast at the Fiscal Year 2021 financial results announcement scheduled in May 2022.

TAK-019 Clinical Trial

This placebo-controlled Phase 1/2 study in Japan evaluated the safety and immunogenicity of two vaccinations of TAK-019 given 21 days apart. The first of 200 subjects aged 20 years and older was dosed in Japan on February 24, 2021, and each participant was assigned to receive a placebo or a 0.5 ml dose of TAK-019 at both vaccinations. Participants Subjects have been followed for 12 months after the second dose of investigational product. The ClinicalTrials.gov identifier for this trial is NCT04712110.

About Takeda's COVID-19 Efforts

Takeda is taking a comprehensive approach to treat and prevent COVID-19 today, and future pandemics through multiple activities and partnerships including, but not limited to:

- **Vaccines:** Takeda has partnered with the Government of Japan, Novavax and Moderna, to help accelerate the availability of COVID-19 vaccines. Through the collaboration with Novavax, Takeda is using its well-established global manufacturing and supply capabilities to develop and commercialize Novavax' vaccine candidate for Japan. The company is also importing and distributing Moderna's COVID-19 vaccine as part of a three-way partnership with Moderna and Japan's MHLW. Takeda supports our partners and alliances in a shared goal to rapidly discover, develop and deliver effective treatments and vaccines for COVID-19 and ensure preparedness for future pandemics.
- **Hyperimmune globulin**: Takeda co-founded the CoVIg-19 Plasma Alliance and joined forces with other leading plasma companies to evaluate a hyperimmune globulin medicine in a global clinical trial. While the data did not meet its endpoints, the program has contributed to the scientific understanding of antibody-based treatment to address the virus and highlighted the broader therapeutic value and importance of plasma to treat rare diseases.
- **Additional therapeutics:** The company has assessed existing Takeda products for activity against the COVID-19 virus and co-founded the COVID R&D Alliance. In addition, Takeda has joined the Innovative Medicines Initiative (IMI) CARE consortium, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership and the COVID RED project.

Takeda's Commitment to Vaccines

Vaccines prevent 2 to 3 million deaths each year and have transformed global public health.[1] 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, pandemic influenza and Zika. 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.

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.

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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.

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; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; 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/reports/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.

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Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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References

1. World Health Organization. Vaccines and immunization. Retrieved December 2021.