Better Health, Brighter Future

News Release

Takeda Submits New Drug Application for Novavax' COVID-19 Vaccine Candidate in Japan

- *Submission Includes an Analysis from the Ongoing Phase 1/2 Immunogenicity and Safety Clinical Trial of TAK-019 in Japan as well as Safety and Efficacy Data from Novavax' Two Pivotal Phase 3 Trials*
- *Takeda is Establishing the Capability to Manufacture TAK-019 at its Facilities in Japan*

OSAKA, Japan, December 16, 2021 -- Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) announced the submission of a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare (MHLW) in Japan for Novavax' recombinant COVID-19 vaccine candidate, known as TAK-019 in Japan and NVX-CoV2373 outside Japan. The NDA submission includes an analysis from the ongoing Phase 1/2 immunogenicity and safety clinical trial of TAK-019 in Japan as well as safety and efficacy data from Novavax' global clinical trial program with more than 50,000 participants, including two pivotal Phase 3 trials, one conducted in the U.K. and the PREVENT-19 trial, conducted in the U.S. and Mexico. Through its partnership with Novavax including technology transfer, Takeda is establishing the capability to manufacture TAK-019 at its facilities in Japan and aims to begin distribution in early calendar year 2022, pending regulatory approval.

Takeda's interim trial results showed that two 0.5 ml doses given 21 days apart induced robust anti-SARS-CoV-2 immune responses in healthy Japanese adults. No serious adverse events were reported in the TAK-019 group and the vaccine candidate was also well-tolerated. These results are consistent with previously reported global clinical trial results of Novavax' recombinant protein COVID-19 vaccine candidate (NVX-CoV2373). Both Phase 3 pivotal trials achieved their primary endpoints in which NVX-CoV2373 demonstrated 89.7% and 90.4% efficacy against all symptomatic COVID-19 illness, respectively. In both trials, NVX-CoV2373 demonstrated a reassuring safety and tolerability profile. Takeda submitted all available Chemistry, Manufacturing and Controls (CMC), non-clinical and clinical data as of December 2021. Some additional CMC data will be subsequently submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) during the NDA review period.

"Today's filing reinforces our commitment to provide safe and effective vaccines to protect the people of Japan against COVID-19– today and into the future," said Masayuki Imagawa, head of the Japan Vaccine Business Unit at Takeda. "Safety and quality are top priorities for Takeda, and we will continue to work to ensure the study, production and distribution of our vaccines meet the highest standards."

Takeda's efforts to transfer technology, establish production facilities and distribute Novavax' vaccine candidate in Japan are supported by the MHLW under its supplementary budget for emergency maintenance associated with the vaccine production system. Domestic development of Novavax' vaccine candidate by Takeda is subsidized by the Japan Agency for Medical Research and Development (AMED).

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 will continue to be followed for 12 months following their second vaccination.

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 will build on its well-established global manufacturing and supply capabilities and be responsible for developing and commercializing Novavax' vaccine candidate. The company is also importing and distributing Moderna's COVID-19 vaccine as part of a three-way partnership with Moderna and the Government of Japan's Ministry of Health Labour and Welfare. Takeda also entered into an agreement with IDT Biologika GmbH (IDT) to utilize capacity for three months at IDT previously reserved for Takeda's dengue vaccine candidate, to manufacture the single-shot COVID-19 vaccine developed by Janssen, the Pharmaceutical Companies of Johnson & Johnson. The three-month period is now complete. 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.[i] 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 Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) 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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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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[i] World Health Organization. Vaccines and immunization. Retrieved December 2021.