Better Health, Brighter Future

News Release

Takeda Announces Positive Interim Safety and Immunogenicity Data from its Phase 1/2 Study of Moderna's COVID-19 Vaccine Candidate (TAK-919) in Japan

- *Interim Results Indicate Immune Response Consistent With Clinical Study Data Previously Reported by Moderna*
- *Results Were Submitted to the Japan Pharmaceuticals and Medical Devices Agency to Support Review of the Company's New Drug Application to Import and Distribute the Vaccine Candidate in Japan*

Osaka, Japan, May 10, 2021 -- Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) today announced positive interim results from the ongoing Phase 1/2 immunogenicity and safety clinical trial of Moderna's mRNA COVID-19 vaccine candidate (TAK-919) in Japan have been submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA). Takeda currently has a three-way agreement with Moderna and the Government of Japan's Ministry of Health Labour and Welfare (MHLW) to import and distribute 50 million doses of TAK-919 in Japan, pending regulatory approval.

This interim analysis showed binding antibody and neutralizing antibody titres were elevated at 28 days after the second dose in 100% of people vaccinated with two 0.5ml doses of TAK-919 given 28 days apart. The vaccine candidate was generally well-tolerated with no significant safety concerns reported.

"These data reinforce previously reported findings from Moderna clinical trials and suggest the potential for this vaccine candidate to protect the Japanese population from COVID-19," said Masayuki Imagawa, Head of Japan Vaccine Business Unit, Takeda. "Moderna's COVID-19 vaccine is already being used in countries around the world, and we embrace the opportunity to work with regulatory authorities to bring options that are proven safe and effective to the people of Japan. Every approved COVID-19 vaccine brings us closer to ending the pandemic and providing a safer and healthier world for all."

The study results were submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) to be evaluated as part of the New Drug Application submitted in March 2021, which also includes safety and efficacy results from Moderna's pivotal Phase 3 COVE trial conducted in the U.S. Takeda aims to begin distribution of TAK-919 immediately following regulatory approval, should it be granted.

Takeda's efforts to bring Moderna's and Novavax' vaccine candidates to Japan are supported by the MHLW and the Japan Agency for Medical Research and Development (AMED).

TAK-919 Clinical Trial
Takeda is conducting a placebo-controlled Phase 1/2 study in Japan to evaluate the safety and immunogenicity of two vaccinations of TAK-919 given 28 days apart. Takeda has enrolled 200 participants aged 20 years and older. Each participant was assigned to receive a placebo or a 0.5 ml dose of TAK-919 at both vaccinations. Participants will be followed for 12 months after the second vaccination.

The ClinicalTrials.gov identifier for this trial is NCT04677660.

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:

- **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 is assessing 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.
- **Vaccines:** Takeda has partnered with the Government of Japan, Novavax and Moderna, to help accelerate the availability of a COVID-19 vaccine. We are leveraging our extensive and well-established global manufacturing and supply capabilities and building upon our existing influenza pandemic preparedness efforts in Japan. Takeda also announced a mutual agreement with IDT Biologika GmbH (IDT) to utilize capacity at IDT for three months previously reserved for Takeda's dengue vaccine candidate to manufacture the single-shot COVID-19 vaccine developed by Janssen Pharmaceutical Companies of Johnson & Johnson. 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.

Takeda's Commitment to Vaccines
Vaccines prevent 2 to 3 million deaths each year and have transformed global public health. For the past 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, manufacturing and global access 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. 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 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/ 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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