



## News Release

### **Takeda Submits New Drug Application to Import and Distribute Moderna's COVID-19 Vaccine Candidate in Japan**

- *50 million doses of Moderna's COVID-19 vaccine are expected to be distributed beginning in the first half of 2021, pending licensure in Japan*

**Osaka, Japan, March 5, 2021** -- Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) today announced that it has submitted a New Drug Application to the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to import and distribute Moderna's mRNA COVID-19 vaccine candidate (TAK-919).

Takeda is currently conducting a Phase 1/2 immunogenicity and safety trial studying two vaccinations of TAK-919 given 28 days apart versus placebo in 200 healthy Japanese adults. Study results are expected to be available in May, at which point they will be submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA). The submission today included safety and efficacy results from Moderna's pivotal Phase 3 COVE trial conducted in the US.

"Building on our existing influenza pandemic preparedness efforts, Takeda commits to delivering Moderna's COVID-19 vaccine candidate in Japan as soon as possible," said Masayuki Imagawa, head of the Japan Vaccines Business Unit at Takeda. "We are grateful for our partners, Moderna and the MHLW, and all the study participants who have helped us move one step closer to providing a COVID-19 vaccine in Japan."

In 2020, Takeda announced two partnerships to support the need for rapid and sustained access to COVID-19 vaccines in Japan. The [three-way agreement](#) with Moderna and the MHLW is to import and distribute 50 million doses of TAK-919 in Japan. The [partnership with Novavax](#) is for the development and commercialization based on manufacturing capacity of over 250 million doses of their COVID-19 vaccine candidate (TAK-019) in Japan. In both cases, Takeda will be the Marketing Authorization Holder in Japan if the vaccine candidates are approved.

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).

### **About Takeda's COVID-19 Efforts**

Takeda is taking a comprehensive approach to treat and prevent COVID-19 through multiple activities and partnerships focused on advancing development of a variety of potential therapies and vaccines. Takeda co-founded the CoVig-19 Plasma Alliance and joined forces with other leading plasma companies to develop and manufacture a hyperimmune globulin medicine which is currently being evaluated in a clinical trial. The Alliance is also participating in The Fight Is In Us coalition and related convalescent plasma donation campaign. The company is also assessing existing Takeda products and those in development for activity against the COVID-19 virus, and has joined the [COVID R&D Alliance](#), the IMI Care Alliance and the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\) partnership](#). 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 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](http://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 Genetic 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 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](http://www.sec.gov). Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other

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