



News Release

Takeda Provides Updates on Phase 1/2 Clinical Trials of Novavax' and Moderna's COVID-19 Vaccine Candidates in Japan

- *Takeda is making two COVID-19 vaccines available in Japan, by manufacturing Novavax' recombinant vaccine candidate and distributing Moderna's mRNA vaccine candidate, with the support of the Japanese Government*
- *Phase 1/2 immunogenicity and safety trials designed to include 200 healthy Japanese adults followed for 12 months after second vaccination*
- *Primary analysis results from both studies expected in CY2021 and will support New Drug Applications (NDA) in Japan*

Osaka, Japan, February 24, 2021 -- Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) announced today that the first subject was dosed in its Phase 1/2 immunogenicity and safety study of Novavax' COVID-19 vaccine candidate (TAK-019) in Japan. Earlier this month, Takeda completed enrollment in the company's Phase 1/2 immunogenicity and safety study of Moderna's COVID-19 vaccine candidate (TAK-919) in Japan.

“Early in the pandemic, we made the decision to partner with other companies and leverage our substantial vaccine experience and capabilities to make COVID-19 vaccines available in Japan,” said Rajeev Venkayya, M.D., President of the Global Vaccine Business Unit, Takeda. “We have been pleased to see the outstanding Phase 3 efficacy data from the Moderna and Novavax programs and are excited to work with each company and the Government of Japan to help bring the pandemic to an end.”

Takeda previously announced its commitment to providing rapid and sustained access to COVID-19 vaccines in Japan through partnerships with [Novavax](#) and [Moderna](#). Takeda will receive a manufacturing technology transfer from Novavax and will be responsible for the development and commercialization based on manufacturing capacity of over 250 million doses of TAK-019. The company will also import and distribute 50 million doses of TAK-919 as part of a joint partnership with Moderna and the Government of Japan's Ministry of Health Labour and Welfare (MHLW).

Results from the TAK-919 study are expected in the first half of 2021 and results from the TAK-019 study in the second half of 2021. Once available, the study results will be submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) as part of the NDA filing process. Pending regulatory approval, Takeda intends to start distributing TAK-919 in the first half of 2021 and aims to start distributing TAK-019 in late 2021.

TAK-919 clinical trial

This placebo-controlled Phase 1/2 study in Japan will evaluate the safety and immunogenicity of two vaccinations of TAK-919 given 28 days apart. Each participant was assigned to receive a placebo or a 0.5 ml dose of TAK-919 at both vaccinations. The trial completed enrollment of 200 participants aged 20 years and older on February 3, 2021. Participants will be followed for 12 months after the second vaccination.

The [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04677660) identifier for this trial is [NCT04677660](https://clinicaltrials.gov/ct2/show/study/NCT04677660).

TAK-019 clinical trial

This placebo-controlled Phase 1/2 study in Japan will evaluate the safety and immunogenicity of two vaccinations of TAK-019 given 21 days apart. The first subject in the TAK-019 trial was dosed in Japan on February 24, 2021 and Takeda intends to enroll 200 participants aged 20 years and older. Each participant will be assigned to receive a placebo or a 0.5 ml dose of TAK-019 at both vaccinations. Participants will be followed for 12 months after the second vaccination.

The [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04712110) identifier for this trial is [NCT04712110](https://clinicaltrials.gov/ct2/show/study/NCT04712110).

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.

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”,

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