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Takeda to import & distribute Moderna's vaccine in Japan

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TAK-919 is Takeda's development code for Moderna's COVID-19 vaccine candidate.



Moderna, Inc has announced that Takeda Pharmaceutical Co, Ltd submitted a new drug application to the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to import and distribute Moderna's vaccine candidate against COVID-19 (mRNA-1273 or TAK-919) in Japan. TAK-919 is Takeda's development code for Moderna's COVID-19 vaccine candidate.

"Submitting this NDA is an important step in the clinical development of our COVID-19 vaccine in Japan," said Stéphane Bancel, Chief Executive Officer, Moderna. "The Phase 1/2 study is the first clinical trial of a Moderna product in Japan. We thank Takeda, the MHLW and the participants in the study for helping advance our goal to protect the Japanese population from COVID-19 with a vaccine."

Takeda is conducting a placebo-controlled Phase 1/2 study designed to evaluate the safety and immunogenicity of two vaccinations of mRNA-1273 at the 100 ?g dose level given 28 days apart in 200 participants aged 20 years and above in Japan. Participants will be followed through 12 months after the second vaccination. The ClinicalTrials.gov identifier is NCT04677660. Takeda completed enrollment of this Phase 1/2 study in February, 2021. Once available, the Phase 1/2 study results will be submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA).

Takeda and Moderna previously announced that Takeda will import and distribute 50 million doses of Moderna's COVID-19 vaccine candidate starting in the first half of 2021, pending licensure in Japan.