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Japan approves Novavax's COVID-19 vaccine for primary and booster immunisation

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Takeda is manufacturing Nuvaxovid at its Hikari facility and will begin distribution in Japan as soon as possible



Takeda Pharma has received manufacturing and marketing approval from the Japan Ministry of Health, Labour and Welfare (MHLW) for Nuvaxovid Intramuscular Injection (Nuvaxovid), a novel recombinant protein-based COVID-19 vaccine, for primary and booster immunization in individuals aged 18 and older.

Novavax licensed and transferred its manufacturing technologies to enable Takeda to develop and manufacture the vaccine at its facility in Hikari. Takeda will begin distribution of Nuvaxovid doses purchased by the Government of Japan as soon as possible.

The approval is based on Takeda's New Drug Application (NDA) submission which included interim results from a Phase 1/2 study conducted by Takeda in Japan and several studies conducted by Novavax, including two pivotal Phase 3 clinical trials in the U.K., the U.S. and Mexico, and Phase 1/2 studies in Australia and the U.S. Interim results from the Phase 1/2 study in Japan were positive and consistent with previously reported clinical trial results.

Nuvaxovid is stored at a refrigerated temperature of 2 -8Ã¢â??Æ? and will be transported using a conventional vaccine supply chain.

Takeda received funding for the technology transfer and research and development to manufacture Nuvaxovid at its Hikari facility through the MHLW and Japan Agency for Medical Research and Development.