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Moderna to become marketing authorization holder in Japan for Spikevax COVID-19 Vaccine

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For all import, local regulatory, development, quality assurance and commercial activities for Spikevax from 1st August 2022



Moderna and Takeda have announced to transfer the marketing authorization in Japan for Moderna's COVID-19 vaccine Spikevax^{T} (mRNA-1273) from Takeda to Moderna in Japan as of August 1, 2022.

Moderna will assume responsibility for all Spikevax activities, including import, local regulatory, development, quality assurance and commercialization. Japanese firm Takeda will continue to provide distribution support under the current national vaccination campaign for Moderna COVID-19 vaccines for a transitional period. Both companies will be responsible for ensuring proper implementation of operations associated with this transfer.

Moderna's COVID-19 vaccine Spikevax has been granted authorization for special approval by the Ministry of Health, Labour and Welfare of Japan. In Japan, it is indicated for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. A dose may be given to people aged 12 years or older. A second dose should be given as soon as possible if more than four weeks have passed since the first vaccination. A booster dose may be given at least five months after the second dose for people aged 18 years and older. A fourth dose may be given at least five months after the third dose for the elderly etc. considering the benefits and risks.