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Moderna’s COVID-19 mRNA vaccine targeting SARS-COV-2 Variant JN.1 receives approval in Taiwan

04 September 2024 | News

JN.1 variant of COVID-19 has emerged as the dominant strain worldwide since the end of 2023

Moderna, Inc. has announced that the Taiwan Food & Drug Administration (FDA) has approved an updated formulation of the COVID-19 mRNA vaccine Spikevax, targeting the SARS-CoV-2 variant JN.1., for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals six months of age and older.

The JN.1 variant of COVID-19 has emerged as the dominant strain worldwide since the end of 2023. As a subclade of the BA.2.86 variant, JN.1 harbors a unique combination of mutations inherited from the BA.2.86 lineage, notably featuring the novel L455S mutation within its receptor-binding motif. This mutation has been linked to increased transmissibility and enhanced immune evasion capabilities.

In April 2024, the World Health Organization (WHO) Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) issued guidance recommending the use of a monovalent JN.1 lineage for COVID-19 vaccine antigen composition.

Regulatory applications for Moderna's updated COVID-19 vaccine are under review by regulatory agencies worldwide, with decisions anticipated in the coming weeks.

Spikevax is approved as a two-dose series for prevention of COVID-19 in individuals 18 years of age and older.