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Japan approves self-amplifying mRNA COVID-19 vaccine for protection against JN.1 strain

September 13, 2024 | News

Approval underscores CSL and Arcturus Therapeutics' commitment to delivering disruptive technologies to combat COVID-19 and other respiratory viral diseases



Global biotechnology leader CSL and self amplifying-mRNA pioneer Arcturus Therapeutics have announced that Japan's Ministry of Health, Labor and Welfare (MHLWs) has granted approval and authorisation for their updated self-amplifying mRNA (sa-mRNA) COVID-19 vaccine, KOSTAIVE. The updated vaccine is targeted to protect against the JN.1 lineage of Omicron subvariants for adults 18 years of age and older.

CSL's exclusive partner in Japan, Meiji Seika Pharma, will begin distributing the updated vaccine in time for the October COVID-19 vaccination campaign, marking the world's first commercially available sa-mRNA COVID-19 vaccine for adults 18 and older.

In May 2024, a Japanese health ministry panel recommended that COVID-19 vaccines be updated to target the JN.1 lineage of Omicron subvariants for the 2024/2025 national immunisation programme. This aligns with recent recommendations from the World Health Organisation.

The approval is based on clinical evidence supporting the safety and effectiveness of CSL and Arcturus Therapeutics' sa-mRNA COVID-19 vaccine, including published data demonstrating superior immunogenicity to Omicron BA 4/5 compared to a conventional mRNA COVID-19 vaccine booster and follow-up data demonstrating duration of immunity lasting up to one year.