12 December 2024
EMA/392588/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kostaive

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On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kostaive, a vaccine intended for the prevention of COVID-19 in adults.

The applicant for this medicinal product is Arcturus Therapeutics Europe B.V.

Kostaive will be available as a powder for dispersion for injection. Kostaive is a RNA-based COVID-19 vaccine (ATC code: J07BN01). It contains a self-amplifying mRNA that encodes the SARS-CoV-2 spike protein. Self-amplifying means that the mRNA also carries instructions to make a protein called replicase. Once administered into a muscle, the replicase protein makes more copies of the mRNA, which the cell can use to make more spike protein. Vaccination with Kostaive induces the production of neutralising antibodies and a cellular immune response targeting the spike protein, which helps protect people against COVID-19.

The benefit of Kostaive as a primary vaccination against COVID-19 was shown in a large study in which adults received either two doses of Kostaive or placebo. Compared with placebo, vaccination with Kostaive led to a reduction in the proportion of patients who developed symptomatic COVID-19 between one week and 3 months after the second vaccine dose. A smaller immunobridging study also showed that Kostaive is effective as a heterologous booster vaccination (when the primary vaccination was made with another COVID-19 vaccine). The most common side effects with Kostaive are injection-site reactions (pain and tenderness), arthralgia, myalgia, headache, dizziness, fatigue, chills and pyrexia.

The full indication is:

> Kostaive is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
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> The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.