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Withdrawal of application for the marketing authorisation of Skycovion (COVID-19 vaccine [recombinant, adjuvanted])

SK Chemicals GmbH withdrew its application for a marketing authorisation of Skycovion for the prevention of coronavirus disease 2019 (COVID-19).

The company withdrew the application on 1 September 2023.

What is Skycovion and what was it intended to be used for?

Skycovion was developed as a vaccine to protect adults against COVID-19, the disease caused by the SARS-CoV-2 virus.

Skycovion contains small particles (known as nanoparticles) containing parts of the spike protein found on the surface of SARS-CoV-2, which have been produced in the laboratory. The vaccine was to be given as an injection.

How does Skycovion work?

Skycovion works by preparing the body to defend itself against COVID-19. The nanoparticles in the vaccine contain parts of the spike protein of the SARS-CoV-2 virus strain. The vaccine also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system is expected to identify the nanoparticles containing parts of the spike protein as foreign and produce natural defences — antibodies and T cells — against them. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

What did the company present to support its application?

The company presented results from a study involving over 4,000 adults which looked at how well the vaccine triggered the production of antibodies against the original strain of the SARS-CoV-2 virus. The company also submitted data on the safety and quality of the vaccine.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had concerns related to the quality of the medicine and the validation of the tests used to measure the immune response. In addition, the Agency considered that the application for a Conditional Marketing Authorisation, as requested by the company, was not appropriate. Such an authorisation can only be considered when a medicine addresses an unmet medical need, and the Agency noted that other vaccines against the original strain of the SARS-CoV-2 virus are widely available.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough data to support the application for Skycovion, and its provisional opinion was that Skycovion could not have been authorised for the prevention of COVID-19.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that its withdrawal was based on commercial reasons.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Skycovion.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.