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EMA starts rolling review of Novavax's COVID-19 vaccine (NVX-CoV2373)

EMA's human medicines committee (CHMP) has started a rolling review of NVX-CoV2373, a COVID-19 vaccine being developed by Novavax CZ AS (a subsidiary of Novavax, Inc.).

The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and early clinical studies in adults. These studies suggest that the vaccine triggers the production of antibodies and immune cells that target SARS-CoV-2, the virus that causes COVID-19.

The company is currently conducting trials in people to assess its safety, immunogenicity (how well it triggers a response against the virus) and its effectiveness against COVID-19. EMA will evaluate data from these and other clinical trials as they become available.

The rolling review will continue until enough evidence is available for a formal marketing authorisation application.

EMA will assess the vaccine's compliance with the usual standards for effectiveness, safety and pharmaceutical quality. While EMA cannot predict the overall timelines, it should take less time than normal to evaluate an eventual application because of the work done during the rolling review.

How is the vaccine expected to work?

Like other vaccines, NVX-CoV2373 is expected to prepare the body to defend itself against infection. The vaccine is a protein-based vaccine which contains tiny particles made from a laboratory-grown version of the spike (S) protein found on the surface of SARS-CoV-2 coronavirus. It also contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine.

When a person is given the vaccine, their immune system will identify the protein particles 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.

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What is a rolling review?

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine during a public health emergency. Normally, all data on a medicine or vaccine's effectiveness, safety and quality and all required documents must be ready at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies. Once the CHMP decides that sufficient data are available, the company can submit a formal application. By reviewing the data as they become available, the CHMP can come to an opinion on the medicine's authorisation sooner.

During the rolling review, and throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group brings together experts from across the European medicines regulatory network to advise on the development, authorisation and safety monitoring of medicines and vaccines for COVID-19 and facilitate quick and coordinated regulatory action.