EMA receives application for conditional marketing authorisation of Novavax's COVID-19 vaccine, Nuvaxovid - European Medicines Agency

EMA has started evaluating an application for conditional marketing authorisation for Novavax's COVID-19 vaccine, Nuvaxovid (also known as NVX-CoV2373). The assessment will proceed under an accelerated timeline, and an opinion on the marketing authorisation could be issued within weeks if the data submitted are sufficiently robust and complete to show the efficacy, safety and quality of the vaccine.

Such a short timeframe is only possible because EMA has already reviewed a substantial portion of the data on the vaccine during a rolling review. During this phase, EMA's human medicines committee (CHMP) assessed data from laboratory studies (non-clinical data), some information on the quality of the vaccine and the way it will be produced, and data on its safety, immunogenicity (how well it triggers a response against the virus) and efficacy against COVID-19 from clinical studies in adults.

In parallel, EMA's safety committee (PRAC) completed the preliminary assessment of the risk management plan (RMP) proposed by the company, which outlines measures to identify, characterise and minimise the medicine's risks.

Furthermore, EMA's committee for medicines for children (PDCO) has issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 medicines.

If EMA concludes that the benefits of Nuvaxovid outweigh its risks in protecting against COVID-19, it will recommend granting a conditional marketing authorisation. The European Commission will then fast-track its decision-making process with a view to granting a conditional marketing authorisation valid in all EU and EEA Member States within days.

EMA will communicate at the time of CHMP's opinion.

How is the vaccine expected to work?

Like other vaccines, Nuvaxovid is expected to prepare the body to defend itself against infection. The vaccine contains tiny particles made from a version of a protein found on the surface of SARS-CoV-2 (the spike (S) protein), which has been produced in the laboratory. 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.