

Beat: Health

## FRANCE TO RECEIVE M6.4 DOSES OF NOVAVAX'S ANTI COVID-19 VACCINE

### NUVAXOVID BY EARLY FEBRUARY

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**USPA NEWS** - The European Union recently (December 20, 2021) authorized the new vaccine Nuvaxovid from the American Novavax, after a positive recommendation from the European Medicines Agency (EMA), and is announced to enter France soon ( Debut February 2022) to fight against COVID-19. Indeed EMA has recommended granting a conditional marketing authorization for Novavax's COVID-19 vaccine Nuvaxovid (also known as NVX-CoV2373) to prevent COVID-19 in people from 18 years of age. The first doses of this vaccine from the American laboratory Novavax, the fifth anti-COVID-19 authorized in Europe, should be delivered to France "from the end of January", according to a spokesperson for the Ministry of Solidarity and Health. France is expected to receive 3.2 million doses of the anti-COVID-19 vaccine from the American Novavax in the first quarter, and has activated an option for 3.2 additional doses to be delivered in the second quarter. However, the High Health Authority (HAS) has still not commented on the place of this more classic vaccine in the vaccination campaign. The first study, conducted in Mexico and the United States, found a 90.4% reduction in the number of symptomatic COVID-19 cases

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### EMA HAS APPROVED NUVAXOVID BY NOVAVAX IN EUROPE O PREVENT COVID-19 IN PEORPLE FROM 18 YEARS

EMA has recommended granting a conditional marketing authorisation for Novavax's COVID-19 vaccine Nuvaxovid (also known as NVX-CoV2373) to prevent COVID-19 in people from 18 years of age. Nuvaxovid is the fifth vaccine recommended in the EU for preventing COVID-19. It is a protein-based vaccine and, together with the already authorised vaccines, will support vaccination campaigns in EU Member States during a crucial phase of the pandemic. After a thorough evaluation, EMA's human medicines committee (CHMP) concluded by consensus that the data on the vaccine were robust and met the EU criteria for efficacy, safety and quality. Results from two main clinical trials found that Nuvaxovid was effective at preventing COVID-19 in people from 18 years of age. The studies involved over 45,000 people in total. In the first study, around two thirds of participants received the vaccine and the others were given a placebo (dummy) injection; in the other study, participants were equally split between Nuvaxovid and placebo. People did not know if they had been given Nuvaxovid or placebo.

### 1ST STUDY IN MEXICO FOUND A 90,4% REDUCTION IN THE NUMBER OF SYMPTOMATIC COVID-19 CASES

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The second study conducted in the United Kingdom also showed a similar reduction in the number of symptomatic COVID-19 cases in people who received Nuvaxovid (10 cases out of 7,020 people) compared with people given placebo (96 out of 7,019 people); in this study, the vaccine efficacy was 89.7%. Taken together, the results of the two studies show a vaccine efficacy for Nuvaxovid of around

90%. The original strain of SARS-CoV-2 and some variants of concern such as Alpha and Beta were the most common viral strains circulating when the studies were ongoing. There is currently limited data on the efficacy of Nuvaxovid against other variants of concern, including Omicron. The side effects observed with Nuvaxovid in the studies were usually mild or moderate and cleared within a couple of days after vaccination. The most common ones were tenderness or pain at the injection site, tiredness, muscle pain, headache, a general feeling of being unwell, joint pain, and nausea or vomiting. The safety and effectiveness of the vaccine will continue to be monitored as it is used across the EU, through the EU pharmacovigilance system and additional studies by the company and European authorities. The ? product information for Nuvaxovid contains information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation. An assessment report with details of EMA's evaluation of Nuvaxovid and the full risk management plan will be published shortly. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's clinical data website in due course.

#### NUVAXOVID WHICH CONTAINS A VERSION OF A PROTEIN & NATURAL ADJUVANT IS GIVEN AS 2 SHOTS

Nuvaxovid works by preparing the body to defend itself against COVID-19. The vaccine contains a version of a protein found on the surface of SARS-CoV-2 (the spike 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 as foreign and produce natural defences — antibodies and T cells — against it. 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. Nuvaxovid is given as two injections, usually into the muscle of the upper arm, 3 weeks apart. Source : European Union, French Ministry of Health, French High Authority of Health

#### Article online:

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