Novavax Investor Relations

Today, the European Medicines Agency (EMA) updated the label for our COVID-19 vaccine (NVX-CoV2373) to include the risk of severe allergic reactions. This update is a warning commonly included for commercially available vaccines, including COVID-19 vaccines. Novavax' clinical development program reported no severe allergic reactions and therefore, this risk was not listed in the initial product label.

With broader deployment of doses, we have received reports of two cases of anaphylaxis (allergic reaction) that met a probable/definite case definition. Because anaphylaxis can occur with all vaccines and based on these cases, Novavax and the EMA agreed to update the label accordingly. We will continue to monitor all adverse events, including allergic reactions.

Authorization in the U.S.

The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration.

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https://ir.novavax.com/Novavax-Statement-on-European-Medicines-Agency-Nuvaxovid-TM-Label-Update-Related-to-Allergic-Reaction