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EU Approves 5th COVID-19 Vaccine, by Novavax

The European Commission granted conditional marketing authorisation for Novavax's COVID-19 Vaccine for individuals 18 years or older. The U.S. biotech, Novavax, currently holds emergency use authorisations for its two-dose vaccine in the Philippines and Indonesia and has received emergency use listing from the World Health Organization.

Unlike the approved vaccines produced by Pfizer/BioNTech, Moderna, Janssen, and AstraZeneca, Nuvaxovid is the first protein-based COVID-19 vaccine. Recombinant SARS-CoV-2 spike protein is grown and harvested from insect cells and then mixed with an adjuvant, an immune-boosting chemical.

The European Medicines Agency and European Commission based their decision on data, including two clinical trials. The results, which included 30,000 participants in the U.S. and Mexico and 15,000 participants in the U.K., were published in *The New England Journal of Medicine*. The vaccine demonstrated high efficacy and an acceptable safety and tolerability profile. A third dose also increased neutralising antibodies enough to address the delta variant. Novavax will continue to monitor the vaccine's safety and effectiveness against the variants.

The EU ordered up to 100 million doses of the Novavax vaccine with the option for 100 million more. This authorisation leverages Novavax's manufacturing partnership with Serum Institute of India, the world's largest vaccine manufacturer by volume, to supply the first doses for the EU, which will arrive in January.

Sources: NEJM, NEJM, Novavax

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