



A volunteer receives a COVID-19 vaccine candidate or placebo in October in the phase III trial Novavax launched in the United Kingdom. KIRSTY O'CONNOR/PRESS ASSOCIATION Dec. 28, 2020

Novavax launches pivotal U.S. trial of dark horse COVID-19 vaccine after manufacturing delays

Novavax, **a once-struggling biotech company** that **was rescued by \$2 billion in funding for its promising COVID-19 vaccine candidate from the Coalition for Epidemic Preparedness Innovations and the U.S. government, announced today** the long-awaited start of its U.S. efficacy trial. Novavax has already fully enrolled an efficacy trial in the United Kingdom with more than 15,000 volunteers, whose data it plans to use to support its application for European regulatory approval.

But the U.K. trial hasn't delivered its results yet and the company postponed the launch of its larger U.S. trial several times this fall as it struggled to scale up vaccine manufacturing. The results from the first human trial of the candidate, announced in August, **were promising**. Nonetheless, **despite a nearly 30-year history making vaccines, Novavax has never won regulatory approval for one of its candidates**, and whether the pandemic will finally change that remains to be seen.

Novavax's COVID-19 candidate is one of two protein subunit vaccines—the other is made by the vaccine-making giant Sanofi Pasteur—on which the U.S. government has bet billions of dollars, and the first to enter a pivotal efficacy trial. It consists of tiny lipid particles studded with copies of the spike protein from the pandemic coronavirus SARS-CoV-2. The vaccine's lipids do not contain the polymer polyethylene glycol that has raised allergic reaction concerns for other COVID-19 vaccines, but it is supplemented by an immune-boosting, plant-derived compound called a saponin.

Two-thirds of up to 30,000 volunteers in the North American **placebo-controlled trial** will receive the active vaccine. There will be 108 U.S trial sites and seven in Mexico