FDA experts weigh authorizing Novavax COVID-19 vaccine in US

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A panel of experts convened by the US drug regulator was meeting Tuesday to consider authorizing the Novavax COVID-19 shot, a late runner in the fight against the virus that could nonetheless play a role in overcoming vaccine hesitancy.

Three vaccines are currently approved in the United States: Pfizer and Moderna, which are based on messenger RNA, and Johnson and Johnson, an adenovirus vector vaccine.

But the last of these, the J&J vaccine, was recently restricted in the US after being linked to a rare but serious clotting condition, especially in women of reproductive age.

It is now only recommended for adults who cannot access Pfizer or Moderna for medical or other serious reasons.

The Novavax vaccine was an early frontrunner in the vaccine race, but fell behind after being hit by manufacturing and regulatory delays.

Though the company is American, the US is one of the few major markets where it hasn't yet received authorization—the EU, UK, Canada, Australia are among many that have already given it the green light.

Officials hope that the shot, which is based on synthetic proteins, could provide an alternative to the mRNA vaccines for people still hesitant.

"We do have a problem with vaccine uptake that is very serious in the United States," Peter Marks, a senior scientist for the Food and Drug administration, said at the start of the meeting.

"And anything we can do to get people more comfortable to be able to accept these potentially life saving medical products, is something that we feel we are compelled to do."

Of the various vaccine technologies, mRNA has been subject to the most misinformation efforts.

Novavax's vaccine was found to be 90 percent effective against symptomatic cases of the disease, in trials conducted before the appearance of the Omicron variant, according to the FDA.

But six cases of myocarditis, an inflammation of the heart muscle, were detected in the group that received the vaccine, against one case in the placebo group, in a trial of around 40,000 people.

Novavax says there is insufficient evidence to establish a causal relationship between the cases of myocarditis and the vaccine.

The FDA voiced concern over the myocarditis link on Friday, sending Novavax shares to drop 20 percent on the New York Stock Exchange. And trading of Novavax stock was halted on Monday pending news from the FDA panel.

Known as a protein subunit vaccine, Novavax is administered in two doses.

It uses a synthetic version of the virus' spike protein to evoke an immune response.

The same technique is used in vaccines against whooping cough, meningococcal meningitis and hepatitis B.