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National Coronavirus pandemic

Is Novavax the dark horse of Australia's COVID-19 vaccines?

By **Liam Mannix** and **Emma Koehn**

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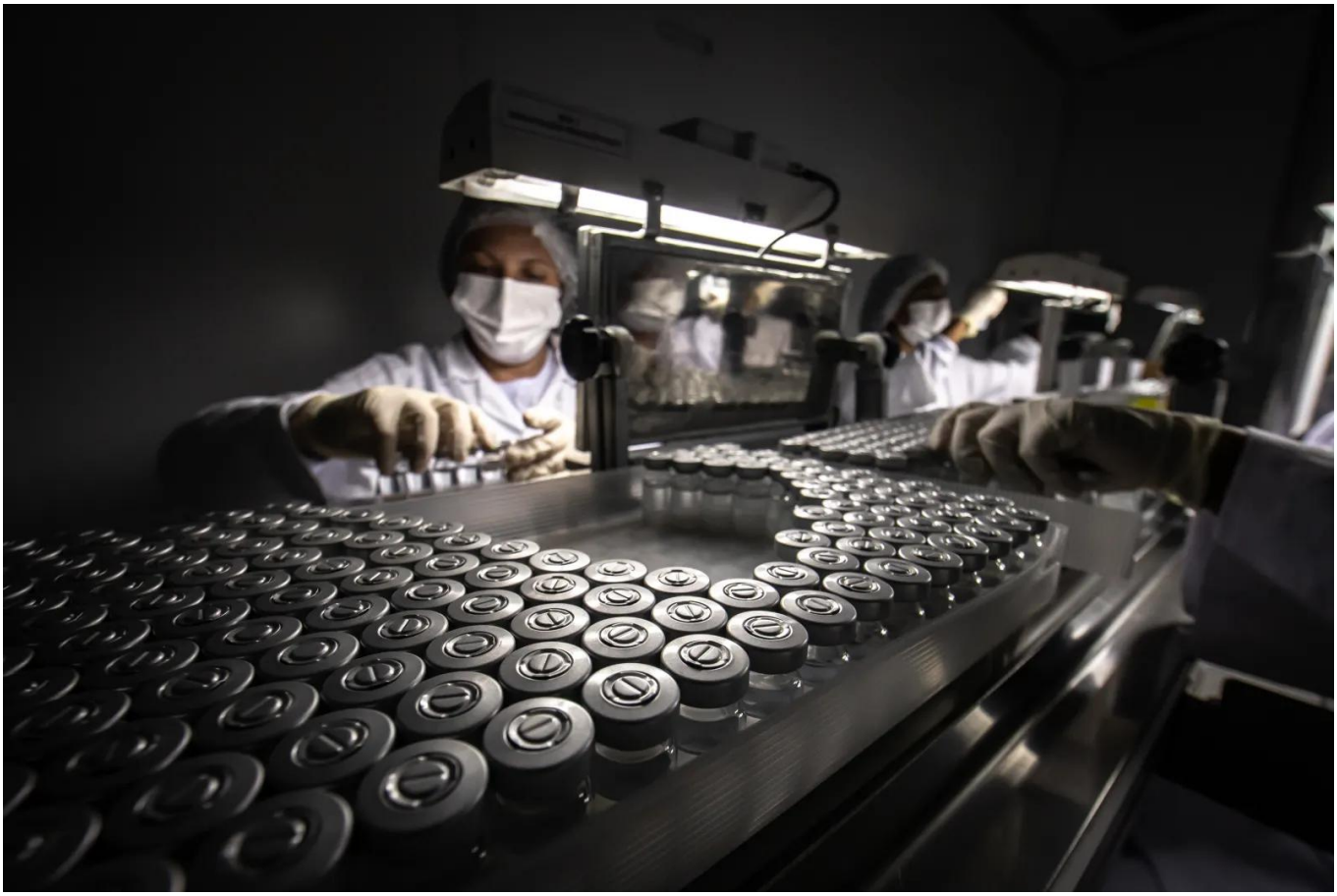
Experts say early clinical data on Australia's third COVID-19 vaccine, Novavax, is promising enough to suggest it could play a significant role in the nation's pandemic strategy.

The federal government has signed up to buy 51 million doses of Novavax's two-shot vaccine and those involved in trials say it is expected to be made available as early as the middle of this year, in addition to COVID-19 vaccines from Pfizer and AstraZeneca that will be available in coming weeks.



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Australia's Chief Medical Officer Paul Kelly on Tuesday confirmed the nation's drug regulator was in direct talks with European and Norwegian authorities after several elderly people died

after receiving Pfizer's vaccine. It is not yet clear if there was a link between the deaths and the vaccine.

While large phase three studies for the Novavax vaccine are ongoing, early data released in December suggests it is likely to offer strong protection against COVID-19. There are even hints it may do something other vaccines have struggled with: stop the coronavirus' spread.

"The phase one data was really convincing. The immune responses were really strong – up there in the realms we saw with the mRNA vaccines. That level of immune response tends to be a bit of a correlation ... those are the vaccines that have ended up giving very strong efficacy," said University of Sydney professor of medical microbiology James Triccas.

Paul Young, co-leader of the University of Queensland's aborted COVID-19 vaccine project, agreed the data "does look promising".

"The preclinical animal data showed that viral titres in the upper respiratory tract were lower in vaccinated animals, suggesting but not proving that infectivity and transmission may be lower," he said.

Paul Griffin, medical director of the Nucleus Network – contracted by Novavax to conduct clinical trials in Australia – said if all went well, the vaccine could be available for use by May or June.

"I think this is one, just based on where it's up to timing wise, that has fallen off the radar in this country. There has been a lot of attention on Pfizer, AstraZeneca and Moderna," he said. "It is looking very safe and effective."

It is difficult to directly compare phase one trial results, but data reported in the *New England Journal of Medicine* in December suggested Novavax's vaccine produced an immune response similar to vaccines from Pfizer and Moderna.

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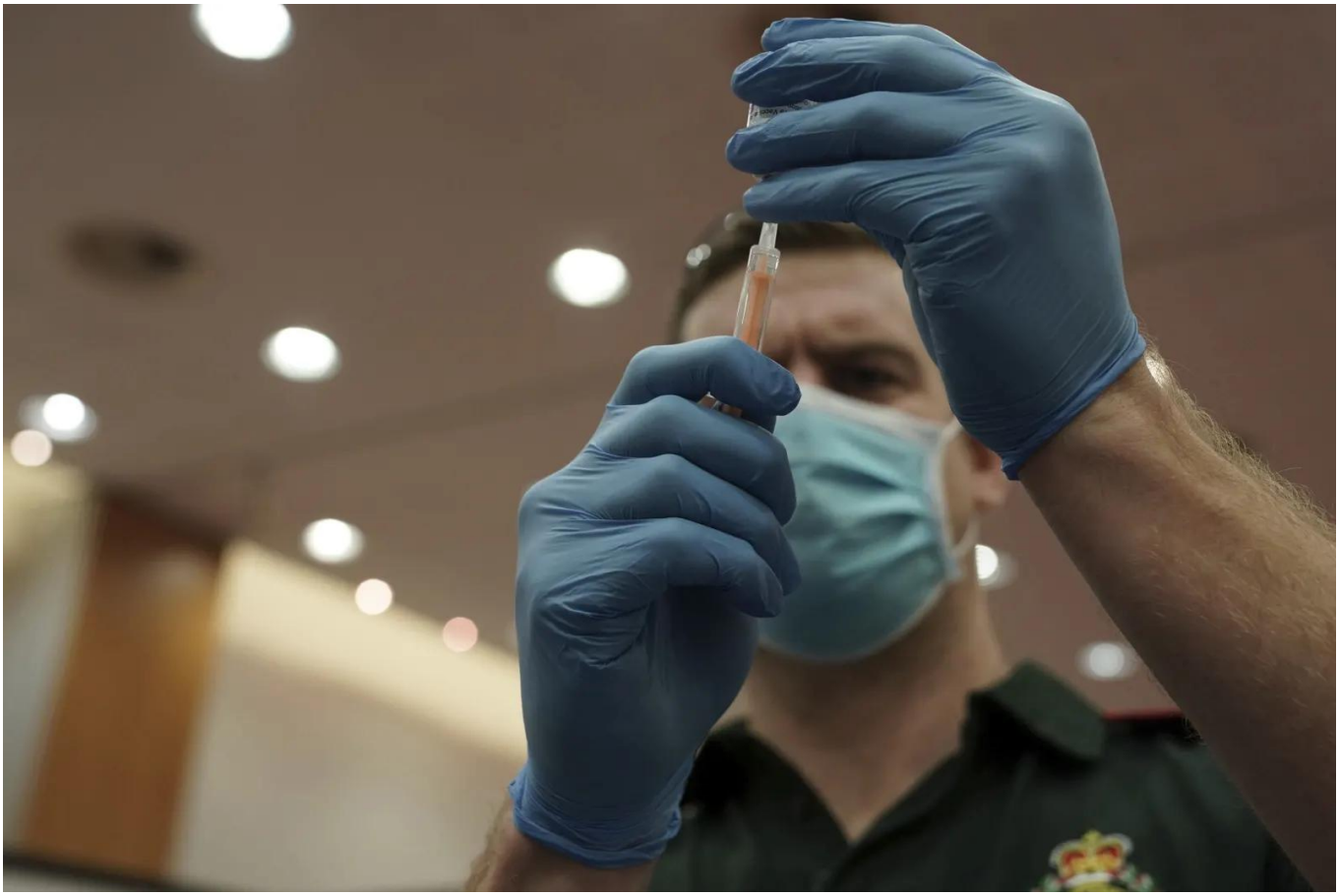
"They were able to induce higher [antibody] titres than recovered COVID patients. And that's a really good sign. When we were seeing results like that, it did highlight Novavax is one to watch, and a really promising formulation," said Kylie Quinn, an RMIT vaccine designer.

Griffith University virologist Adam Taylor said the trials showed the vaccine was safe and generated good antibody responses. "Certainly, this is a useful candidate."

Other vaccines have already shown themselves capable of inducing strong immune responses and protecting people from the virus.

What makes Novavax different is a hint in the early data it could not just protect people but also stop the virus spreading. Stopping or reducing transmission of the virus is valuable to protect people who cannot or will not get vaccinated. At this stage, it remains unclear if any of the vaccines available can prevent transmission.

In a small study, Novavax's vaccine effectively prevented COVID-19 growing in the noses of monkeys. Results in animals often do not translate to humans. But other vaccines have struggled to repeat the achievement; they effectively protect the lungs but still allow the virus to grow in the nose, where it could spread.



A healthcare worker fills a syringe with the AstraZeneca vaccine. PAMPC

While other vaccines quickly moved from phase one to phase three trials and then approval, Novavax's progress has been slower. The company started its key phase three trial on December 28 after several delays due to issues scaling up vaccine manufacture.

Novavax has had a chequered history. Two failed vaccine trials in recent years led to the company's stock plunging; it sacked 100 employees and closed two manufacturing plants. In its near-30-year history it is yet to develop an approved vaccine.

Nevertheless, the company is aiming to produce 2 billion doses of vaccine this year.

Novavax's jab combines traditional and cutting-edge technology. Inside each vial are copies of COVID-19's spike protein – the cellular harpoon it uses to attach to and enter our cells – and a dose of the company's adjuvant. The adjuvant triggers the immune system, which recognises the spike protein and builds antibodies and immune cells capable of defending the body against the virus.

"It's more of a traditional vaccine – the same type we have used for other vaccines we have in use," said Professor Triccas.

Novavax produces the spike proteins using moth cells, and then studs them on a nanoparticle, creating a shape that looks much like the spike-covered virus. In theory, immune cells should be much more likely to spot and attack these nanoparticles, as they look just like little viruses.

The company used similar technology in a flu vaccine it is developing. In a late-stage clinical trial, it produced much stronger antibody results than a current flu vaccine.

Addressing the deaths in Norway, Chief Medical Officer Professor Kelly said on Tuesday: "In a normal week, 400 people do pass away in their aged care facilities.

"In general terms, they were very old, they were frail, some of them were basically terminally ill."

It is not yet clear if the deaths are linked to the vaccine, and Australian experts have already said they are no reason to slow the vaccine's rollout.

Professor Kelly said it was possible Australia's drugs regulator would advise against giving the very elderly and frail the vaccine.

"That is a very tricky balance. We know elderly people, as is the case in Norway, elderly people in aged care facilities are towards the end of their life. We know from our own data from the Australian pandemic, of the 900 people who have died, they have mostly been in the very elderly group, they are of the greatest risk of severe infection," he said.

"The mortality rate is very high once you get over 80 or 90 if you get COVID-19. It's that risk balance equation which the [regulator] will need to do around which people should be excluded from the vaccine."

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