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Novavax firms as third vaccine for Australia

Jill Margo *Health editor*

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Australia's regulator is assessing early data about the Novavax vaccine, which has a high chance of becoming the country's third vaccine against COVID-19.

The Therapeutics Goods Administration in January granted a provisional determination to Biocelect Pty Ltd, on behalf of Novavax Inc.

This meant Novavax was eligible to apply for provisional registration, the first step in the complex and technical assessment process.

Professor Paul Griffin was principal investigator for Novavax's phase one human trials in Australia. **Justin McManus**

While Novavax's phase three trials – conducted mainly in the UK and US – are not complete, interim data is being made available as it emerges.

Interim results suggest it has 95.6 per cent efficacy against COVID-19, dropping to 86 per cent against the UK variant and 49 per cent against the South African variant.

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Should the US vaccine prove safe and effective, Australia has a deal for 51 million doses. While supply cannot be predicted, the Department of Health website says some could arrive in the first half of this year and the complete number within the year.

As a traditional protein vaccine, Novavax is in a different class to the AstraZeneca and Pfizer jabs now in use in Australia.

It is in the same class as the University of Queensland vaccine that was withdrawn last year but has since resumed development. Being traditional, there is confidence in the methodology. Both are expected to require two doses.

Novavax's phase one human trials were conducted exclusively in Australia last year. Paul Griffin, an associate professor at the University of Queensland, was the principal investigator in his capacity as medical director of the Nucleus Network, a company specialising in early trials.

He said the trial was conducted in Melbourne and Brisbane and involved about 120 people. The phase two trials were conducted by other parties in a few sites in Australia and other countries.

"While we obviously have to wait for the full phase three data, the vaccine is

looking to be safe and effective," Professor Griffin said.

"It looks very well tolerated and I think there is a strong chance it will be approved and be in use in Australia later this year."

The vaccine is also being evaluated by the New Zealand government.

A TGA spokesperson said that to expedite COVID-19 vaccines, including Novavax, it was working with rolling submissions, collaborating with international regulators and proactively working with sponsors to evaluate the candidates without compromising the authority's strict standards.

"However, the time frame for each vaccine will ultimately depend on when the complete data package is provided by sponsors to enable the required regulatory processes."

The TGA is part of a network of international regulators that meet regularly to discuss the development of COVID-19 vaccines and systems to monitor them. This, together with the ability to access early data, helps it expedite the evaluation of new vaccines.

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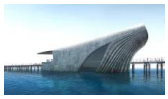

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