

Nucleus Network Begins Recruitment for Phase 2 Trial of Promising Novavax NVX-CoV2373 COVID-19 Vaccine

Nucleus Network, has commenced recruitment of volunteers for the Phase 2 trial of Novavax' COVID-19 vaccine, at its Melbourne and Brisbane clinics in Australia.

MELBOURNE, VICTORIA, AUSTRALIA, August 28, 2020 /EINPresswire.com/ -- Australia's largest Phase 1 Clinical trials specialist, Nucleus Network, has today commenced recruitment of volunteers for the Phase 2 trial of NVX CoV2373, a SARS-CoV-2 Recombinant Spike Protein Nanoparticle vaccine, at its Melbourne and Brisbane clinics.

"Following on from a positive Phase 1 trial that started back in May, Nucleus Network has begun the process of recruiting participants for the Phase 2 COVID-19 vaccine trial in Australia on behalf of Novavax, Inc.," Says Nucleus Network Principal Investigator Dr Paul Griffin. "Novavax is the developer of NVX-CoV2373 and sponsor of the trial, with funding support from the Norway-based Coalition for Epidemic Preparedness Innovations (CEPI), joining the global response to this pandemic.

Dosing will commence in Melbourne on the 2nd of September. The study will comprise of approximately 155



Dr Jason Lickliter Nucleus Network Chief Medical Officer speaking with a participant.



Nucleus Network staff authenticating the dosing.

people will be part of this randomised, placebo-controlled, observer-blinded study, with 125 at the Melbourne clinic, and a further 30 at Nucleus Network's Brisbane facility.

Clinical trials will continue at Nucleus Network's Melbourne facility during the Stage 4 lockdown, with Nucleus Network able to continue operations as part of the Professional, Scientific and Technical services sector. With the Melbourne clinic classified as a permitted workplace, participants will be allowed to travel beyond 5km from their home to participate as a volunteer.



Clinical trial participants.

Participants will initially be screened via phone call, before attending a screening session on the day of dosing. Additional safeguards include temperature screening on arrival, nasal swab tests for all participants, frequent sanitising and cleaning for all staff and participants, increased bed

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Dr Jason Lickliter, Chief Medical Officer at Nucleus Network spacing, wearing of Personal Protective Equipment (PPE) by medical officers, nursing staff and other clinical staff during all participant interactions, and infection prevention and control procedures in line with the Victorian Department of Health and Human Services.

"We appreciate the interest from the general public, and the willingness to continue participating with us in this essential medical research," says Dr Jason Lickliter, Chief Medical Officer at Nucleus Network. "We've had an unprecedented level of interest in participating in a clinical trial for a COVID vaccine, and we hope for this to continue, so we can provide the vaccine developers with the most reliable data on the effects and safety of their vaccine."

NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology and contains Novavax' patented saponin-based Matrix $M^{\text{\tiny{M}}}$ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. This is considered a critical aspect for effective vaccine protection and offers a promising avenue for vaccine development. The results are further detailed in Novavax's announcement from August.

"We expect this Phase 2 portion of the trial to expand on the encouraging Phase 1 safety and immunogenicity data for NVX-CoV2373, and we will now look for robust immune responses in older adults," said Gregory M. Glenn, M.D., President, Research and Development at Novavax. "Our Phase 3 trial of NanoFlu, which we reported in March of 2020, provided us with a deep understanding of the unique needs of older adults, who are particularly vulnerable to COVID-19. We know that the world is closely watching all of these trials, and we anticipate interim data from this trial in the fourth quarter of this year."

"This progression to Phase 2 is an enormously positive event," says Cameron Johnson, CEO of Nucleus Network. "That we are able to progress to Phase 2 almost immediately after Phase 1 without cutting any corners speaks volumes about the collaborative approach between Nucleus Network and Novavax, as well as the contributions from our staff, and the general public's willingness to participate in these vital trials. With the help of all involved, we hope to move through the pandemic as quickly and as safely as possible once a vaccine becomes available."

Joshua Eddy Nucleus Network +61 404446174 email us here

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