



ASX Announcement

Medlab (ASX:MDC) receives UK Ethics favourable opinion for upcoming NanaBis™ P3 Trial. An important step in the NanaBis™ Drug Application

SYDNEY, February 07, 2022 - Medlab Clinical Ltd (ASX:MDC) is pleased to announce the receipt of "Favourable Opinion" status from the UK Research Ethics Committee for the forthcoming NanaBis™ Phase 3 trial, with no additional conditions or submission required.

Prior to this, MDC had announced Australian Ethics acceptance and Clinical Trial Notification (CTN).

Dr Sean Hall, CEO & Managing Director of Medlab said "UK Ethics approval is an important step towards our NanaBis™ P3 trial and we are very happy with the result. We can now move forward with final UK clinical trials approval, at which point we will announce the UK Hospitals and Principal Investigators."

The next steps for Medlab in relation to UK Ethics will be Clinical Trial Approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Medlab's forthcoming Phase 3 trials are cited on:

- ANZCTR: <https://www.anzctr.org.au>
- Clinicaltrials.gov: <https://clinicaltrials.gov>

2021 showed strong progression in the CMC (chemistry, manufacturing, and controls) aspect of the overall new drug application for NanaBis™.

Drug Master Files for both synthetic CBD and THC are now recognised at the Food and Drug Administration (FDA). All packaging and manufacturing compounds used have been upgraded to an *approved* standard and scalable manufacturing processes and subsequent write-ups to support the CMC package are well underway.

Five US sites have indicated their interest in Phase 3 participation and site agreements, and near future ethics requirements for each site are underway.

Medlab plans to start Phase 3 trials with approximately 120 patients in each Australia, UK & USA.

About NanaBis™

NanaBis™ is a viable, globally patented non-opioid analgesic designed to treat cancer and non-cancer bone pain. NanaBis™ is scientifically optimised to use a 1 to 1 ratio of THC and CBD and is enhanced by the NanoCelle® drug delivery platform for intra-oral (buccal) spray formulations.

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Authorisation & Additional information

This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

About Medlab Clinical:

Medlab Clinical Ltd (ASX:MDC) is pioneering the development and commercialisation of a delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab's pipeline comprises a number of small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies.

Patented lead drug candidate NanaBis™ has been developed for cancer bone pain as a viable alternative to opioid use. Data to date, strongly suggests NanaBis™ may be equally effective in non-cancer neuropathic pain.

NanoCelle®, the patented delivery platform is wholly owned by Medlab and developed in Medlab's owned OGTR Registered Laboratory. Medlab operates in Australia (Head Office), USA, and the UK. For more information, please visit www.medlab.co

Medlab – *better medicines, better patient care*

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