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## **Medlab to prioritise synthetic formulation of lead candidate in pending global Phase III non-opioid cancer bone pain trial**

### **Key points:**

- **Positioned to provide a solution to global opioid addiction crisis**
- **Move to synthetic formulation based on regulatory guidance**
- **Significant regulatory, manufacturing and quality control advantages**
- **Synthetic CBD and THC preferred by global regulators over botanical extracts**
- **Approach potentially faster path to market**
- **Botanical formulations continue to play major role in multiple Medlab products**

**SYDNEY Australia: 20 May 2021:** Medlab Clinical Limited (ASX: MDC), the Australian company commercialising an enhanced drug delivery platform to maximise the efficacy of medicines, today announced its Phase III clinical trial will use a synthetic cannabinoid formulation for its lead non-opioid pain relief candidate, NanaBis™.

Medlab Clinical CEO Dr Sean Hall said, “Our clinical work over the past year has recently revealed a synthetic formulation will allow us to more closely control product development variables that could otherwise impact the manufacture and delivery of a pharmaceutical product at scale over a botanical formulation.”

Medlab continues to develop therapies based on natural plant extracts for other indications.

Based upon feedback from a number of regulators, including the U.S. FDA, Medlab believes that a synthetic pharmaceutical-grade formulation of NanaBis™ would be preferred over a botanical formulation, which allows for greater product control from downscale development activities through to manufacturing.

Synthetic formulation will allow Medlab to produce NanaBis™ at an industrial scale to the highest quality and consistency. This is a challenge if we need to rely on botanical extracts which, by their very nature and reproductive patterns, have multiple variations and well-documented purity issues.

The most aggressive path to market for Medlab is via a biosynthetic manufacturing process that can produce high-quality cannabinoids for major unmet medical needs and the multi-billion-dollar global markets we are targeting such as bone cancer pain and non-opioid pain alternatives.

Dr Hall said, “the company would refile its IND to reflect the new formulation which would deliver improved control over costs, certainty of supply, higher levels of purity, manufacturing, and a well-established regulatory pathway.”

“We have recently produced our first batch of synthetic CBD and THC. Synthetic CBD now has a US FDA recognised Drug Master File and Medlab is working to submit a Drug Master File to the FDA for a 100 per cent synthetic THC known as a neat dronabinol,” he said.

Research and evaluations performed to date have demonstrated that NanaBis™ is a fast-acting viable alternative to opioids, improving pain management and quality of life. As cancer survival rates increase, so does the need for better approaches to address long-term pain often experienced by patients.

Medlab’s Phase III clinical trial in 360 patients with cancer bone pain will seek to demonstrate patients treated with NanaBis™ have a higher response rate after six weeks compared to patients in the placebo group.

## **ENDS**

### **Authorisation & Additional information**

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

### **For further information contact:**

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### **About Medlab – [www.medlab.co](http://www.medlab.co)**

Medlab Clinical Limited is pioneering the development and commercialisation of a delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. its pipeline comprises of small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies. Medlab’s 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 Clinical and developed in Medlab’s owned OGTR Registered Laboratory. NanoCelle® is designed to address known medication problems, addressing global unmet medical needs. Medlab operates in Australia (Head Office), USA, and the UK. Details about the NanaBis™ clinical trials can be found at [clinicaltrials.gov](https://clinicaltrials.gov) and searching for the clinical trial identifier NCT04808531.