



11 November 2020

Company Announcements Office  
Australian Securities Exchange  
Exchange Centre  
20 Bridge Street  
Sydney, NSW 2000

## **IMPORTANT NANABIS™ PROGRESSION**

### **NANABIS™ PHASE III TRIAL LAUNCHING IN THE UK WITH SUPPORT FROM THE NATIONAL INSTITUTE FOR HEALTH RESEARCH**

Medlab Clinical (ASX.MDC) a company with a portfolio of novel drug candidates enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, is pleased to announce that the NanaBis™ PIII cancer bone pain trial has been accepted onto the National Institute for Health Research (NIHR) portfolio to receive support in the set-up, recruitment and delivery of the UK arm of the trial.

Medlab is pursuing a differentiated path to market for its medicinal cannabis products, undertaking comprehensive clinical trials and pursuing global opportunities, commencing with regulatory clearance from the US Food and Drug Administration. The company is currently preparing to file an Investigational New Drug (IND) with the FDA in late 2020, and initiate a pivotal Phase III study in Australia, the USA and the UK.

Dr Sean Hall, CEO of Medlab, said the company was delighted to access the support services of the NIHR, one of the world's leading organisations delivering clinical research, to further investigate the clinical efficacy of NanaBis™.

“As use of medicinal cannabis increases under various compassionate use schemes, there is growing interest from clinicians and regulators to see clinical evidence to support claims and ensure patients can have access to validated products that have proven efficacy, safety and tolerability.

“Medlab has one of the most clinically advanced medicinal cannabis treatments for pain and this is generating significant interest in the global investment and medical communities. We have a highly purified cannabinoid that has been scientifically optimised to improve performance, with the potential to provide a much-needed alternative to opioid treatment for cancer-related pain.”

It is expected that two UK sites will participate in the trial, with site feasibility near completion. Additional sites in the US will be managed by George Clinical, while Medlab's internal clinical trial team will oversee the Australian sites.

NanaBis™ comprises of CBD:THC (cannabis-based medicine) for the treatment of cancer-induced bone pain. The Phase III trial will target bone pain in cancer patients for its first indication, with the possibility to expand the market opportunity into all cancer-related pain following regulatory clearance.

The current standard of treatment for cancer-induced bone pain is opioids. There is a high unmet need for a non-opioid alternative that is safer and more effective. The Phase I/IIa trial of NanaBis™ met its primary and secondary endpoints, delivering a 40% reduction in pain and reduced dosage of opioids together with strong quality of life outcomes. These results are being replicated in a Therapeutics Goods Administration (TGA) approved real-world observation study that is currently underway. NanaBis™ is currently available to patients in Australia under the TGA's Special Access Scheme.

## ENDS

### Authorisation & Additional information

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

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

Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and the United States. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, NanoCelle™ is being applied to its medicines, nutritional products and off-patent drugs like statins, Medlab has a growing patent portfolio.

### About the NIHR - [www.nihr.ac.uk](http://www.nihr.ac.uk)

The National Institute for Health Research (NIHR) is the UK's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy

The NIHR was established in 2006 to improve the health and wealth of the UK through research, and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR supports applied health research for the direct and primary benefit of people in low- and middle-income countries, using UK aid from the UK government.

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