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

US FDA GRANTS INVESTIGATIONAL NEW DRUG (IND) STATUS FOR NANABIS™

Allows NanaBis™ Phase III clinical trial to launch in US, joining UK and Australia.

- **NanaBis™ granted US FDA IND approval**
- **Other INDs to follow**

Medlab Clinical (ASX.MDC) a company with a portfolio of novel pharmaceutical candidates enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, is pleased to announce the US Food and Drug Administration (FDA) has granted clinical Investigational New Drug (IND) status for its lead candidate NanaBis™. The approval allows Medlab to initiate its pivotal Phase III trial at US sites and is an important validation of the strong safety and efficacy data supporting the NanaBis™ program.

NanaBis™ comprises of CBD:THC (cannabis-based medicine) formulation optimised by Medlab's proprietary delivery platform, NanoCelle®. The Phase III trial will investigate NanaBis™ as a monotherapy for the most common type of cancer pain, metastatic cancer-induced bone pain (CIBP) [i] , as its first indication, with the possibility to expand the market opportunity to all cancer-related pain following regulatory clearance. Currently, NanaBis™ is the only cannabinoid-based pharmaceutical under development for cancer pain initiating Phase III trials in the US.

The current standard of treatment for cancer-related bone pain includes opioids, which have shown to be ineffective in many cases. There is a high unmet need for a non-opioid pain alternative that is safer and more effective.

The IND grant submission to the FDA includes robust data generated from the Company's Phase I/II trial which was completed in March 2020 and met its primary and secondary endpoints. Also included was supporting data from Medlab's real world observational study, which is presently showing a 55% reduction in pain together with improved quality of life outcomes.

With this acceptance, the US joins the UK and Australia as approved Phase III trial jurisdictions. In the UK, the National Institute of Health Research (NIHR), one of the world's leading healthcare research organisations, announced its support as a strategic stakeholder in the UK arm of NanaBis™ Phase III trials.

In upcoming months, the granting of IND status will see:

- Lodgement Medlab's Phase III clinical trial to clinicaltrials.gov
- FDA and Drug Enforcement Administration (DEA) release scheduling recommendations for NanaBis™
- DEA is expected approve NanaBis™ for shipping to the US in preparation for the trial to commence
- First introduction of NanaBis™ into US market

Medlab Clinical Managing Director, Dr Sean Hall said, "Receiving clinical IND status is a major milestone for our NanaBis™ program and a recognition of the robust clinical and real-world data backing NanaBis™ for cancer bone pain. We have now received clearance in the US, UK and Australia to commence clinical entry and are making preparations for study initiation later this year. A successful Phase III trial could see NanaBis™ as the first cannabis-based pharmaceutical containing THC in the United States."

In the US, the Company has made a second IND submission for Expanded Access, which if successful, will enable compassionate use sales in the US to commence.

Investor webcast scheduled

Medlab Clinical Managing Director and CEO Dr Sean Hall will host a webcast and Q&A with investors today, Tuesday 19 January 2021 at 3:00PM AEDT. The webcast will discuss the importance of IND acceptance and Medlab's upcoming Phase III trial plans. Webcast slides have been released separately to the ASX.

Investors are invited to register for the webcast at the following link:
http://www.medlab.co/asx

Registered participants will receive a confirmation email containing the Zoom access link and alternative phone dial-in details.

ENDS

Authorisation & Additional information
This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

About Medlab – 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, and depression as well as earning revenue from sale of nutritional products in Australia and overseas. 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 pharmaceuticals like statins, Medlab has a growing patent portfolio.

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[i] Mucke M, et al. Cannabis-based medicines for chronic neuropathic pain in adults. The Cochrane database of systematic reviews 2018;