



## **ASX Announcement**

### **NanaBis™ independently confirmed to have double the bioavailability of ARTG approved oral cannabis spray.**

**SYDNEY, JUNE 27, 2022** – Medlab Clinical Ltd (ASX:MDC) (Medlab, the Company), an Australian biotech using nano-particle delivery technology to enhance medicines' effectiveness, is pleased to update shareholders on the progress of our NanoCelle® NanaBis™ program.

**Researchers at the School of Pharmacy and Medical Sciences at University of South Australia have independently confirmed that NanaBis™ has two times more bioavailability than an ARTG (Australian Register of Therapeutic Goods) approved oral cannabis (CBD and THC) medicine.**

This research was conducted using a Population pharmacokinetics (PopPK) study, which examines the variability in drug concentrations within a patient population receiving clinically relevant doses of a drug of interest. PopPK methods use mathematical models to describe PK data and draw conclusions.

Bioavailability is a key indicator of drug absorption and refers to the extent and rate at which the active moiety (drug or metabolite) is absorbed from a drug product and successfully enters systemic circulation, thereby accessing the site of action.

The NanoCelle® delivery platform is a patented chemical construct that uses approved (FDA) compounds for the creation of standardised nanoparticles. Prior work demonstrated a five times bioavailability to other ingested (swallowed) medicines.

NanoCelle® represents a central technology that we employ in all primary and secondary drug development programs:

#### **PRIMARY Drug Development:**

1. NANABIS™, cannabinoids (THC & CBD) with FDA recognised API Drug Master Files (DMFs) for proposed indication of Cancer Bone Pain (Bone METs), with line of sight on benefiting larger neuropathic pain populations.

#### **SECONDARY Drug Development:**

2. NANOCBD™, cannabinoid (CBD) with a FDA recognised API DMF for proposed indication of Occupational Stress, with line of sight on benefiting mild, chronic pain populations.
3. MDC2000, proposed FDA 505(b)(2) program using an earlier, approved drug substance for Depression for proposed indication of Major Depressive Disorders.



4. NASAL RNA, Nucleic Acid collaboration with Woolcock Institute at Macquarie University and University of New South Wales in pre-clinical stages for a nasal vaccine delivery utilising nucleic acid, leading to new vaccine and/or anti-viral technologies.

#### **About NanaBis™**

NanaBis™ is scientifically optimised to use a 1 to 1 ratio of THC and CBD and is enhanced by Medlab's proprietary nano-particle drug delivery technology, NanoCelle® for intra-oral (buccal) spray formulations. NanoCelle® provides quicker onset and superior bioavailability than tablets, sublingual emulsions, and liposomes at equivalent doses.

As previously announced (9 March 2020), NanaBis met both primary and secondary endpoints in the advanced cancer pain trial at Royal North Shore Hospital and has now received Australian and UK ethics approvals for phase 3 trials.

#### **NanaBis™ currently has two variants:**

1. A botanical construct currently available for compassionate use under the Australian Special Access Scheme (SAS), and ...
2. A fully characterised synthetic construct which will be used in future clinical trials.

During the course of last year, the two drug substances in the synthetic construct of NanaBis™ (being synthetic CBD and THC) completed Drug Master File (DMF) recognition with the US FDA. The FDA has indicated a preference for synthetic versions of these compounds due to inherent advantages for purity control and significantly reduced inter-batch variance.

- ENDS -

#### **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 technology, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability.

Medlab's pipeline comprises several small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies.

NanoCelle®, the patented delivery platform is wholly owned by Medlab 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.

For more information, please visit [www.medlab.co](http://www.medlab.co)

**Medlab** – *better medicines, better patient care*

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**Glossary**

Abbreviation	Meaning
API	Active Pharmaceutical Ingredient
ARTG	Australian Register of Therapeutic Goods
ASX	Australian Stock Exchange
CBD	Cannabidiol
CMC	Chemicals, Manufacturing and Controls
DMF	Drug Master File
FDA	Food and Drug Administration
FDA 505(b)(2)	Specific streamlined and abbreviated new drug application process
TGA	Therapeutic Goods Administration
THC	Tetrahydrocannabinol