ASX and MEDIA Announcement

CLINICAL DEVELOPMENT FOR NANABIS™ AND NANOCBD™ UPDATE

Sydney, September 16, 2022 - Medlab Clinical Ltd (ASX:MDC) (Medlab, the Company), an Australian biotech using delivery technology to enhance medicines effectiveness, is pleased to announce that it has been granted the required regulatory approvals (human research ethics and clinical trial registration) for undertaking observational clinical trials of NanaBis™ and NanoCBD™ to gather information on side effects and treatment success over a long-time frame.

This is now implemented in a bid to accelerate necessary information, with two new studies approved. Please refer to the Appendix below for further information on the details of the two studies and approvals.

Our current observational study, which now has approximately 1,200 patients, demonstrated positive tolerability in relation to:

- Use with important cancer therapies
- Co-prescribed tolerance and efficacy
- Pain reduction and sustainable improvement in quality of life
- Overall medication reductions

The new studies are designed to elicit adverse event information, dosing verses outcomes and ongoing cognitive assessment.

Dr Jeremy Henson, Director of Research at Medlab said, “These studies will provide a wealth of data for supporting registration and also facilitate valuable engagement with prescribers, consumers and key opinion leaders”

- 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.

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.

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

Medlab – *better medicines, better patient care*

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APPENDIX: CLINICAL DEVELOPMENT FURTHER DETAILS

Australian Ethics approval and Clinical Trial Notification for two new Real-World Evidence (RWE) studies focusing on key endpoints, accelerating the company's knowledge on the use of NanaBis™ or NanoCBD™ in key patient groups with existing prescribed medicines, allowing a heightened understanding of medication contra-indication, adverse events, side effects and health impact.

Historical learnings from the current NanaBis™ Observational study across circa ~1,200 Australian patients demonstrated key data points across a wide range of patients. These included:

- Non-serious adverse events profile of 12.3% and a serious adverse reaction profile of 1.3%
- Use with/without "checkpoint inhibitors", second line but important cancer therapies.
- Dosing models for tolerance and efficacy, including when co-prescribed
- Strong trend lines for pain reduction and improvements in quality of life demonstrating sustainability over time periods of 6 and 12 months.
- Overall medication reduction sustainable over same time periods.

The two new studies which are expected to start recruiting in the next few months, are:

New Australian NanaBis™ Observation study:

Human Research Ethics Committee (HREC) approval: NIIM HREC Reference number: 0109E_2022
Project title: Observational Study of the Safety, Tolerability and Efficacy of Tetrahydrocannabinol-Cannabidiol Oro-buccal Sprays, MC-1019 and MC-1022
Australian New Zealand Clinical Trials Registry (ANZCTR) registration: https://www.anzctr.org.au/ACTRN12622001133729.aspx
Australian Clinical Trial Registration Number: ACTRN12622001133729
Study duration: 2 years, N=1000, participants 18 years or older
Primary endpoint: The incidence, type, and severity of adverse events for the entire cohort and among subgroups.
Secondary endpoints: (i) efficacy for treating the indication and improving the quality of life (ii) patterns of NanaBis™ use (iii) change in the use of other medications.

Australian NanoCBD™ Observation Study:

Human Research Ethics Committee (HREC) approval: NIIM HREC Reference number: 0104E_2022
Project title: Observational Study of the Safety, Tolerability and Efficacy of Cannabidiol (CBD) Oro-buccal Sprays for Treating Pain and/or Stress
Australian New Zealand Clinical Trials Registry (ANZCTR) registration: https://www.anzctr.org.au/ACTRN12622001137785.aspx
Australian Clinical Trial Registration Number: ACTRN12622001137785
Study duration: 5 years (max 2 years per participant), N=2000, participants 18 years or older
Primary endpoint: The incidence, type, and severity of adverse events for the entire cohort and among subgroups.
Secondary endpoints: (i) efficacy for treating the indication and improving the quality of life (ii) patterns of NanoCBD™ use (iii) change in the use of other medications.

Dr Sean Hall, CEO at Medlab said, "Both studies are designed to closely reflect data points typical to a Phase 4 study, with stronger focus on eliciting adverse event information, dosing versus outcome and ongoing cognitive assessment, and expansion of our longitudinal data."

Data from both studies will be combined with data obtained from a compatible clinical trial run by Medlab in the United Kingdom (UK), which is currently in the initial stages of UK clinical trial registration.

About Phase 4 Studies
A type of clinical trial that studies the side effects caused over time by a new treatment after it has been approved and is in the market or in compassionate use. These trials look for side effects that were not seen in earlier trials and may also study how well a new treatment works over a long period of time. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-iv-clinical-trial

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