ASX and MEDIA Announcement

MEDLAB ANNOUNCES FAVOURABLE INTERIM READOUT OF NANABIS™ REAL-WORLD EVIDENCE (RWE) MEDCARE STUDY

- **N=1,172 Australian pain patients**
- **Datapoints collected from commencing NanaBis™ (baseline) up to month 12**
- **55% improvement in pain relief**
- **75% of patients reduced their opioid use**
- **31% Improvements in Quality of Life as it relates to pain interference**
- **92% of patients with bone metastasis from cancer had reduced their pain severity and pain interference (Quality of Life) scores at 6-months**
- **New "ENHANCE" study expects to onboard March 2023**

Sydney, January 12, 2023 - Medlab Clinical Ltd (ASX:MDC) (Medlab, the Company) is very pleased to announce interim readouts of its Medcare Observational Study, Human Research Ethic Committee (HREC) number 005E_2019, titled "*An observational study investigating and auditing the safety, tolerability and further efficacy characteristics of a pharmaceutical-grade cannabis medicine (NanaBis™) that is currently or will be prescribed to eligible patients for the management of cancer-related and non-cancer related pain in general and speciality medical practices.*"

By way of summary, 244 doctors attended 1,172 Australian patients and collected data monthly from the start of the study (baseline) to a maximum of 12 months, as appropriate to the patient and their disease condition.

Patients and Doctors were consented into a long-term real-world program with the following outcomes:

Primary Outcomes:

- The collection of Adverse Events/Serious Adverse Event that may occur
- Patient withdrawal and reason
- Indication and dosage capture and subsequent changes

Secondary Outcomes:

- Efficacy in treating pain and quality of life (BPI-SF and SF-12)
- Concomitant medications and changes thereof
- Rationale for dosage/treatment changes

The average duration of NanaBis™ treatment under this study was 5.4 months (95% confidence interval [CI], 5.1-5.6 months), with at least 77 patients continuing to receive NanaBis™ post study completion. The female to male ratio was 3:2, with the 36-55 years old and 56-70 years old age ranges comprising 32.5% and 26.0% of all patients, respectively, and representing the two major age segments in the study.

Of the study group:

- 98.5% had chronic pain, 1.5% had acute pain
- 85% had non-cancer pain and 15% had cancer pain
- 55% had a neuropathic component

Pain Severity[1] reduction profiles (Brief Pain Inventory) across the study group showed an average pain reduction of 23% (95% CI, 16-30%; p<0.0001) after 6-months of NanaBis™ treatment, and a 27% (95% CI, 17-37%; p<0.0001) average pain reduction at the 12-month time point. Patients reported a 55% (95% CI, 36-74%; p<0.00001) improvement in Pain Relief[2] after 6 months of NanaBis™ treatment, which was a significantly larger improvement than the 23% reduction in Pain Severity (p = 0.001). This could be due to patients increasing activity levels and reducing opioid use because of NanaBis™ treatment[3]. The cancer-pain patient subgroup showed an average Pain Severity reduction of 25% (95% CI, 9-41%), 33% (95% CI, 9-57%), 24% (95% CI, 2-46%) and 31% (95% CI, 2-58%) after 1, 3, 6 and 9 months of NanaBis™ treatment and a 49% (95% CI, 20-78%) average Pain Severity reduction at the 12-month timepoint.

Opioid sparing was demonstrated when NanaBis treatment was given to patients already treated with opioids. Of these patients, 75% were able to decrease opioid use and 60% reduced their opioid use by more than 50%.

Quality of Life (QoL) improvements were reported, specifically in general activity, walking, work, enjoyment of life, sleep, mood, and personal relationships as it relates to pain interference with an average 31% (95% CI, 23-38%) improvement at 6 months.

In the bone metastasis cancer pain subgroup, 92% of these patients individually improved their pain severity and pain interference (Quality of Life) scores after 6 months of NanaBis™ treatment. This validates the improvements found with average pain severity and average Quality of Life scores in this group, which were 26% improvement (95% CI, 1-52%; p = 0.022) and 34% improvement (95% CI, 4-63%; p=0.016) after six months, respectively.

Median dosage was six sprays per day.

Overall, 454 patients withdrew from the study, of which the largest group 33% were lost to follow-up. Only 12.4% of patients experienced a non-serious adverse reaction and 1.3% experienced a serious adverse reaction.

Dr Sean Hall, CEO of Medlab stated, “The value of RWE, if done right cannot be under-estimated, this study demonstrated quantifiable sustainability. It is encouraging to see both patients and prescribers wanting to continue past the 12-month mark, to which we saw similar in the Royal North Shore Hospital trial with advanced cancer, pain patients. In all the interim data demonstrates a good safety, tolerability, and sustainability profile for NanaBis™.”

Dr Jeremy Henson, Director of Research stated, “It is invaluable for us to get data on the real-world use of NanaBis™ from a large number of patients and doctors. These results have confirmed that NanaBis™ provides a safe and tolerable option for pain relief and reduced pain simultaneous with allowing reduced opioid use and increased patient activity. I was especially encouraged that cancer bone metastasis patients, continued to report above average efficacy, which gives us confidence that our pivotal Phase III clinical trial will be a success.”

Next Steps, the Medcare study will relaunch in about March 2023 as the ENHANCE Study, more streamlined and focused on specific data we are wanting to gather. Secondly, July 2023 is approximately when the full readout of this Medcare study is expected.

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NanaBis™ is an investigative novel analgesic for cancer patients comprising equal parts of CBD and THC encapsulated in Medlab's patented delivery platform, NanoCelle®. NanaBis™ is a low dose cannabinoid-based medicine applied to the oro-buccal membrane (interior of the check) for rapid uptake whilst bypassing 1st pass metabolism, thus avoid gastrointestinal degradation and reduced viability of the drug substance.

Footnotes

[1]Brief Pain Inventory (BPI) Pain Severity was an average of the response to four questions: rate your pain in the last 24 hours at its (i) worst (ii) least and (iii) average and (iv) rate your pain right now.
[2]BPI Improvement in Pain Relief is based on the response to the question "In the past 24 hours, how much pain relief have pain treatments or medications provided?"
[3]A new pain medication can improve pain relief but not improve pain severity to the same extent, if it simultaneously results in a reduction in opioid use and an increase in activity, both of which tend to increase pain severity counteracting the pain relief provided by the new pain medication.

- 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 use of **NanoCelle®** a proprietary, patented delivery technology using water soluble nanoparticles®, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab's investigative drug pipeline comprises several small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies. Patented lead drug candidate **NanaBis™** is being 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. 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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