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

NANABIS™ OBSERVATIONAL STUDY PROGRESS UPDATE

Third Monitoring Report completed – encouraging results consistent with March 2020 RNSH clinical trial findings

HIGHLIGHTS:

- Third monitoring report shows 59.5% reported reduction in pain (unadjusted), based on average dose of four sprays per day
- 12 month observational study for collection of real-world evidence
- 432 of 2000 patients enrolled since study commenced in early 2020
- Observational data showing consistency with earlier clinical trial completed at Royal Sydney North Shore Hospital

Medlab Clinical (ASX.MDC) a company with a portfolio of novel drug candidates, including cannabinoids and nutraceuticals, enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, reports positive data from the ongoing observational study of NanaBis™, which is being developed as non-opioid alternative for the treatment of cancer-induced bone pain.

The study (HREC Approval ID: H0052E_2019) which was formally launched 2020 has now enrolled 432 of a target 2000 patients (21.6%), of these 15% in cancer-related pain and 85% in non-cancer related pain. 59% of patients enrolled in the study to date are female (vs 41% male), with an age range between 20 to 80+ years.

Data from the third monitoring report shows that patients are averaging a dosage of four sprays of NanaBis™ per day, corresponding to a 59.5% reported reduction in pain (unadjusted). NanaBis™ is the company's lead drug candidate, a 1:1 formulation of Delta-9-Tetrahydrocannabinol (THC) and cannabidiol (CBD), that has been optimized via the company's drug delivery platform NanoCelle®.

Importantly, this is consistent with the findings from the Royal North Shore Hospital clinical trial completed in March 2020, which showed pain score improvement, reduction in morphine equivalents, safety and tolerability as well as notable quality of life score improvements.

Medlab CEO Dr Sean Hall commented, "It is significant that the body of evidence on the safety, tolerability and efficacy of NanaBis™ is growing. We are looking to formally submit our multi-centred Phase III trials protocol to the US, UK and Australian regulatory authorities this calendar year. The confirmation of the performance of our product through these real world trials encourages us to continue to push ahead aggressively with our ultimate objective of a drug registration for NanaBis™."

Purpose of the Observational Study

The express purpose of the Observational Study is to provide Real World Evidence (RWE). With a body of clinical and real world evidence in hand, it is expected that the total number of patients required in clinical trials required for the regulatory approval for NanaBis™ could be reduced, thus possibly reducing the time, cost and duration of clinical trials required for approval. The observational study was initiated following discussions with the US Food and Drug Administration (FDA) regarding the pathway to regulatory approval.

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As the study is being conducted in Australia it is subject to the TGA Special Access Scheme (SAS) for non-approved drugs and allows doctors to prescribe the drugs at a compassionate price. Under this scheme, patients (and their doctors) are obligated to provide formal feedback on the efficacy of the product, which Medlab is able to use to bolster its eventual drug approval submissions.

Medlab sees the commitment to clinical trials an essential element of differentiating its products and most especially delivering the scientific/clinical evidence of cannabis based medicines, which is universally lacking and needed more than ever as the market for cannabis derived products grows substantially on a global basis.

Patients are currently paying a compassionate rate for access to NanaBis™ via the observational study and the number of SAS applications via the observational study continue to grow.

Dr Hall said, “The findings of the OBS study and the consistent results across our clinical trials for NanaBis™ are highly encouraging, in light of our goal to give cancer patients a more effective alternative to manage pain and to achieve regulatory approval and ensure this is widely available to all patients in need.

“Furthermore, with our new manufacturing agreement with Tasmanian Alkaloids (TasAlk) we are able to ensure sufficient supply to support the study and support the continued strong momentum of enrolment. Lastly, due to recent economies of scale, NanaBis™ is expecting a price reduction in the immediate future.”

In accordance with CTN guidelines, the OBS Study is listed on the Australian and New Zealand Clinical Trials Registry: <http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=376913&isReview=true>.

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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, 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.

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