30 November 2020

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

NanaBis™: Progress update on Observational Study and Phase III trial preparations

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, is pleased to provide a progress update on the ongoing 12 month observation study of NanaBis™, a cannabinoid treatment for cancer-induced bone pain and its progress towards a global Phase III study to commence in 2021.

Highlight:

- Observation study shows positive results across all criteria to date
    - Pain reduction on average remains consistent to prior NanaBis™ discovery (55%) with reports indicating significant improvements in specific quality of life outcomes such as "general activities", "sleep" and "mood"
- Observational study now 33.5% (668 participants) recruited
- Phase III trial launch on track with pre-IND submission now completed

Observation study update: Positive results across all criteria

Consistent with the previous update and the results from the earlier Phase I/II study undertaken at the Royal North Shore Hospital, the fourth monitoring report on the 12 month observational study of NanaBis™ has demonstrated a 55% reduction in pain scores. The study report is also indicating significant improvements in specific quality of life outcomes such as "general activities", "sleep" and "mood".

The study (HREC Approval ID: H0052E_2019) which was formally launched in 2020 has now enrolled 668 participants from a target of 2,000 (33.5% recruited), of these 16% of participants are in cancer-related pain and 84% are in non-cancer related pain. Of those with cancer-related pain, 3% have cancer bone pain. 99% of participants have chronic pain and 1% have acute pain.

NanaBis™ is a highly purified blend of THC:CBD, which has been optimised for use at sub-micron (nano-sized) doses using Medlab's proprietary drug delivery platform, NanoCelle®. It is being developed as non-opioid alternative for the treatment of cancer-induced bone pain.

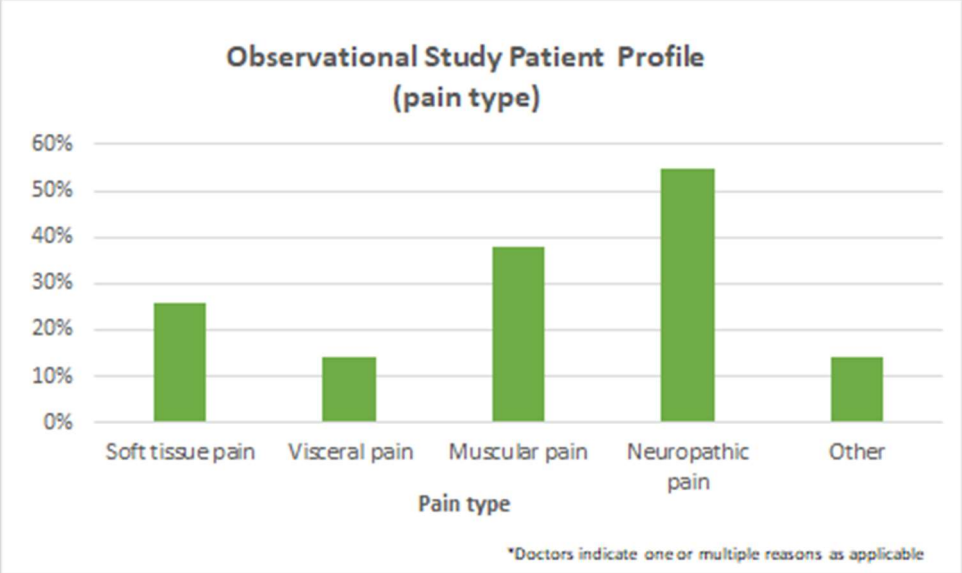
The purpose of the Observational Study is to provide Real World Evidence (RWE). With a body of clinical and real world evidence in hand, it is expected that the total number of patients required in clinical trials required for the regulatory approval for NanaBis™ could be reduced, thus possibly reducing 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.

Dr Sean Hall, Managing Director of Medlab Clinical said, "We continue to be encouraged by the pace of enrolment in the study and the positive results, which are consistent with our existing clinical data. Not only does the study help us to build a base of prescribers and patients for NanaBis™ who can access this drug under Special Access Scheme, it supports our ultimate goal of achieving US regulatory approval for NanaBis™ as a treatment for cancer-induced bone pain.

"There is an urgent need to provide a viable alternative to opioids for the treatment of cancer-related pain – and ultimately chronic pain in general. The strong body of evidence we are collecting, the scientific quality of our

product and the progress we are making towards a global Phase III study differentiates us from other medicinal cannabis plays."

Of the 668 patients enrolled in the study to date 59% are female (vs 41% male), with an age range 21-99 years. The graph below shows the patient profile by pain type.



59% of patients enrolled in the study to date are female (vs 41% male), with an age range 21-99 years.

Phase III Trial update: Pre-IND submission complete

Medlab continues to progress key activities required ahead of initiation of a global Phase III study in 2021.

The company has prepared the first of its Investigational New Drug (IND) submissions to the US Food and Drug Administration (FDA), for approval of NanaBis™ use in connection to the study. This submission has been prepared taking into account feedback from ongoing dialogue with the FDA.

"Acceptance of the IND(s) will be important milestones, enabling us to move forward with the study but also providing validation from the regulator of the merit of our safety, quality and clinical data collected to date," concluded Dr Sean Hall.

The company anticipates several IND approvals, allowing for both compassionate US use and clinical investigation.

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, depression and obesity as well as earning revenue from sale of nutritional products in Australia and other global territories. 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.

For further information contact:

Dr Sean Hall, CEO Medlab Clinical T: + 61 2 8203 9520 – sean_hall@medlab.co	Kyahn Williamson, WE Communications T: + 61 0401018828 - kwilliamson@we-worldwide.com