



ASX & MEDIA RELEASE

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ROYAL NORTH SHORE HOSPITAL NANABIS™ ADVANCED CANCER TRIAL RESULTS

Medlab Clinical Ltd (ASX: MDC) is extremely pleased to announce it has received the results from an Independent Reviewer for the NanaBis™ advanced cancer pain trial conducted at the Royal North Shore Hospital (RNSH) with Principal Investigator Professor Stephen Clarke.

The clinical trial was a Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) investigation into pain management of patients with metastatic cancers (n = 30). The trial was Ethics approved by the Kolling Institute and given a Clinical Trial Number (CTN) by the Australian Federal Government. The Trial was listed in accordance to CTN guidelines on the Australian New Zealand Clinical Trial Registry (ANZCTR) under:

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371985&isReview=true>

Primary Endpoints Met:

- NanaBis™ is safe.
- NanaBis™ is tolerable. Dosage tolerance achieved at 60% of maximum dosage.
- NanaBis™ is efficacious.
- Adverse Events were predominantly mild or moderate and expected.
- NanaBis™ is demonstrated to be fast acting as it showed time to with maximum concentration in serum to be 54 minutes.
- Improvements in Quality of Life (QoL) measures, specific in role and emotional functioning and insomnia.

Secondary Endpoints Met:

- Total cohort had meaningful pain reduction, a specific patient subset being breast or prostate cancers with bone metastasis had an average of 40% improvement in pain scores from baseline.
- Breast or prostate cancers with bone metastasis showed significantly less Morphine Milliequivalent (MMEq) of dispensed opioid analgesics prescribed, than the remaining cohort (see MMEq table below).
- No change in number of rescue medication doses during the course of the Trial.

NanaBis™ is a 1:1 purified, standardised blend of CBD and THC in MDC's proprietary delivery platform, NanoCelle™, manufactured and full drug release at Tasmanian Alkaloids as recently announced.

The trial was designed to accelerate the traditional phased trial pathway through typical Phase 1 and Phase 2 programmes.

The result is a robust trial that has delivered strong results allowing MDC to focus on Phase 3 designs, specifically in the patient group with metastatic bone pain where breast or prostate are the primary cancers.

Metastatic breast or prostate cancers have a high unmet need with conservative 2017 numbers suggesting 600,000 patients in USA, Canada, Europe and Australia.

Since the completion of the Trial, the majority of patients have elected and approved by Professor Stephen Clarke to continue on NanaBis™ (free of charge) post Trial.

Dr Sean Hall, CEO of MDC states, “with a strong trial design, that involved a professional and strong clinical trial team and collaborators, today we have primary evidence that NanaBis™ is safe, tolerable and provided a significant benefit in managing pain associated with metastatic cancers. There were a number of notable secondary gains, one of the biggest worth mentioning was a drastic reduction of breakthrough medication used by those patients with breast or prostate cancers with bone METs.”

“We can confidently argue, NanaBis™ has a strong indication for use in pain management and is a compelling therapy for this patient group,” Dr Hall added.

Professor Luis Vitetta, Director of Medical Research at MDC states, “the completion of Medlab’s SAD/MAD clinical study with NanaBis™ in advanced cancer pain management has proven safe. Furthermore, the results relevant to pain management provides information that allows progression to the next phase of NanaBis™’ development. The design of a robust Phase 3 clinical study and it’s successful completion will advance the path toward registration for NanaBis™, as an alternative analgesic medication.”

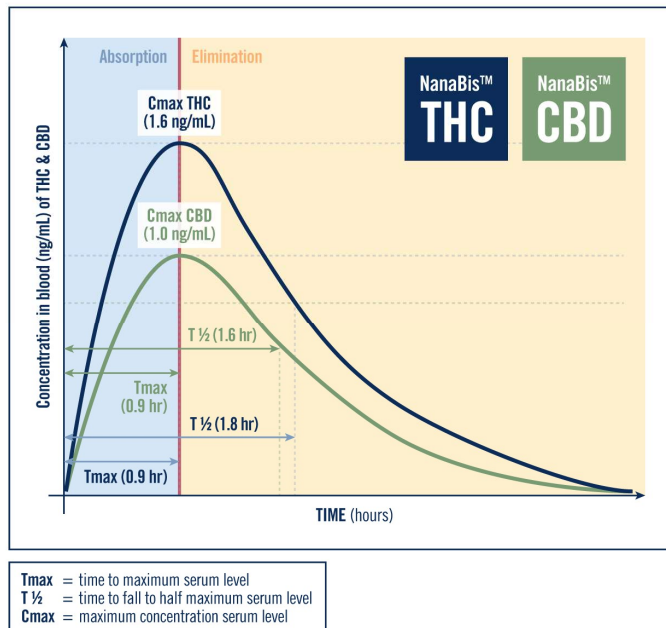
Moving forward, Medlab will undertake secondary analysis of the data whilst canvassing with various global regulatory agencies in preparation of the forthcoming Phase 3 clinical trials.

MMEq (Morphine Milligram Equivalent) Comparison: (see below)

Over the 30-day (MAD) trial Sample 1 - patients (all other cancers) prescribed significantly higher mean doses of MMEq of morphine as compared to Sample 2 -patients (Breast & Prostate Cancers with Bone Mets).

SAMPLE 1 (All other cancers)					
Variable	Obs.	Mean	Std. Dev.	Min.	Max.
MMEq Day 1	17	214.0588	353.8235	15	1480
MMEq Day 7	14	174.4286	300.4153	15	1150
MMEq Day 13	14	225.2857	442.6972	15	1690
MMEq Day 16	14	212	391.7297	15	1510
MMEq Day 30	13	322.6923	714.5855	0	2650
SAMPLE 2 (Breast & Prostate cancers with Bone Mets)					
Variable	Obs.	Mean	Std. Dev.	Min.	Max.
MMEq Day 1	8	61	38.95785	0	126
MMEq Day 7	8	58	38.26225	0	126
MMEq Day 13	8	57.125	37.14619	0	119
MMEq Day 16	8	57.125	36.52568	0	119
MMEq Day 30	8	64.5	51.23057	8	171

AUC (Area Under the Curve) Model: (see below)



Developed from Stage 1 (SAD) data on Patients with metastatic cancers, demonstrates NanaBis™ is fast acting, using Day 1, 1 dose, once, versus Day 2, 3 dosages once. NanaBis™ showed time to maximum concentration in serum to be 54 minutes.

For and behalf of the Board.

Dr Sean Hall
Managing Director

ISSUED FOR: MEDLAB CLINICAL LTD (ASX: MDC) – www.medlab.co

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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.