MEDIA RELEASE

Australia Leading the Way in Pain Solutions

New landmark clinical trial into the efficacy of medicinal cannabis tablets on mild-to-moderate pain.

Embargoed until 28 November, 2023: Promethean BioPharma, a globally integrated market-leading manufacturer and distributor of medical products and novel medicines, is currently running a landmark clinical trial into the efficacy, safety and tolerability of its technology-leading, CBD-only medicinal cannabis tablets for mild-to-moderate pain for registration on the Australian Register of Therapeutic Goods (ARTG).

Promethean BioPharma has set a global benchmark in medicinal cannabis products and is licensed for the commercialisation of novel medicines such as psilocybin and MDMA. Its latest innovation – a medicinal cannabis tablet – is the sixth-generation of cannabis-based treatments, with previous generations starting with the plant (Gen 1) and oil squeezed from the plant (Gen 2) through to capsules and micro-sprays and arriving at sub-micron particle products including Gen 5 emulsions.

The new tablet, manufactured from plant-based extracts, is the first of its kind and has been formulated using patented sub-micron technology to create a regulated 30 mg medicinal cannabis tablet. A maximum daily dosage of 150 mg will be administered in the trial to comply with TGA guidelines for over-the-counter medicine (Schedule 3, Pharmacist-only medication).

Peter Comerford, Global CEO for Promethean BioPharma, says Australia is in the "driving seat" globally for medicinal cannabis technologies thanks to the federal government and TGA's progressive approach to legalising medicinal cannabis. In 2018 the government identified medicinal cannabis as an emerging industry and medical opportunity with key economic benefits for Australia. This resulted in world-leading frameworks being developed with the view to Australia becoming the world's number one exporter of medicinal cannabis.

"The legal framework created by the federal and state governments along with the TGA has been critical in supporting and growing the industry while helping patients. As a result, while Australia leads, Europe is only at the start of the journey, the United Kingdom is tied up in red tape, the industry in Canada is in collapse, California is a regulatory mess, and the United States is chasing medical technology but does not have Phase 3 clinical trials running as we do here in Australia. Like the Australian invention wifi that revolutionised digital access, the tablet format has the potential to be a game-changer for pain sufferers," says Mr Comerford.

"The trial is aiming to prove the efficacy of a tablet with a sub-micron molecule of medicinal cannabis that contains no THC. The simple white tablet being trialled is a manageable dosage, sub-micron molecule that decreases medicine wastage to around 40 per cent (instead of over 90 per cent as seen in other formats) making it more potent and effective at a lower dose than other forms of medicinal cannabis. This significantly increases the chance that the registration of the tablet as an over-the-counter medicine is possible within the Australian regulatory framework."

More than 3.6 million Australians are living with chronic pain that impacts their quality of life. While few new pain medicines have been developed in the past 30 years, the quest to discover better pain medicine options is ongoing, with the medical cannabis tablet viewed as a promising alternative to standard pain treatments that come with significant side effects.

Nicolette Ellis, President of Chronic Pain Australia, says, "Despite chronic pain costing the economy more than diabetes, cardiovascular disease and cancer combined, little innovation or new treatments have been in the pipeline for the chronic pain community. Chronic Pain Australia is supportive of Promethean BioPharma's landmark trial to review the efficacy and safety of an over-the-counter medicinal cannabis option.

"We know from the National Pain Survey and from our members' lived experience that many Australians have found benefits from medicinal cannabis for their chronic pain condition and secondary sleep and mental health challenges. Side effects from current pain medications such as addiction, weight gain, brain fog, fatigue and sedation can be a major barrier and why people living with pain have looked to plant-based derivatives for pain relief. We also know that 18% of the chronic pain community is self-medicating with illicit cannabis due to costs and access issues. This is an alarming statistic and why we need to invest in new treatments that are safe and effective for pain. Medicinal cannabis has certainly been the biggest disruptor in treatment options for pain, and we eagerly await the results of this landmark trial," adds Ms Ellis.

This clinical trial is testing the safety, tolerability and pain relief of a regulated dosage of cannabis in the form of a water-based dissolvable tablet. Initial testing has shown the tablet to have a faster onset than that of oil-based treatments and up to 60 per cent absorption rate, compared to a 4 per cent absorption rate for other products (oils, capsules and micro-sprays). The randomised, double-blind placebo-controlled study is being administered through GP Research Network (GPRN) clinic sites in Sydney, Central Coast, Brisbane and Canberra, and pain sufferers are encouraged to learn about the trial, which can be found publicly on the ANZCTR (Australia New Zealand Clinical Trials Register).

The Hon. Dr Lyle Oberg, Medical Director for Promethean BioPharma and Chair of Alberta Health Services, says, "The purpose of the trial is to bring clarity to the usage of medical cannabis and establish without doubt the beneficial effects that anecdotally we hear about all the time from patients.

"The trial is utilising standardised pain assessments so that the results can be compared to each other as well as other modalities of treatment and complications. This is the same due diligence that would occur with any medication on the market and gives both the patient and the doctor comfort knowing that it really works," adds Dr Oberg.

Participants in the trial will be asked to take an oral sublingual tablet three times a day for a period of 30 days, with a total daily dose of 150 mg. The dosing schedule was selected based on the half-life of the formulation (approximately six hours), with three times daily allowing the broadest schedule that can be achieved through waking hours. The daily 150 mg dosage was also selected to comply with TGA guidance for Schedule 3 registration for an over-the-counter medicine.

During the treatment period, participants will be required to attend the clinic on days one, 15 and 30 for study assessments. In addition, participants will also be required to attend a telehealth appointment (or receive a phone call) on days two, eight and 22 to monitor the potential impact of other medications they may be taking concurrently. The end-of-study visit will be on day 44.

"Thanks to our leadership team's expertise within the industry it has secured the support of extremely senior, eminent doctors and of an excellent professional research organisation Avance Clinical in designing this trial. Pain and rehab specialists, palliative care specialists, oncologists, pharmacologists and research doctors with deep experience in statistics as well as in the medical field have contributed their time voluntarily to this because they believe in it," says Mr Comerford.

"The clinical trial into the efficacy of medicinal cannabis tablets on mild-to-moderate pain has closely followed the instructions from the TGA to ensure it is robust in its processes to best secure a positive result. Our hope is to be registered as an over-the-counter medicine to help patients replace pharmaceuticals with many side effects while managing their pain so that they can get back to exercise and good living."

Participants in the trial need to be over 18 years of age and must be experiencing mild-to-moderate acute, subacute or chronic non-palliative pain. All participants will be screened by the GPRN team to ensure compliance and to protect the integrity of the trial.

To find out more information about Promethean BioPharma, visit www.prometheanbiopharma.com

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