



Tetra Bio-Pharma Receives Health Canada Phase 3 Clinical Trial Approval For Smokable Dried Cannabis Prescription Drug

Ottawa, Ontario - (Marketwired –February 4th , 2017) – Tetra Bio-Pharma Inc. ("Tetra" or the "Company") (TSX-V: TBP) (OTCQB: TBPMF), a global leader in cannabinoid-based drug development and discovery, is pleased to announce that it has received a No Objection Letter (NOL) from the Therapeutic Products Directorate (TPD) Health Canada to its Clinical trial application (CTA) for the Company's PPP001 prescription smokable dried cannabis product.

Coinciding with World Cancer Day 2018, Tetra is now ready to initiate its Phase 3 clinical trial of PPP001 in terminal cancer patients, the first registration trial in the world for smokable cannabinoid-based drug. This trial is expected to be a landmark study, enrolling a total of 946 subjects, evaluating the therapeutic benefits of a cannabinoid prescription drug in improving quality of life and treating pain in terminal cancer patients.

"This is an especially significant and noteworthy milestone for the lead candidate in our product pipeline," said Bernard Fortier, Tetra's CEO, "as it positions Tetra to potentially be the first company with a Health Canada approved, cannabinoid-based drug on the market aimed at treating breakthrough pain in cancer patients. The advanced cancer pain market is a \$2.4B market¹; this is a significant and important opportunity for the Company as our drug PPP001 has the potential to help reduce the reliance on opioids for the management of severe pain."

The first and main recruitment center of the trial will be in Montreal at Santé Cannabis, Québec's first medical clinic and resource centre specializing in cannabis and cannabinoids for medical purposes.

The PPP001 Phase 3 trial will evaluate the effects of Tetra's smokable cannabinoid-based drug made from natural dried cannabis. Tetra previously entered into a supply agreement with Aphria Inc., to use Aphria's unique blend of dried medical cannabis in its PPP001 clinical trial. Aphria owns an 8.5% stake in Tetra.

As part of the clinical trial, Tetra will also collect the pharmaco-economics evidence required from insurers in order to support the reimbursement of the first cannabis prescription drug. "Today, most private insurance plans do not cover cannabis treatment, nor is public reimbursement available, making this therapeutic option costly for patients. It is very

important for us to bring a new therapeutic option for patients in the form of an approved prescription drug and to take action in order to have it reimbursed for patients" commented Bernard Fortier, CEO.

The trial aims to demonstrate that PPP001 eases suffering and facilitates a more serene experience of living and dying in terminal cancer patients. If conclusive, Tetra will submit a filing for a Drug Identification Number (DIN) to Health Canada in 2019, thus providing a new noninvasive treatment to relieve pain for cancer patient. With this approval, Tetra expects to be on time with its previously announced schedule with the development of PPP001, culminating in a potential launch in Canada by Q1, 2020 and in the US by Q3, 2020.

Dr Guy Chamberland, Tetra's Chief Scientific Officer (CSO) explained that: "The development of PPP001 for patients with advanced cancer is an important commitment for Tetra, given that cancer patients suffer from severe pain which is often accompanied by depression and insomnia. Medical cannabis has been shown to help patients beyond the immediate benefit of pain relief."

"With the expertise of Santé Cannabis, we expect to demonstrate the clinical benefits of PPP001 on the quality of life of advanced cancer patients. It's important to note that our clinical program will also address the potential of PPP001 to reduce the reliance on opioids for management of severe pain. We expect that, once it is approved as a drug under prescription, PPP001 will be included over time ahead of opioids treatment for those patients with terminal cancer pain. The Company will continue to maintain a transparent and direct line of communication with Health Canada and the U.S. FDA to ensure that we address the issues required for drug approval. PPP001 is about patients first, " added Dr. Guy Chamberland.

Tetra worked with Santé Cannabis physicians to design a clinical trial that would demonstrate the safety and efficacy of PPP001 in terminal cancer patients and have focused the clinical development on a first indication in patients with advanced cancer. The Phase III clinical trial will be performed by the medical team of Santé Cannabis.

"Throughout my clinical experience assessing and following more than 600 medical cannabis patients, cannabis inhalation remains a critical option to provide rapid relief from a wide variety of symptoms associated with advanced cancer, " said Dr. Antonio Vigano, Principal Investigator of the trial and Research Director of Santé Cannabis. "We will rigorously assess the safety, efficacy and tolerability of PPP001 to support the population of cancer patients by bringing an important therapeutic tool to the same standard of prescription drugs It is great to be celebrating World Cancer Day 2018 with the first large scale clinical study to prove that medical cannabis can ease the suffering and improve quality of life of many cancer patients, particularly when they most need it."

About Cancer Pain:

In the USA, 1,5 million patients suffer from cancer pain². Pain is one of the most frightening of all cancer symptoms for patients and their families³. According to statistics published by the American Cancer Society in 2002⁴, 50% to 70% of people with cancer experience some

degree of pain, with a quarter of them actually dying in pain. Without adequate relief of their pain, their quality of life is negatively impacted. Furthermore, the incidence of pain in advanced stages of invasive cancer approaches 80% and it is 90% in patients with bone metastases⁵.

- 1- https://decisionresourcesgroup.com/report/141466-biopharma-cancer-pain-2015
- 2- Melnikova I. Pain market 2010 ;, doi:10.1038/nrd3226
- 3- Winslow M, Seymour J, Clark D. 2005. Stories of cancer pain: a historical perspective. J Pain Symptom Manage, 29:22–31.
- 4- American Cancer Society. 2002. Cancer facts and figures 2002
- 5- Pharo GH, Zhou L. 2005. Pharmacologic Management of Cancer Pain. JAOA, 105:S21–28.

About PPP001:

PPP001 aims to be the first smokable marihuana for advanced cancer pain under prescription. It is a dried cannabis pellet designed to be smoked in an inhalation device specifically developed for this product. PPP001 is a unique blend of 3 strains of standardized dried cannabis, creating a drug substance with 9,5% THC and 2,5% CBD.

About Aphria:

Aphria Inc., one of Canada's lowest cost producers, produces, supplies and sells medical cannabis. Located in Leamington, Ontario, the greenhouse capital of Canada, Aphria is truly powered by sunlight, allowing for the most natural growing conditions available. Aphria is committed to providing pharma-grade medical cannabis, superior patient care while balancing patient economics and returns to shareholders.

About Tetra Bio-Pharma:

Tetra Bio-Pharma (TSX-V: TBP) (OTCQB: TBPMF) is a biopharmaceutical leader in cannabinoid-based drug discovery and clinical development. Tetra is focusing on three core business pillars: clinical research, pharmaceutical promotion and retail commercialization of cannabinoid-based products.

More information at: www.tetrabiopharma.com

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