



## **TETRA BIO-PHARMA TAKES ON FENTANYL IN HEAD TO HEAD TRIAL FOR THE TREATMENT OF BREAKTHROUGH PAIN**

**First Clinical Study to Assess Cannabis as an Alternative to Fentanyl**

**ORLEANS, Ontario, June 18, 2018 (GLOBE NEWSWIRE) - Tetra Bio-Pharma Inc.**, a leader in cannabinoid-based drug discovery and development (TSX VENTURE: TBP) (OTCQB: TBPMF), is pleased to announce that Santé Cannabis, the independently credentialed research organization they work with has finalized the clinical study protocol evaluation of PPP001, which will be the first time that cannabis is being compared to fentanyl in a clinical trial. The study protocol has received approval from the Independent Ethics Board (IRB Services) and was recently submitted for review to Health Canada. PPP001 will investigate cannabis as an alternative to fentanyl in the management of breakthrough pain. Santé Cannabis is a Quebec-based medical clinic specialized in clinical research and cannabis - based therapies.

Health Canada approved clinical trials completed by Tetra Bio-Pharma in 2017 and 2018 have led to a significantly improved understanding of the safety, pharmacokinetics and pharmacodynamics of PPP001 in the treatment of pain and suffering. The development of clinical research protocols to investigate the use of cannabis as an alternative to fentanyl followed Tetra's meeting with the Therapeutic Products Directorate (TPD), Health Canada in early 2018. As a prescription drug, PPP001 will be eligible for insurance coverage.

The trial is designed to assess the time-to-relief in patients suffering from breakthrough pain. Based on its clinical data, Tetra believes that the pharmacodynamic properties of PPP001 may provide a novel alternative to fentanyl. In addition, the time-to-maximal plasma concentrations of THC suggests that PPP001 will provide rapid relief to the patient's suffering.

"Patients suffering from breakthrough pain require fast relief. Overdosing from fentanyl may occur in patients that exceed the recommended dosage in the hope of obtaining a more rapid relief. The development of a THC-based alternative would help provide a safer option to these patients and help prevent overdosing on fentanyl," said Dr. Antonio Vigano, an Attending Physician at the Supportive and Palliative Care Division, McGill University Health Centre, an Associate Professor in the department of oncology, McGill University and the Research Director of Santé Cannabis where he is a Principal Investigator in a Phase 3 clinical trial for pain associated with advanced cancer, in addition to a phase 2 trial for chronic pain. "PPP001 has the potential to become the long-awaited alternative to opioids for the management of breakthrough pain in cancer patients. Through this trial we are going to gather more evidence-based data on the safety, efficacy and ease of administration of inhaled cannabinoids as the complementary therapy of choice for cancer related pain." said Dr. Vigano.

In Canada, the opioid crisis is serious and growing, and imposes devastating effects on families and communities. From January to September 2017, there were at least 2,923 apparent opioid-related deaths of which 92% were accidental. While males make up 76% of these fatalities, the highest percentage (28%) occurred among individuals between the ages of 30 and 39 years.<sup>1</sup> From January to September 2017, 72% of accidental apparent opioid-related deaths involved fentanyl or fentanyl analogues compared to 55% in 2016.

“Our rich cannabinoid-derived product pipeline has the potential to play a major role in opioid sparing, thus addressing a societal issue of critical proportion,” said Guy Chamberland, Interim CEO and Chief of Scientific Affairs at Tetra Bio-Pharma. In addition, the R&D team is in discussions with Health Canada to take PPP001 into other therapeutic indications including fibromyalgia. In taking on new therapeutic indications for PPP001 we can, if successful, significantly increase the potential market as well shareholder value,” said Mr. Chamberland.

#### **About Tetra Bio-Pharma**

Tetra Bio-Pharma (TSX-V: TBP) (OTCQB: TBPMF) is a biopharmaceutical leader in cannabinoid-based drug discovery and development with a Health Canada approved, and FDA reviewed, clinical program aimed at bringing novel prescription drugs and treatments to patients and their healthcare providers. The Company has several subsidiaries engaged in the development of an advanced and growing pipeline of Bio Pharmaceuticals, Natural Health and Veterinary Products containing cannabis and other medicinal plant-based elements. With patients at the core of what we do, Tetra Bio-Pharma is focused on providing rigorous scientific validation and safety data required for inclusion into the existing bio pharma industry by regulators, physicians and insurance companies. For more information visit: [www.tetrabiopharma.com](http://www.tetrabiopharma.com)

#### **About Santé Cannabis**

Established in Montreal, Quebec in 2014, Santé Cannabis is a Centre of Excellence in medical cannabis research, clinical practice and healthcare professional training. Since its inception, Santé Cannabis has provided medical assessment, education, monitoring and follow-up to 5000 patients referred by more than 2,000 Quebec physicians. Santé Cannabis operates within the guidelines for the authorization of medical cannabis as set out by the Collège des médecins du Québec. As an independently credentialed clinical trial research organization, and with unparalleled clinical experience supporting both patients and healthcare professionals, Santé Cannabis has established itself as a global leader in medical cannabis research. Santé Cannabis is currently conducting a Health Canada approved Phase 3 trial for PPP001 for advanced cancer patients suffering from uncontrolled pain and associated symptoms, as well as a Phase 2 trial for PPP005 investigating the use of oral capsules of cannabis oil for the treatment of chronic pain. For more information visit [www.santecannabis.ca](http://www.santecannabis.ca)

More information at: [www.tetrabiopharma.com](http://www.tetrabiopharma.com)

Source: Tetra Bio-Pharma

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#### **Forward-looking statements**

*Some statements in this release may contain forward-looking information. All statements, other than of historical fact, that address activities, events or developments that the Company believes, expects or anticipates will or may occur in the future (including, without limitation, statements regarding potential acquisitions and financings) are forward-looking statements. Forward-looking statements are generally identifiable by use of the words "may", "will", "should", "continue", "expect", "anticipate", "estimate", "believe", "intend", "plan" or "project" or the negative of these words or other variations on these words or comparable terminology. Forward-looking statements are subject to a number of risks and uncertainties, many of which are beyond the Company's ability to control or predict, that may cause the actual results of the Company to differ materially from those discussed in the forward-looking*

*statements. Factors that could cause actual results or events to differ materially from current expectations include, among other things, without limitation, the inability of the Company to obtain sufficient financing to execute the Company's business plan; competition; regulation and anticipated and unanticipated costs and delays, the success of the Company's research and development strategies, the applicability of the discoveries made therein, the successful and timely completion and uncertainties related to the regulatory process, the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions and other risks disclosed in the Company's public disclosure record on file with the relevant securities regulatory authorities. Although the Company has attempted to identify important factors that could cause actual results or events to differ materially from those described in forward-looking statements, there may be other factors that cause results or events not to be as anticipated, estimated or intended. Readers should not place undue reliance on forward-looking statements. While no definitive documentation has yet been signed by the parties and there is no certainty that such documentation will be signed The forward-looking statements included in this news release are made as of the date of this news release and the Company does not undertake an obligation to publicly update such forward-looking statements to reflect new information, subsequent events or otherwise unless required by applicable securities legislation.*

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<sup>i</sup> <https://www.canada.ca/en/health-canada/services/substance-abuse/prescription-drug-abuse/opioids/apparent-opioid-related-deaths.html>