



Tetra Bio-Pharma Accelerates PLENITUDE© Clinical Trial to Evaluate the Effect of Cannabis for Use in Managing Uncontrolled Cancer Pain

- **First ever clinical trial using pharmaceutical grade cannabis medication for use in managing uncontrolled cancer pain due to advanced cancer**
- **QIXLEEF™ has the potential to transform the pain market**

Ottawa, May 11, 2021 (ACCESSWIRE) – **Tetra Bio-Pharma Inc. ("Tetra" or the "Company")** ([TSX: TBP](#)) ([OTCQB: TBPMF](#)) ([FRA: JAM1](#)), a leader in cannabinoid-derived drug discovery and development announced today the acceleration of a revolutionary Phase 2 clinical trial, PLENITUDE©, to evaluate the safety and efficacy of the investigational cannabis medicine, QIXLEEF™, for use in managing uncontrolled pain in patients with advanced cancer.

QIXLEEF™ is the Company's inhaled proprietary drug formulation which has a fixed ratio of THC and CBD. The medication is inhaled through a Class II medical vaporizer. When pharmaceutical grade cannabis is vaporized rather than smoked, the beneficial components can be inhaled without the generation of smoke and combusted by-products.

Dr. Guy Chamberland, CEO and CRO comments, "The PLENITUDE© study has been underway for many months and we are now accelerating its enrollment activities. Tetra currently has two Phase 2 clinical trials ongoing in the United States. Though both trials, PLENITUDE© and REBORN1©, will evaluate QIXLEEF™, each has a very different objective. The PLENITUDE© trial will assess how QIXLEEF™ may manage uncontrolled cancer pain in patients living with advanced cancer and the REBORN1© trial is a head-to-head study against an opioid treatment in the management of short and frequent episodes of incapacitating pain requesting immediate release opioid treatment in cancer patients. We believe based on our years of research that QIXLEEF™ will be proven to be safe and effective, and if so, provide patients with cancer pain a safer treatment option with potentially greater benefits than the current standard of care."

The PLENITUDE© trial is a four-week randomized, double-blind, placebo-controlled study and has been reviewed by an ethics committee and follows Good Clinical Practices. Patients will receive four weeks of either the study treatment or a placebo, after which all patients will be eligible to receive the active study drug for up to an additional 48 weeks. Pain levels will be measured throughout the course of the study to determine the efficacy of the study medication.

Dr. Sue Sisley, Medical Expert and Principal Investigator states, "The goal of the PLENITUDE© study is to help patients with advanced cancer manage their pain to improve their overall quality of life. I am excited about this study because it offers hope to patients who experience severe pain. Many patients have difficulty tolerating powerful therapies, like opioids. I am encouraged because cannabis has been long considered a low-risk option for patients with cancer with few and tolerable side effects. Together we may discover a new treatment option for managing pain!"

About Advanced Cancer Pain

Advanced cancer pain is defined by the International Association for the Study of Pain as “unpleasant sensory and emotional experience associated with actual or potential tissue damage”. Pain is a common symptom associated with a cancer diagnosis. Market studies performed on behalf of Tetra for advanced cancer pain in the United States estimate that the addressable market will be worth over USD\$900 million by 2030. This figure takes in consideration the off-label market, which will continue to demand non-opioid treatments.

To learn more about the PLENITUDE© study and eligibility requirements, please visit : www.plenitude-study.com.

About Dr. Sue Sisley, MD



Dr. Sue Sisley MD is an Arizona-based physician practicing Internal Medicine & Psychiatry. She is President of Scottsdale Research Institute, a company which coordinates rigorous, scientific studies to assess the safety and efficacy of cannabis and cannabis compounds for treating medical conditions. Dr. Sisley is committed to evaluating the use of pharmaceutical grade cannabis to treat chronic pain, opioid dependence, and PTSD as a safer alternative to synthetic pharmaceuticals.

About Tetra Bio-Pharma

Tetra Bio-Pharma ([TSX: TBP](#)) ([OTCQB: TBPMF](#)) ([FRA:JAM1](#)) is a leader in cannabinoid-derived drug discovery and development with a FDA and a Health Canada cleared clinical program aimed at bringing novel prescription drugs and treatments to patients and their healthcare providers. Our evidence-based scientific approach has enabled us to develop a pipeline of cannabinoid-based drug products for a range of medical conditions, including pain, inflammation, and oncology. 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 biopharma industry by regulators, physicians and insurance companies.

For more information visit: www.tetrabiopharma.com

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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, including the success of this product or any other product, 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. 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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