



Tetra Bio-Pharma Submits Request for Scientific Advice to Malta Medicines Authority

- Tetra plans for global commercialization of QIXLEEF

Ottawa, April 28, 2021 (ACCESSWIRE) – Tetra Bio-Pharma Inc. (“Tetra” or the “Company”) ([TSX: TBP](#)) ([OTCQB: TBPMF](#)) ([FRA:JAM1](#)), a biopharmaceutical pioneer in immunomodulator drug discovery and development announced today that it has submitted a request to the Malta Medicines Authority for a Scientific Opinion on its investigational new drug (IND) QIXLEEF for Tetra’s clinical trial programs. This request includes guidance on the REBORN2 trial to be performed in Europe. QIXLEEF is a botanical drug product with a "fixed ratio" of THC and CBD and is inhaled through a vaporizer.

“Based on the speed of onset of the pharmacodynamic effects of QIXLEEF, Tetra has positioned this inhaled IND as a potential therapy for the rapid relief of severe acute pain, such as breakthrough pain. Patients require fast relief when suffering from excruciating pain and we believe that the fast onset of QIXLEEF might be a viable alternative to opioids. We are seeking guidance from the Malta Medicines Authority on Tetra’s clinical development program of REBORN2 as we plan for global commercialization of QIXLEEF,” said Guy Chamberland, CEO and CRO of Tetra Bio-Pharma Inc.

REBORN2 is a 7-week randomized double-blind, placebo-controlled, dose-ranging study to evaluate the effect of three strengths of inhaled QIXLEEF compared to morphine sulfate immediate release (MSIR) to improve fast onset of pain relief of breakthrough cancer pain (BTcP). BTcP is a rapid onset, high intensity, and short duration pain episode, which takes place within stable background pain control. The time to peak intensity of an episode ranges from 3 to 15 minutes with a duration of 30 to 60 minutes. They occur with a frequency of 1.5 to 6 times per day and the majority are moderate to severe in intensity (Portenoy and Hagen 1990; Portenoy et al. 1999; Davies et al. 2011). It significantly affects the quality of life of patients with cancer and their ability to function normally (Zeppetella and Davies 2013).

About Tetra Bio-Pharma

Tetra Bio-Pharma ([TSX: TBP](#)) ([OTCQB: TBPMF](#)) ([FRA:JAM1](#)) is a biopharmaceutical pioneer in immunomodulator 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

Neither the TSX Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Exchange) accepts responsibility for the adequacy or accuracy of this release.

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.

For further information, please contact Tetra Bio-Pharma Inc.:

Tetra Bio-Pharma Inc.
Ms. Natalie Leroux
Phone: + 1 (833) 977-7575
Email: investors@tetrabiopharma.com
media@tetrabiopharma.com

Source: Tetra Bio-Pharma

