Tetra Bio-Pharma Hits Another Milestone Before Year End

- Tetra will accelerate its Inhaled synthetic THC drug approvals under a 505(b)(2) marketing application pathway
- FDA confirms clinical development program to support marketing application of Tetra's inhaled innovative THC drug

Ottawa, December 16, 2020 (ACCESSWIRE) – **Tetra Bio-Pharma Inc. ("Tetra" or the "Company")** (TSX: TBP) (OTCQB: TBPMF), a leader in cannabinoid-derived drug discovery and development, today announced it conducted a Type B meeting with the United States Food and Drug Administration (FDA) for an inhaled THC-based innovative drug for the treatment of chemotherapy induced nausea and vomiting (CINV). This new drug will be part of Tetra's global commercialization strategy to maintain a lead position in the treatment of CINV in patients with cancer who have failed to respond adequately to conventional anti-vomiting treatments. This inhaled THC drug, along with the Dronabinol Adversa® drug product, will target global markets.

Last week, Tetra completed a new Pre-IND meeting with the FDA for the inhaled THC drug. The 505(b)(2) regulatory pathway supports accelerated development of a drug to market as it relies partially on published literature references and data previously reviewed by the FDA for the approval of a separate application.

The FDA reviewed and provided guidance on the proposed clinical program for the inhaled THC drug. The FDA stated that the study design appeared generally reasonable to compare the bioavailability between the proposed inhaled product and the listed drug (i.e., Marinol®) and assessed the dose proportionality for the inhaled THC drug product. In addition, they agreed that the proposed phase 2 study population (adult patients going through chemotherapy who have failed to respond adequately to anti-vomiting treatments) is reasonable. Tetra proposed a phase 2 trial to show a superior safety profile while maintaining the efficacy of the reference approved drug Marinol®. This will be important for maintaining a market lead over any new dronabinol competing products that emerge.

Furthermore, the Dronabinol Adversa® drug product (also known as PPP-002) is also eligible for the 505(b)(2) New Drug Application (NDA) regulatory pathway as previously announced in September and October 2018.

"The addition of an inhaled THC product to our CINV portfolio will further expand our product offer to all patients affected by nausea while receiving chemotherapy. The different route of administration whether it is bucco adhesive (Adversa®) or through inhalation will offer healthcare professionals and patients more flexibility to administer or receive a cannabinoid-derived medicine. The inhaled THC product will be delivered through our class two medical device vaporizer, similar to the one used with QIXLEEF™ and CAUMZ™. Our plan is to include the use of the device to our 505(b)(2) application at no additional cost. This regulatory pathway will allow us to efficiently bring our inhaled THC innovative drug to the US market", said Guy Chamberland, CEO and CRO of Tetra Bio-Pharma.

“In 2021 we will have a transformative and pivotal change going from a pre-revenue biotech company into a clinical stage biopharmaceutical company with revenue to help fund further drug development. We know that our investors have waited quite a while for this phase and we are confident that our extensive and innovative CINV portfolio will yield the expected results. We are currently working on a forecast methodology to establish the inhaled THC market potential. Finally, the product differentiation between the Dronabinol Adversa® version and the inhaled THC version will be easily achieved as we finalize the Marketing Strategy”, said Steeve Néron, CCO of Tetra Bio Pharma.

About Tetra Bio-Pharma

Tetra Bio-Pharma (TSX: TBP) (OTCQB: TBPMF), is a biopharmaceutical leader in cannabinoid-based drug discovery and development with a FDA and a Health Canada approved 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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