FDA Provides Positive Feedback on Tetra Bio-Pharma's Application for ARDS-003 Clinical Development in COVID-19 Patients

- **FDA acknowledged that the preclinical safety data are acceptable to file an Investigational New Drug Application (IND) aimed at treating hospitalized COVID-19 patients at risk of developing ARDS**

Ottawa, April 5, 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 is pleased to announce that the U.S. Food and Drug Administration (FDA) has favorably reviewed the preclinical data package and clinical development plan of ARDS-003 to treat COVID-19 patients.

The review was conducted within the framework of the Coronavirus Treatment Acceleration Program (CTAP), the FDA's expedited process for investigational therapies to treat COVID-19 patients. Overall, the FDA agreed with the animal toxicology and safety data to ensure that ARDS-003 is safe for human use, and approved the sample size, safety procedures and duration of treatment in severe COVID-19 patients. As a result of this feedback, the Company looks forward to filing an Investigational New Drug Application to initiate the clinical trial.

The proposed patient study is a randomized, double-blind, placebo-controlled trial to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of ascending doses of ARDS-003 in hospitalized COVID-19 patients with pneumonia and at risk of developing acute respiratory distress syndrome.

Seeking guidance on clinical study protocol to be conducted in patients with COVID-19 is a pre-requisite of the FDA regulatory process for COVID-related trials, as it is for Health Canada.

Dr. Guy Chamberland, CEO and CRO commented, "I'm very pleased with the FDA feedback on our data package and clinical strategy. Such feedback gives us a great insight on the authority's positive perception of our product and will facilitate the IND review process. I'm confident that we are now aligned with the authorities for the development plan of ARDS003".

ARDS-003 is a new patent protected therapeutic developed to treat hyperinflammatory conditions, such as those seen in patients suffering from COVID-19 viral infections. The investigational drug is designed to dampen the cytokine release syndrome and will be administered in combination with dexamethasone. The Company is not making any express or implied claims that its product has the ability to eliminate, cure and/or contain the COVID-19 virus at this time.

Severe COVID-19-induced hyperinflammatory syndrome
ARDS is the leading cause of mortality in COVID-19 patients and develops in 20-67% of critically ill patients diagnosed with COVID-19 (Yang et al. 2020; Vittori et al. 2020) and 76% of patients requiring ICU care (Tan et al. 2020). Studies report that of those COVID-19 patients who are

critically ill, profound acute hypoxemic respiratory failure secondary to ARDS represents the leading finding, and that 30–100% of these patients require mechanical ventilation (Anesi 2020). Further, additional organ systems including the cardiovascular system are profoundly impacted by the hyperinflammation in COVID-19 patients (Capone et al. 2020; Hendren et al. 2020). Presently, no standard, approved treatment for hyperinflammation and associated ARDS or multi-organ dysfunction syndrome (MODS; a common cause of death) exists for these patients, rendering the indication a significant unmet medical need. Targeting hyperinflammation via immunosuppressive or anti-inflammatory agents is likely to be beneficial in COVID-19-associated CRS. The use of low-dose dexamethasone is part of standard of care for COVID-19 and has been correlated with decreased COVID-19 mortality and reduction in need for mechanical ventilation (Sterne et al. 2020; Siemieniuk et al. 2020). Given that the anti-inflammatory effect of ARDS-003 is broader than the anti-inflammatory effect of dexamethasone and presents a safer safety profile, it is believed that the addition of ARDS-003 to dexamethasone standard of care treatment will result in additional benefit for the patients.

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

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