



Tetra Bio-Pharma Provides PPP003 Inflammatory Cytokine Reduction Drug Program

Ottawa, May 6, 2020 (ACCESSWIRE) – **Tetra Bio-Pharma Inc.** ("**Tetra**" or the "**Company**") (TSX-V:TBP) (OTCQB:TBPMF), a leader in cannabinoid-derived drug discovery and development, is pleased to announce that it has now completed the modifications to the nonclinical safety program of PPP003 to ensure the launch of a Phase 1 trial in healthy volunteers later this year and subsequently be able to initiate a Phase 2 trial in patients with COVID-19 immediately after.

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the Covid-19 (or SARS-2 Coronavirus) at this time. As with any new drug candidate, PPP003 has not been shown to be safe or effective in the prevention or treatment of inflammatory cytokine conditions. Dr. Melanie Kelly, Ph.D., Chief Scientific Officer, Tetra Bio-Pharma has read and approves of the scientific disclosure in this news release.

Tetra's drug development program for PPP003 was adjusted to support a Clinical Trial Application (CTA) in Canada and an Investigational New Drug (IND) application in the USA for an intravenous sterile finished drug product. The nonclinical safety studies required to support a CTA/IND in healthy volunteers for a new molecular entity (NME) include: drug metabolism, pharmacokinetics, cardiovascular and respiratory safety pharmacology, genetic toxicology and repeat dose toxicology in accordance with the regulatory requirements. The intention is to have completed these CTA/IND-enabling studies to allow initiation of the Phase 1 single ascending and multiple ascending dose with complete cardiovascular assessment by late calendar Q3 2020.

Once human studies begin, the research and development team will continue to advance the nonclinical safety studies to ensure readiness for an eventual Phase 2 trial in patients with moderate to severe COVID-19. In parallel, Tetra will complete the nonclinical safety studies required to support a new drug submission/application in Canada/USA. These latter studies include longer term repeat dose toxicology, teratology and fertility and early embryonic toxicology.

The phase I study will enroll approximately 100 healthy volunteers and will be conducted at one clinical site located in Montreal, Quebec. The study will include standard safety assessments, pharmacokinetics and cardiovascular evaluations. The phase II study will enroll approximately 100 covid-19 infected patients in several hospitals. A Phase II sub-study will explore the molecular mechanisms of the cytokine release syndrome in treated

and non-treated patients. This latter sub-study will be performed with Tetra's partner Onegevity Health and will aim to monitor select cytokines and biomarkers to predict organ damage.

Guy Chamberland, CEO & CRO of Tetra commented, "the nonclinical safety program is typical for any intravenous NME drug and these studies will also be part of the toxicology package for the ophthalmic indications. We want to ensure that PPP003-covid will be safe for use in patients struggling COVID-19. We are excited to be working on an NME that may provide a solution to physicians battling COVID-19. The research performed since 2014 by Panag Pharma (PANAG) demonstrating PPP003-covid's ability to potentially decrease the inflammatory cytokines in severe systemic inflammatory disease models is amazing and demonstrates their leadership in this field."

Dr. Chamberland further commented, "Tetra has submitted a grant application to the Strategic Innovation Fund announced two weeks ago by Prime Minister Justin Trudeau. We hope that this committee will recognize the extensive research performed by the PANAG founders at Dalhousie University. This level of in-depth research, which has been published in over ten peer reviewed scientific journals, is exceptional for a biotechnology company, especially when it is recognized by the international scientific and medical community.

About PPP003 in COVID-19 Infected Patients

Severe coronavirus disease 2019 (COVID-19) represents viral pneumonia from SARS-CoV-2 leading to acute respiratory distress syndrome (ARDS) with lung inflammation and damage (alveolar damage). These patients have exaggerated inflammatory and immune responses, with enhanced release of pro-inflammatory molecules - referred to as "cytokine storm". Essentially the immune system is in overdrive/out of control which can lead to further complications including blood clots and scarring or fibrosis. ARDS develops in 42% of patients presenting with COVID-19 pneumonia, and 61-81% of those requiring ICU care.

The "cytokine storm" in this context is easier to consider as a symptom than a cause, and is triggered by infection (viral e.g. SARS-CoV-2 or bacterial e.g. sepsis). As with other potential Covid-19 therapies being considered, PPP003 will target symptoms rather than the origin of the disease to reduce the extreme outcomes of a "cytokine storm" in patients with ARDS.

In sepsis, ARDS represents the severe end of lung dysfunction which can result from systemic inflammatory responses or from infection in the lungs, themselves. This cytokine-mediated inflammatory response is very similar to what is seen in viral infections like influenza or Covid-19. PPP003 was shown in experimental models to decrease pro-inflammatory cytokines (IL-6 and TNF) in acute lung injury models similar to what occurs in sepsis. PPP003, a specific CB2 agonist, also stops the efflux of inflammatory cytokines like TNF and IL-1 β in acute lung injury induced in other experimental models.

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 and approved, 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

Source: Tetra Bio-Pharma

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Forward-looking statements

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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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