Tetra Bio-Pharma Receives Positive Scientific Advice Assessment (SAA) Report for QIXLEEF™

- SAA Report endorsed Tetra Bio-Pharma's proposed nonclinical development and quality programs for QIXLEEF™.
- SAA Report provides clarity on clinical requirements for registration in Europe.

OTTAWA, ON, Sept. 2, 2021 /CNW/ - **Tetra Bio-Pharma Inc. ("Tetra"** or the **"Company")** (TSX: TBP) (OTCQB: TBPMF) (FRA: JAM1), a leader in cannabinoid-derived drug discovery and development is pleased to announce that it received the Scientific Advice Assessment (SAA) Report from the Malta Medicines Authority. Overall, the SAA Report provided positive feedback on Tetra's drug development plan for QIXLEEF™ and eligibility for submitting a Marketing Authorization Application (MAA) under Directive 2001/83/EC (Directive). QIXLEEF™ is the Company's inhaled proprietary drug which has a fixed ratio of THC and CBD. The medication is inhaled through a Class II medical vaporizer.

The SAA Report endorses Tetra's proposed plan to address the nonclinical safety requirements for submitting a MAA for QIXLEEF™. Similarly, the SAA Report endorses the Company's quality program for QIXLEEF™ as a medicine. In both cases, the SAA Report provides guidance on requirements for MAA approval.

The SAA Report discusses the assessment of both the PLENITUDE© and REBORN© clinical programs with regards to a MAA. The SAA Report provides guidance on the endpoints and other aspects of the protocol. The REBORN2© trial was identified as pivotal for the MAA because of its dose-response endpoint requirements of the Directive. Depending on the outcome in the REBORN1© and REBORN2© clinical trials, full Marketing Authorization would require confirmation of the outcome of REBORN1©.

Dr. Guy Chamberland, Chief Executive Officer and Chief Regulatory Officer of Tetra Bio-Pharma said "the endorsement of the proposed nonclinical and quality programs is an exciting achievement that affirms the robustness of our drug development approach. The Medicine Authority's response confirms that our development strategy, adjusted with their guidance on the clinical program, could allow QIXLEEF™ to satisfy the requirements of article 8 of the Directive. The timing of this news is important for us as we try to finalize a single global clinical program for bringing QIXLEEF™ to patients."

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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