

13 July 2021

## **DanCann Pharma A/S: Tetra Bio-Pharma Accelerates REBORN1© Trial**

**COPENHAGEN, Denmark, 13 July 2021 - DanCann Pharma A/S (SS: DANCAN) ("DanCann Pharma") hereby on behalf of Tetra Bio-Pharma Inc. ("Tetra"), announce that Tetra Bio-Pharma - a leader in cannabinoid-derived drug discovery and development – yesterday announced that the Central Ethics Committee has approved the proposed protocol modifications allowing additional immediate release oral opioids to be used as comparators in the REBORN1© study. Expanding to three (3) immediate release oral opioids will allow for the acceleration of patient enrolment in the REBORN1© trial.**

DanCann Pharma signed May 5th a definitive distribution agreement with Canadian Tetra Bio-Pharma Inc. concerning the exclusive distribution of the cannabinoid-based medicines Reduvo™ Adversa® and Qixleef™ in Denmark, Norway, Sweden, Finland, and Germany. This press release is passed on from Tetra's own press release, concerning the acceleration of the REBORN1© clinical trial.

- Ethics Committee approves REBORN1© protocol amendment allowing for the addition of two immediate release oral opioids to be compared against QIXLEEF™.
- REBORN1© is the first of its kind proof-of-concept phase 2 study comparing a cannabinoid-based drug, QIXLEEF™, to immediate release oral opioid for the treatment of breakthrough cancer pain.
- QIXLEEF™ has the potential to transform the pain market, offering an alternative to prescribed opioids in the management of breakthrough pain.

Dr. Guy Chamberland, CEO and CRO commented, "The amended protocol allows QIXLEEF™ to be studied against three types of immediate release oral opioids instead of just one. It will facilitate the recruitment of patients who can benefit from QIXLEEF™ to treat their breakthrough pain as it broadens the pool of qualified patients. Once the Schedule I license is approved, a process that usually takes a couple of weeks, the amended protocol will enhance the recruitment rate, thereby accelerating the study conduct. The approval by the DEA is a formality as the amendment does not modify the amount of controlled substance at the clinical site. Further, there have been numerous news reports recently of drug makers exiting the opioid business, however for patients suffering from uncontrolled pain, this news does not provide them with an alternative to alleviate their pain. Tetra is in the business of providing the evidence which would see QIXLEEF™ become an alternative prescription therapy to opioids".

## **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.

### **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](http://www.tetrabiopharma.com)

### **About DanCann Pharma**

DanCann Pharma A/S (SS: DANCAN) was founded in 2018 and is a Danish biopharmaceutical Company powered by cannabinoids. DanCann Pharma is a vertically integrated, licensed production and distribution Company based in Denmark. The Company focuses on discovering, developing, manufacturing, and commercializing new therapeutic cannabinoids in a wide range of disease areas.

DanCann Pharma A/S (SS: DANCAN) is listed on the Spotlight Stock Market in Copenhagen.

For more information, visit: [www.dancann.com](http://www.dancann.com)

### **For further information, please contact:**

Jeppe Krog Rasmussen, CEO  
E-mail: [jkr@dancann.com](mailto:jkr@dancann.com)  
Website: [www.dancann.com](http://www.dancann.com)