

29 April 2021

DanCann Pharma A/S: Tetra Bio-Pharma Submits Request for Scientific Advice to Malta Medicines Authority

COPENHAGEN, Denmark, 29 April 2021 - DanCann Pharma A/S (SS: DANCAN) ("DanCann Pharma" or the "Company") hereby on behalf of Tetra Bio-Pharma Inc. ("Tetra"), announce that Tetra has submitted a request to the Malta Medicines Authority for a Scientific Opinion on its investigational new drug (IND) QIXLEEF for Tetra's clinical trial programs.

DanCann Pharma signed February 25th a Letter of Intent (LOI) 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 that Tetra has submitted a request to the Malta Medicines Authority for a Scientific Opinion on its investigational new drug (IND) QIXLEEF for Tetra's clinical trial programs. This request includes guidance on the REBORN2 trial to be performed in Europe. QIXLEEF is a botanical drug product with a "fixed ratio" of THC and CBD and is inhaled through a vaporizer.

"Based on the speed of onset of the pharmacodynamic effects of QIXLEEF, Tetra has positioned this inhaled IND as a potential therapy for the rapid relief of severe acute pain, such as breakthrough pain. Patients require fast relief when suffering from excruciating pain and we believe that the fast onset of QIXLEEF might be a viable alternative to opioids. We are seeking guidance from the Malta Medicines Authority on Tetra's clinical development program of REBORN2 as we plan for global commercialization of QIXLEEF," said Guy Chamberland, CEO and CRO of Tetra Bio-Pharma Inc.

REBORN2 is a 7-week randomized double-blind, placebo-controlled, dose-ranging study to evaluate the effect of three strengths of inhaled QIXLEEF compared to morphine sulfate immediate release (MSIR) to improve fast onset of pain relief of breakthrough cancer pain (BTcP). BTcP is a rapid onset, high intensity, and short duration pain episode, which takes place within stable background pain control. The time to peak intensity of an episode ranges from 3 to 15 minutes with a duration of 30 to 60 minutes. They occur with a frequency of 1.5 to 6 times per day and the majority are moderate to severe in intensity (Portenoy and Hagen 1990; Portenoy et al. 1999; Davies et al. 2011). It significantly affects the quality of life of patients with cancer and their ability to function normally (Zeppetella and Davies 2013).

SOURCE: Tetra Bio-Pharma

View source version on Tetra Bio-Pharma web:

<https://ir.tetrabiopharma.com/newsroom/press-releases/news-details/2021/Tetra-Bio-Pharma-Submits-Request-for-Scientific-Advice-to-Malta-Medicines-Authority/default.aspx?fbclid=IwAR0K6R7feWgtE4oeYtMP3Os0viCFrmdhIF6GOswpOYpZhL2cVWfE-xUdeA>

About Tetra Bio-Pharma

Tetra Bio-Pharma (TSXTBP)(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.

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 further information, please contact:

Jeppe Krog Rasmussen, CEO
E-mail: jkr@dancann.com
Website: www.dancann.com