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DanCann Pharma A/S have signed a definitive distribution agreement with Tetra Bio-Pharma Inc. for the exclusive distribution of Reduvo™ Adversa® and Qixleef™ in Scandinavia and Germany

COPENHAGEN, Denmark, 5 May 2021 - DanCann Pharma A/S (SS: DANCAN) (“DanCann Pharma” or the “Company”) is pleased to announce the signing of an agreement with Canadian Tetra Bio-Pharma Inc. (TSX:TBP) (OTCQB:TBPMF) (“Tetra”) concerning the exclusive distribution of the cannabinoid-based medicines Reduvo™ Adversa® and Qixleef™ in Denmark, Norway, Sweden, Finland, and Germany.

Pursuant to registration with the European Medicines Agency (EMA), DanCann Pharma will handle the exclusive sales and distribution in the Nordics and Germany for the products, Reduvo™ Adversa® and Qixleef™. In addition, the agreement covers Tetra’s medical cannabis product Enjouca™.

Reduvo™ Adversa® (dronabinol using a novel mucoadhesive-tablet route of administration) are indicated for the treatment of CINV patients (Chemotherapy-Induced Nausea and Vomiting) and for AIDS-related anorexia associated with weight loss. Qixleef™ and Enjouca™ are indicated for the treatment of uncontrolled pain with advanced cancer patients as well as for breakthrough pain.

Reduvo™ Adversa® technology will allow DanCann to launch a largely improved dronabinol version in the Nordic countries & Germany. The clinical benefits are numerous, including illimited first-pass metabolism leading to an improved bioavailability and consequently to reduced gastro-intestinal exposure and side-effects. The dosage regimen is likely to become BID as opposed to QID. This new technology signifies important intellectual property.

Qixleef™ is a botanical cannabinoid-derived medicine, planned to become the first prescription product to be dispensed through pharmacies and prescribed by healthcare professionals. Qixleef™ is inhaled through a Health Canada approved class 2 medical device. It is well characterized and will benefit from data protection, once approved by the EMA. The indications for this product are expected to be for advanced cancer pain and breakthrough pain.

Last week Tetra published a press release, stating that Qixleef™ has been shipped to the USA for the initiation of the REBORN1 study. Tetra has completed the manufacturing of Qixleef™ and has received the cannabis export permit from Health Canada. REBORN1 will investigate cannabis as an alternative to morphine sulfate immediate release in the management of breakthrough pain.

Lastly, Enjouca™ is a medical cannabis therapeutic option (a non-registered) which will help European patients to manage their pain.

“We have very high expectations for the collaboration with Tetra Bio-Pharma. They have a unique portfolio within the pain management and CINV segments, and we look forward to introducing these lines to our markets. We have mutual expectations for the sales to commence during the first half of 2022. DanCann estimates reaching peak sales of DKK 340 - 410 million by 2028, depending on the development of the markets,” says DanCann Pharma’s CCO, John Morell Frellsen.

The agreement encompasses a sum of upfront and milestone payments to Tetra of up to DKK 6.25 million, and expected royalties to Tetra reaching up to DKK 62.5 million on DanCann Pharma’s peak sales for Reduvo™ Adversa®, Qixleef™ and Enjouca™ by 2028.

DanCann Pharma’s CEO, Jeppe Krog Rasmussen, has the following statement: “The industry – and hereby also the patients – have had some challenges and restrictions regarding the Danish Pilot Program with medical cannabis (non-registered). With this agreement we are now entering into a completely new path around approved pharmaceuticals with cannabinoid-derived medicines, where these restrictions are assumed to be minimal. This provides us with a portfolio of products, where the risk is widely spread and a much more transparent business plan and future.

With this agreement, we have proven our business model, and the new initiatives we have put on the agenda, and then executed. With our agreement with Tetra and our strategy around IP-based cannabinoid drugs, we are looking into a market in Germany, which today is worth over DKK +1.25 billion, where approx. 80% of these are prescribed to the area for pain treatment and pain patients. A market that is strongly characterized by medical cannabis, and incredibly latent around actual cannabinoid drugs - like the rest of Europe - where today we only have one other player in the market with EMA-approved cannabinoid drugs, which to that is not in direct competition with the drugs covered by our distribution agreement with Tetra. In other words: a huge opportunity for DanCann Pharma.

This is another major step in DanCann Pharma’s vision of improving the health and quality of life for patients with unmet health challenges. By bringing novel products based on cannabinoid derived medicines to the market, we will be able to unleash the true clinical potential of cannabis. A huge journey awaits us, and we look forward to making a difference for the many patients who need us.”

According to Guy Chamberland, CEO at Tetra Bio-Pharma: " I am glad that we have been able to sign this definitive agreement with DanCann Pharma. Both organizations strongly believe that cannabinoid-derived medicines will help to improve the quality of life of patients suffering from pain and chemotherapy induced nausea and vomiting (CINV). We look forward to work with DanCann Pharma in the Nordic Countries and Germany, both organizations set the bar very high when comes to deliver impactful therapeutic value to patients.”

About DanCann Pharma A/S

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

About Tetra Bio-Pharma Inc.

Tetra Bio-Pharma (TSX:TBP)(OTCQB:TBPMF), is a biopharmaceutical leader in cannabinoid-based drug discovery and development with a FDA and a Health Canada approved 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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