



FSD Pharma Begins Phase 1 In-human Safety and Tolerability Study of Ultra Micro-Palmitolyethanolamide (PEA)

TORONTO, March 9, 2020 /CNW/ - **FSD Pharma Inc. (Nasdaq: HUGE) (CSE: HUGE) (FRA: 0K9A) ("FSD Pharma" or the "Company")** today announced receipt of approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of single and multiple ascending doses of ultra-micronized-PEA in normal healthy volunteers.

The study is now underway at Alfred Hospital in Melbourne and is being led by principal researcher Jason Lickliter, MD, Chief Medical Officer of Nucleus Network, Australia's largest and most experienced Phase 1 clinical research organization.

"The initiation of this Phase 1 in-human safety and tolerability clinical study of ultra-micronized formulation of PEA is a ground-breaking milestone for our company as we stride forward to find novel anti-inflammatory treatment outcomes for patients by targeting the CB2 receptors of the endocannabinoid system," said Raza Bokhari, MD, Executive Co-Chairman & CEO. "I must congratulate Dr. Edward Brennan, President of FSD Pharma's BioSciences Division, and his very qualified team on delivering this milestone on schedule. Dr. Brennan's decades of experience in drug development is very noteworthy, and I share his confidence that this Phase 1 in-human study based on U.S. FDA-approved guidelines will produce favorable data. The study would validate considerable scientific literature already published, over the years, in the European Union, that claims safety and tolerability of micro-PEA, which is being dispensed in Italy and Spain as a prescription-based medical food supplement since 2004."

About FSD Pharma

FSD Pharma is a specialty biotech pharmaceutical R&D company focused on developing over time a robust pipeline of FDA-approved synthetic compounds targeting the endocannabinoid system of the human body to treat certain diseases of the central nervous system and autoimmune disorders of the skin, GI tract, and the musculoskeletal system.

Through its acquisition of Prismic Pharmaceuticals in Q2 2019, FSD Pharma is also making an effort to help address the opioid crisis by developing opioid-sparing prescription drugs utilizing the micronized formulations of palmitolyethanolamide (PEA).

The Company has Phase 1 first-in-human safety and tolerability trials for its lead candidate, PP 101 micro-PEA underway in Australia.

FSD's wholly-owned subsidiary, FV Pharma, is a licensed producer under Canada's Cannabis Act and Regulations, having received its cultivation license on October 13, 2017, and its full Sale for Medical Purposes license on June 21, 2019. The Company is licensed to cultivate cannabis in approximately 25,000 square feet of its facility in Cobourg, Ontario.

Forward-Looking Statements

Neither the Canadian Securities Exchange nor its regulation services provider accept responsibility for the adequacy or accuracy of this release.

Certain statements contained in this press release constitute "forward-looking information" and "forward-looking statements" within the meaning of applicable Canadian and U.S. securities laws (collectively, "Forward-Looking Information"). Forward-Looking Information includes, but is not limited to, information with respect to FSD Pharma's strategy, plans or future financial or operating performance, receipt of any U.S. Food and Drug Administration ("FDA") approvals, development of any FDA approved synthetic compounds, the successful treatment of diseases by such compounds, the ability to address the opioid crisis, the development of opioid sparing prescription drugs utilizing the micronized formulations of palmitoylethanolamide ("PEA"), the intention and timing of the initiation of Phase 1 first-in-human safety and tolerability trials for PP 101 micro-PEA, maintenance of FSD Pharma's Cannabis Act License, the ability to cultivate and sell cannabis produced in FSD Pharma's facility, the progress and funding of the CBD Research Project, the ability and technical feasibility of algae being utilized to produce pharmaceutical-grade cannabinoids and the ultimate success of the CBD Research Project, the production of prescription drugs that can treat diseases affecting the central nervous system, and related royalty fees. The use of words such as "budget", "intend", "anticipate", "believe", "expect", "plan", "forecast", "future", "target", "project", "capacity", "could", "should", "focus", "proposed", "scheduled", "outlook", "potential", "estimate" and other similar words, and similar expressions and statements relating to matters that are not historical facts, or statements that certain events or conditions "may" or "will" occur, are intended to identify Forward-Looking Information and are based on FSD Pharma's current beliefs or assumptions as to the outcome and timing of such future events. Such beliefs or assumptions necessarily involve known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such Forward-Looking Information. Forward-Looking Information is not a guarantee of performance. The Forward-Looking Information contained in this press release is made as of the date hereof, and FSD Pharma is not obligated to update or revise any Forward-Looking Information, whether as a result of new information, future events or otherwise, except as required by law. Because of the risks, uncertainties and assumptions contained herein, investors should not place undue reliance on Forward

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