FSD Pharma Reports Favorable Topline Results from Phase 1 First-in-Human Safety and Tolerability Study of Ultramicronized PEA

All subjects completed the trial per protocol, no safety concerns found up to the highest dose tested of 2400 mg/day

TORONTO, CANADA / ACCESSWIRE / June 22, 2020 / FSD Pharma Inc. (NASDAQ:HUGE)(CSE:HUGE)(FRA:0K9A) ("FSD Pharma" or the "Company") today announced favorable topline results from its Phase 1 randomized, double-blind, placebo-controlled study of ultramicronized palmitoylethanolamide (PEA), or FSD201. This single-site study was conducted at the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia and enrolled 48 healthy adult men and women.

The trial sequentially tested single ascending doses ranging from 600 mg to 2400 mg tablets and multiple ascending doses ranging from 600 mg to 1200 mg tablets administered twice daily for 7 consecutive days. The single ascending dose subjects also were tested for food effect.

The study found ultramicronized PEA to be safe and well tolerated. Mild and self-limiting side effects were reported and were deemed unlikely to be related to study drug. There were no abnormal laboratory findings or ECGs observed during the study and no serious adverse events were reported. No subjects withdrew due to an adverse event and all eligible subjects completed all doses. The pharmacokinetic profile of FSD201 in this study is still being analyzed.

The study was led by principal researcher Jason Lickliter, MD, Chief Medical Officer of Nucleus Network, Australia.

"We are delighted to be reporting favorable topline findings from our Phase 1 first-in-human safety and tolerability study with FSD201. I congratulate our pharmaceutical team, led by Dr. Edward Brennan. This study has also successfully validated the considerable scientific literature published over the years in Europe that claims safety and tolerability of micro-PEA," said Raza Bokhari, MD, Executive Co-Chairman & CEO.

"Our immediate plans for FSD201 include submitting these Phase 1 trial results for publication in a peer-reviewed journal and advancing this compound into a Phase 2a proof-of-concept trial for the treatment of COVID-19," continued Dr. Bokhari. "The U.S. Food and Drug Administration recently gave the Company permission to submit an Investigational New Drug application for the use of FSD201 to treat COVID-19. We contacted the FDA after becoming aware that Italian physicians and scientists were advocating for use of ultramicronized PEA for patients suffering from symptoms of COVID-19, based on the drug's mechanism of action as a potent and safe anti-inflammatory agent that reduces the production of pro-inflammatory cytokines and may help mitigate a cytokine storm."

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the Covid-19 (or SARS-2 Coronavirus) at this time.

About FSD Pharma

FSD Pharma, Inc. (NASDAQ:HUGE)(CSE:HUGE)(FRA:0K9A) is a publicly traded holding company, since May 2018.

FSD Pharma BioSciences, Inc., a wholly-owned subsidiary, is a specialty biotech pharmaceutical R&D company focused on developing over time multiple applications of its lead compound FSD201, ultramicronized palmitoylethanolamide (PEA), by down-regulating the cytokines to effectuate an anti-inflammatory response.

The Company has successfully completed a Phase 1 first-in-human safety and tolerability study for FSD201 that found the compound to be safe with no serious adverse side effects. This study also validated considerable scientific literature published in Europe that claims safety and tolerability of micro-PEA. Ultra-micronized PEA has been dispensed in Italy and Spain as a prescription anti-inflammatory medical food supplement since 2004, with no serious adverse side effects reported.

On June 1, 2020, the Company received permission from the U.S. Food and Drug Administration (FDA) to submit an Investigational New Drug ("IND") application for the use of FSD201 to treat COVID-19, the disease caused by the SARS-CoV-2 virus.

Severe COVID-19 is characterized by an over-exuberant inflammatory response that may lead to a cytokine storm and ultimately death. The Company is focused on developing FSD201 for its anti-inflammatory properties to avoid the cytokine storm associated with acute lung injury in hospitalized COVID-19 patients.

FV Pharma, a wholly-owned subsidiary, 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 press 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, the costs associated with such planned trials, our ability to obtain required funding and the terms and timing thereof, development of any FDA-approved synthetic compounds, and the successful treatment of diseases by such compounds. 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. Certain of these risks and uncertainties are described in the Company's continuous disclosure filings available under the Company's SEDAR profile at www.sedar.com. 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 Looking-Information. The foregoing statements expressly qualify any Forward-Looking Information contained herein.

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