FSD Pharma Begins Phase 2 Clinical Trial to Evaluate FSD201 for the Treatment of Hospitalized COVID-19 Patients

- FDA has authorized randomized, controlled, double-blind, multicenter study on 352 patients

TORONTO, ON / ACCESSWIRE / September 28, 2020 / FSD Pharma Inc. (NASDAQ:HUGE)(CSE:HUGE.CN) ("**FSD Pharma**" or the "**Company**") today announced that the U.S. Food and Drug Administration ("**FDA**") has authorized the initiation of a Phase 2 study for the use of FSD201 (ultramicronized palmitoylethanolamide, or ultramicronized PEA) to treat COVID-19, the disease caused by the SARS-CoV-2 virus (the "**FSD201 COVID-19 Trial**"). The company is expected to start dosing patients in October 2020. We believe FSD201 may have the potential to address the over-exuberant inflammatory response characterized by COVID-19 infection that may lead to a cytokine storm and ultimately death.

"Commencing a phase 2 clinical trial to treat hospitalized COVID-19 patients is a major milestone achieved by our pharmaceutical team led by Dr. Edward Brennan and a huge step forward for FSD Pharma," said Dr. Raza Bokhari, Executive Co-Chairman & CEO. We are joining the global fight against the deadly SARS-CoV-2 virus with a hope to demonstrate down-regulation of the over-expressed immune response in COVID-19 patients leading to better treatment outcome. FSD201 is formulated as a tablet for oral dosing and is a safe compound with no known serious adverse side effects. Numerous studies over the past 40 years have validated micronized PEA for its efficacy and safety in the treatment of, and prophylactic effects with respect to, other respiratory infections."

COVID-19 Trial Design

The FSD201 COVID-19 Trial is a randomized, controlled, double-blind, multicenter study, conducted on 352 patients to assess the efficacy and safety of FSD201 dosed at 600mg or 1200mg twice-daily, together with standard of care ("**SOC**") compared to SOC alone in hospitalized patients with documented COVID-19 disease. Eligible patients will present symptoms consistent with influenza/coronavirus signs (fever, dry cough, malaise, difficulty breathing) and newly documented positive COVID-19 disease.

The primary objective of the FSD201 COVID-19 Trial is to determine whether FSD201 plus SOC provides a significant improvement in the clinical status of patients (e.g., shorter time to symptom relief). Secondary objectives of the FSD201 COVID-19 Trial include determining whether FSD201 plus SOC demonstrates additional benefit in terms of safety, objective assessments such as length of time to normalization of fever, length of time to improvement of oxygen saturation and length of time to clinical progression, including time to mechanical ventilation or hospitalization, and length of hospital stay. The exploratory endpoint is cytokine clearance as measured by Enzyme Linked Immunosorbent Assay (ELISA). The treatment period for patients in the FSD201 COVID-19 Trial is 14 days and the primary end point is determined at 28 days.

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.

Board of Directors Update

FSD Pharma announces the departure of Mr. David Urban from the Board of Directors effective October 31, 2020. Mr. Urban has advised the Chairman of the Board that he is stepping down because of external contractual obligations. We thank David Urban for his significant leadership and services as a valuable board member and we wish him much success in his present and future endeavors.

About FSD Pharma

FSD Pharma Inc. is a publicly-traded holding company.

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, by down-regulating the cytokines to effectuate an anti-inflammatory response.

Forward-Looking Statements

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

The Company's subject area experts continue to review the scientific evidence/claims/research relevant to the application of PEA and ultramicronized-PEA.

The duration and cost of Phase 2 clinical trials can vary significantly depending on multiple factors, including the enrollment rate of patients, country in which trials are conducted, and specific trial protocols required. The process of developing pharmaceutical products and receiving the necessary regulatory approvals for commercialization typically takes several years. Accordingly, no near-term revenues from product sales or services are expected from our ultramicronized-PEA candidate(s). The milestones described above represent customary inflection points for financing by clinical-stage biotech companies. However, there is no assurance that the Company will be able to achieve these clinical milestones, nor, if successful in doing so, that the Company will be able to access additional financing on terms or timing acceptable to the Company.

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 FDA approvals, the completion of any trials regarding the use of FSD201 to treat COVID-19 or whether FSD201 may be effective in treating COVID-19, the costs associated with such planned trials, our ability to obtain required funding and the terms and timing thereof and the ultimate development of any FDA approved synthetic 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 and on the Company's EDGAR profile at www.sec.gov. 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.

For further information:

Sandy Huard, Head of Communications, FSD Pharma Inc.
sandy@fsdpharma.com
(647) 864-7969

Zeeshan Saeed, President, FSD Pharma Inc.
zeeshan@fsdpharma.com

Investor Relations
IR@fsdpharma.com

SOURCE: FSD Pharma, Inc.