FSD Pharma Announces First Patient Randomized in Phase 2 Trial of FSD201 for the Treatment of Hospitalized Patients with COVID-19

-----FDA has authorized randomized, controlled, double-blind study on 352 patients. The Company is expected to conduct this trial in 25-30 Medical Centers and Hospitals in North America

TORONTO--(BUSINESS WIRE)--December 15, 2020--FSD Pharma Inc. (Nasdaq: HUGE) (CSE: HUGE) ("FSD Pharma" or the "Company") today announced the dosing of the first patient in its Phase 2a clinical trial of FSD201 (ultramicronized palmitoylethanolamide, or ultramicronized PEA) for the treatment of hospitalized patients with COVID-19.

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.

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.

The Company filed an IND with the FDA on August 28, 2020 and was approved on September 25, 2020 to initiate a phase 2 clinical trial 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.

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 FDA approvals, the completion of any trials regarding the use of FSD201 to treat COVID-19, the safety of FSD201 or whether FSD201 may be effective in treating COVID-19, the costs associated with such planned trials and our belief that we have sufficient cash to complete the Phase 2 study, our ability to obtain required funding and the terms and timing thereof, the ultimate development of any FDA approved synthetic compounds, the expected insurance recovery related to the settlement agreement, the completion of the settlement contemplated in the settlement agreement and the timing and closing of the sale of certain non-core real estate assets. 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 under 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.

Contacts

For further information:
Donal Carroll, Chief Financial Officer, FSD Pharma Inc.
Dcarroll@fsdpharma.com

Investor Relations
IR@fsdpharma.com