FSD Pharma Announces Phase 2 Clinical Trial IND Filing with the FDA to Treat Patients with COVID-19

- The study is expected to be conducted at 25-30 hospitals in North America -

TORONTO, ON / ACCESSWIRE / August 31, 2020 / FSD Pharma Inc. (CSE:HUGE)(NASDAQ:HUGE)(FRA:0K9A) ("**FSD Pharma**" or the "**Company**") today announced that it has submitted to the U.S. Food and Drug Administration ("**FDA"**) an Investigational New Drug Application (IND) 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**"). Severe COVID-19 is characterized by an over-exuberant inflammatory response that may lead to a cytokine storm and ultimately death. As previously announced, FSD Pharma 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.

COVID-19 Trial Design

The FSD201 COVID-19 Trial will be a randomized, controlled, double-blind, multicenter study, conducted at 25-30 sites in North America 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.

Issuance of Share-Based Compensation and Early Warning Disclosure for Dr. Raza Bokhari, Executive Co-Chairman & CEO

Further to our news release dated July 31, 2020, the Board of Directors has authorized the issuance of an additional 369,255 class B subordinate voting shares ("**Class B Shares**") to certain of the Company's directors, officers, employees and consultants as share-based compensation.

As will be more particularly described in an early warning report to be filed under the Company's SEDAR profile, on August [26], 2020, Dr. Raza Bokhari acquired 805,802 Class B Shares in lieu of cash compensation for his services as Chief Executive Officer and Executive Co-Chairman of the Company. As a result, Dr. Bokhari now beneficially owns, or has control or direction over, in aggregate, approximately 8.5% of the issued and outstanding Class B Shares (on a non-diluted basis). Dr. Bokhari also continues to hold 33.3% of the Company's outstanding class A multiple voting shares (together with the Class B Shares, the "**FSD Shares**"). In aggregate, Dr. Bokhari controls approximately 23% of the voting rights attached to the issued and outstanding FSD Shares.

Dr. Bokhari acquired the Class B Shares for investment purposes and has no present intention to sell such securities. Dr. Bokhari is currently prohibited from selling any securities because of lock-up agreements entered into in connection with the recent equity financings by the Company for C$10.125 million on June 9, 2020 and US$10.0 million on August 6, 2020. Depending on market conditions, general economic and industry conditions, trading prices of the Company's

securities, the Company's business, financial condition and prospects and/or other relevant factors, Dr. Bokhari may develop such plans or intentions in the future and may from time to time acquire or dispose of securities of the Company.

About FSD Pharma

FSD Pharma Inc. 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, 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 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.

The Phase 2 clinical trial program is subject to a favorable toxicology study and successful completion of ongoing laboratory studies, access to additional financing and review by the FDA of our IND application. The duration and cost of 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, including the approval of our IND submission, 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.