FSD Pharma Announces Investigational New Animal Drug Filing With the FDA to Treat Dogs With Enteropathy

- ***The FDA has accepted the Investigational new Animal Drug application for review***
- ***The proposed trial is expected to be conducted at 5-10 sites in USA and will enroll up to 200 dogs***
- ***Shareholders URGED to Vote the BLUE proxy by 9:00 a.m. on May 12, 2021***
- ***Contact Gryphon Advisors Inc. for assistance at 1.833.292.5847 or by email at inquiries@gryphonadvisors.ca***

TORONTO--(BUSINESS WIRE)--May 10, 2021--**FSD Pharma Inc.** (Nasdaq: HUGE) (CSE: HUGE.CN) ("**FSD Pharma**" or the "**Company**") today announced that it has submitted to the U.S. Food and Drug Administration ("**FDA"**) an Investigational New Animal Drug Application (IND) for the use of FSD201 (ultramicronized palmitoylethanolamide, or ultramicronized PEA) to treat Gastrointestinal enteropathy in dogs. The application has been accepted for review.

The proposed trial design is a randomized, double-blind, placebo-controlled, crossover, trial comparing FSD201 (ultramicronized Palmitoylethanolamide (PEA)) dosed twice daily for 30 days to placebo for the treatment of canine inflammatory bowel disease. The primary endpoint will be a validated diarrhea score, evaluated by both treating veterinarian and dog owner. The trial will be conducted at 5-10 sites in the USA, and will enroll up to 200 dogs.

Vote Only the <u>BLUE</u> Proxy FOR the Management Director Nominees

FSD Pharma thanks shareholders for the strong support the Company has received ahead of its upcoming Annual and Special Meeting of Shareholders (the "Meeting").

On May 5, FSD Pharma announced that Institutional Shareholder Services Inc. ("ISS"), a leading independent international corporate governance analysis and proxy advisory firm, had recommended that shareholders vote FOR all Management Director Nominees i and FOR the elimination of the dual-class share structure (the "Dual-Class Sunset") at the Meeting.

FSD Pharma urges shareholders to go to FSD Pharma's website www.fsdfuture.com to cast their vote electronically and for additional information on how the Company has the right strategy and the right Management Director Nominees to build on its positive momentum towards value creation for all shareholders. Shareholders should contrast this plan with that of the Dissidents, whose self-serving approach pulls the Company backwards, making promises that are unlikely to materialize into real shareholder value creation.

Shareholders are urged to vote immediately to ensure their proxies are received by the proxy voting deadline – no later than 9:00 a.m. (Toronto time) on May 12, 2021. Shareholders with questions or who require assistance voting their shares should contact the Company's proxy

solicitation agent, Gryphon Advisors Inc. at 1.833.292.5847 toll-free in North America (1.416.902.5565 by collect call) or by email at inquiries@gryphonadvisors.ca.

Filing of Quarter-End Results

The Company also reported its reviewed financial results for the first quarter ended March 31, 2021. These filings are available for review under the Company's SEDAR profile at www.sedar.com.

About FSD Pharma

FSD Pharma Inc. (www.fsdpharma.com) is a publicly-traded holding company.

FSD 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, ultramicro PEA 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. The trial is currently underway and is expected to randomize 352 patients in a controlled, double-blind multicenter study.

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 ultra-micro PEA for its anti-inflammatory properties to avoid the cytokine storm associated with acute lung injury in hospitalized COVID-19 patients.

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

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.

Contacts

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