

# **FSD Pharma Enters into License Agreement to Develop FDA approved Veterinary Drugs for the Treatment of Gastro-Intestinal Diseases in Dogs and Cats**

## **-Announces Filing of Year-End 2020 Results and Provides Corporate Update**

TORONTO--(BUSINESS WIRE)--March 16, 2021--FSD Pharma Inc. (Nasdaq: HUGE) (CSE: HUGE) (“FSD Pharma” or the “Company”) today announces that it has entered into a license agreement (the “License Agreement”) with Innovet Italia S.R.L. (“Innovet”), under which Innovet granted the Company a license to use ultramicrosized-palmitoylethanolamide (or ultramicrosized PEA) (“ultra-micro PEA”) to develop U.S. Food and Drug Administration (“FDA”) approved veterinary drugs for the treatment of gastro-intestinal diseases in Canine and Feline (Dogs and Cats). In addition, the Company today announces the filing of its year-end results and provides corporate updates.

“The licensing agreement with Innovet Italia S.R.L. to evaluate the use of ultra- micro PEA as a veterinary anti-inflammatory prescription drug, is an exciting opportunity for the company to enter into a new and untapped market,” said Dr. Raza Bokhari, Executive Chairman & CEO. “With a balance sheet that is stronger today than it was when we began our journey nearly three years ago, we are actively exploring other M&A and licensing opportunities to expand our drug development pipeline.”

### **License Agreement**

The License Agreement grants the Company an exclusive, worldwide license (excluding Italy, and subject to a first refusal right maintained by Innovet, any other country in Europe) to research, manufacture and commercialize products using certain proprietary formulations of ultra-micro PEA (the “Licensed Products”) to treat gastro-intestinal diseases in canines and felines. The License Agreement provides that the Company shall develop the Licensed Products with a view to submitting an Investigational Animal Drug Application with the FDA within thirty-six (36) months of the date of the agreement and shall submit a New Animal Drug Application within sixty (60) months of the effective date of the agreement.

Under the terms of the License Agreement, the Company is required to make payments to Innovet upon the achievement of specified milestones. An initial non-refundable sum of US\$500,000 is due and payable to Innovet on the effective date of the License Agreement and a second non-refundable sum of US\$250,000 will be due and payable to Innovet on the first anniversary of the effective date of the License Agreement. Within thirty business days of the first notification of approval of a New Animal Drug Application by the FDA of the first Licensed Product to receive such approval in the United States, the Company is required to pay an additional non-refundable sum of US\$750,000 to Innovet.

---

The License Agreement also specifies certain royalty payments. Pursuant to the License Agreement, the Company is required to pay Innovet 14% of any one-off lump sum payments it

receives as consideration for granting a sub-license to a third-party with respect to a Licensed Product. In addition, the Company is required to pay 5% of net sales of the Licensed Products.

The above description of the License Agreement is qualified in its entirety by reference to the full text of such agreement, a copy of which will be available under the Company's SEDAR and EDGAR profiles.

### **Corporate Update**

The Company's annual and special meeting of shareholders for 2021 ("**2021 AGM**") has been scheduled for May 14, 2021. April 15, 2021 has been fixed as the record date for voting at the 2021 AGM. The Company's management information circular and related proxy materials will be delivered to shareholders and made available under the Company's SEDAR profile on or before April 23, 2021. This 2021 AGM is being held in lieu of Annual meeting of the Shareholders meeting announced earlier for June 29<sup>th</sup> 2021.

The Company also has recently retained Randell J Mack, a veteran pharmaceutical executive as President of FSD BioSciences, Inc. Dr. Edward Brennan, has been named the Chief Medical Officer.

### **Filing of Year-End Results**

The Company also reported its audited financial results for the fourth quarter and full year ended December 31, 2020. These filings are available for review under the Company's SEDAR profile at [www.sedar.com](http://www.sedar.com).

### **About FSD Pharma**

FSD Pharma Inc. ([www.fsdpharma.com](http://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, ultra-micro 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.

## **About Innovet**

Innovet Italia is an innovative animal health company, founded in Italy in 1996. Its main goal is to bring scientific innovation in niche fields of the veterinary market. The philosophy that drives Innovet's development is to follow where nature leads, studying and mimicking natural protective body responses rather than "artificially" fighting the mechanisms of diseases. Based on such a strategic idea, Innovet's research team discovered and patented a family of bioactive lipid amides (i.e., aliamides, whose parent compound is palmitoylethanolamide, PEA) able to naturally restore the physiological balance of the hyper-reactive tissues. PEA, its micronized and ultramicronized forms and various other congeners, are the main components of Innovet's innovative products. Innovet's commercial effort is mainly focused on the small animal health field, in many market segments (i.e. dermatology, orthopedics, oral health, uro-nephrology, behavior, gastroenterology, ophthalmology and algology). For more information: <http://www.innovet.it>

## **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 or other regulatory approvals, the completion of any trials regarding the use of FSD201 to treat COVID-19 or to treat canine and feline gastro-intestinal diseases, the safety of FSD201 or whether FSD201 may be effective in treating COVID-19 or to treat canine and feline gastro-intestinal diseases, the costs associated with such planned trials and our belief that we have sufficient cash to complete any clinical trials or studies with respect to the foregoing, our ability to obtain required funding and the terms and timing thereof. 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](http://www.sedar.com) and under the Company’s EDGAR profile at [www.sec.gov](http://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**

Donal Carroll, Chief Financial Officer, FSD Pharma Inc.  
Dcarroll@fsdpharma.com

**Investor Relations**  
IR@fsdpharma.com