Recruiting Underway in FSD Pharma's Phase 2 Trial of FSD-PEA (FSD201) for the Treatment of Chronic Pain Associated With Idiopathic MCAS (MCAD)

Toronto, January 30, 2023 --FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRA: 0K9A) ("**FSD Pharma**" or the "**Company**"), a biopharmaceutical company dedicated to building a portfolio of innovative assets and biotech solutions to address ailments affecting millions worldwide, today announces recruiting is underway for the Company's Phase 2 clinical trial of FSD201 for the treatment of chronic pain associated with idiopathic MCAS (MCAD) at two clinical sites in the USA, and a Canadian site to be ready to recruit soon. The trial and its status are available on ClinicalTrials.gov (Identifier: NCT05652907).

FSD201 is a proprietary anti-inflammatory compound with the potential to address a wide range of inflammatory diseases and associated conditions. FSD201 successfully completed a Phase 1 safety and tolerability trial with topline results.

The multi-center, randomized, double-blind, placebo controlled parallel group study will enroll 60 idiopathic MCAS patients. Per the protocol, patients will receive either 600-milligram tablets of FSD201 or placebo twice daily for 56 consecutive days. The primary outcome is a 30% decrease from baseline to day 28 in the average daily pain intensity. The trial will also evaluate many secondary outcomes.

"FSD201 is a unique proprietary formulation of palmitoyl ethanolamide, and already received the new molecular entity (NME) designation for a potential 505(b)(1) application to the US FDA. This is attractive because of the potential exclusive regulatory access to the US market. Our clinical team put in a lot of thought into exploring unmet needs in inflammatory disorders and associated conditions. We are excited to evaluate the efficacy and safety of FSD201 in the treatment of chronic widespread musculoskeletal nociplastic pain associated with idiopathic MCAS, a disease that has challenged caregivers and researchers since the first case was diagnosed in 2007, and potentially millions of patients have a significantly reduced quality of life," said Dr. Lakshmi P. Kotra, Head of FSD Pharma's FSD Biosciences and CEO of Lucid Psycheceuticals. "Owing to the complexity of the disease, the therapeutic market is grossly underserved, presenting us with an opportunity as a pioneer in the space to provide a novel therapeutic option to scores of MCAS patients desperately in need of safe alternatives to the current standard of care. We feel we are in a position with only a handful of companies conducting clinical trials for this indication."

Mast cells are the first responders of the innate and adaptive immune systems, responding to endogenous factors to play an important role in anaphylaxis and tissue healing. MCAS refers to a group of disorders characterized by multisystem symptoms resulting from the accumulation of

altered mast cells and/or abnormal mast cell mediator release, causing repeated anaphylactic symptoms/episodes and trapping a patient in a cycle of neurogenic pain and inflammation. Chronic widespread musculoskeletal nociplastic pain, arising from neurogenic inflammation, is associated with MCAS. Symptoms of MCAS can start at any age, but usually begin in adulthood. Due to the ubiquitous nature of mast cells throughout human body tissue, MCAS has the potential to affect every organ system, frequently without showing abnormalities in routine testing and patients suffer from chronic and systemic pain. Up to 30% of the general population can be affected by disorders related to mast cell activation (atopic disorders). Conversely, mastocytosis and MMAS (monoclonal mast cell activation syndrome) are typically considered rare diseases, affecting 1 in 10,000-20,000 subjects.[1] The cause of MCAS is unknown and there is no cure.

[1] https://www.jacionline.org/article/S0091-6749(17)31025-4/pdf

FSD also announces the grant of stock options to directors and officers of the Company to purchase up to an aggregate of 2,000,000 Class B subordinate voting shares in accordance with the Company's stock option plan and subject to vesting terms. The options are exercisable at a price of C$1.30 per share and will expire five years from the date of grant. Certain Independent directors were granted 400,000 PSU's.

About FSD Pharma

FSD Pharma Inc. is a biotechnology company with three drug candidates in different stages of development. FSD BioSciences, Inc., a wholly owned subsidiary, is focused on pharmaceutical research and development of its lead compound, FSD201, a proprietary ultra-micronized PEA formulation, for the treatment of inflammatory diseases. Lucid Psycheceuticals Inc., a wholly owned subsidiary, is focused on the research and development of its lead compounds, Lucid-Psych and Lucid-MS. Lucid-Psych is a molecular compound identified for the potential treatment of mental health disorders, and expanding this category, the Company is investigating other products addressing acute medical needs due to the abuse of drugs such as alcohol. Lucid-MS is a molecular compound identified for the potential treatment of neurodegenerative disorders.

Forward Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, "**forward-looking statements**") within the meaning of applicable securities laws. Any statements that are contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements are often identified by terms such as "plans", "expects", "expected", "scheduled", "estimates", "intends", "anticipates", "hopes", "planned" or "believes", or variations of such words and phrases, or states that certain actions, events or results "may", "could", "would", "might", "potentially" or "will" be taken, occur or be achieved. More particularly, and without limitation, this press release contains forward-looking statements contained in this press release include statements

concerning the future of FSD Pharma Inc. and are based on certain assumptions that FSD Pharma has made in respect thereof as of the date of this press release. FSD Pharma cannot give any assurance that such forward-looking statements will prove to have been correct.

Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. The Company cautions that although it believes the expectations and material factors and assumptions reflected in these forward-looking statements are reasonable as of the date hereof, there can be no assurance that these expectations, factors and assumptions will prove to be correct and these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to a number of known and unknown risks and uncertainties including, but not limited to: the fact that the drug development efforts of both Lucid and FSD BioSciences are at a very early stage; the fact that preclinical drug development is uncertain, and the drug product candidates of Lucid and FSD BioSciences may never advance to clinical trials; the fact that results of preclinical studies and early-stage clinical trials may not be predictive of the results of later stage clinical trials; the uncertain outcome, cost, and timing of product development activities, preclinical studies and clinical trials of Lucid and FSD BioSciences; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; the potential inability to obtain or maintain regulatory approval of the drug product candidates of Lucid and FSD BioSciences; the introduction of competing drugs that are safer, more effective or less expensive than, or otherwise superior to, the drug product candidates of Lucid and FSD BioSciences; the initiation, conduct, and completion of preclinical studies and clinical trials may be delayed, adversely affected, or impacted by COVID-19 related issues; the potential inability to obtain adequate financing; the potential inability to obtain or maintain intellectual property protection for the drug product candidates of Lucid and FSD BioSciences; and other risks. Accordingly, readers should not place undue reliance on the forward-looking statements contained in this press release, which speak only as of the date of this press release.

Further information regarding factors that may cause actual results to differ materially are included in the Company's annual and other reports filed from time to time with the Canadian Securities Administrators on SEDAR (www.sedar.com) and with the U.S. Securities and Exchange Commission on EDGAR (www.sec.gov), including the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2021, under the heading "Risk Factors." This list of risk factors should not be construed as exhaustive. Readers are cautioned that events or circumstances could cause results to differ materially from those predicted, forecasted or projected. The forward-looking statements contained in this document speak only as of the date of this document. FSD Pharma does not undertake any obligation to publicly update or revise any forward-looking statements or information contained herein, except as required by applicable laws. The forward-looking statements contained in this document are expressly qualified by this cautionary statement.

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

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