FDA and Health Canada Clear IND for FSD Pharma to Proceed with Phase 2 Trial of FSD201 for Nociplastic Pain Associated with Idiopathic Mast Cell Activation Syndrome

TORONTO--(BUSINESS WIRE)--September 6, 2022--FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRE: 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 that it received "Study May Proceed" letter for the Investigational New Drug ("IND") application from the U.S. Food and Drug Administration ("FDA") and "Notice of Authorization" from Health Canada for its Phase 2 clinical trial of FSD201. The corresponding study protocol is titled "A Randomized, Double-Blind Placebo Controlled Parallel Group Study of Safety and Efficacy of FSD201 in Patients with Chronic Widespread Musculoskeletal Nociplastic Pain Associated with Idiopathic Mast Cell Activation Syndrome (Disorder)".

"We are delighted to receive authorization to proceed with our planned efficacy clinical trial of FSD201 from both FDA and Health Canada. We are working with our clinical sites in the U.S. and Canada to initiate the study and intend to release more details on the study very soon," said Dr. Lakshmi Kotra, CEO of FSD Pharma subsidiary Lucid Psycheceuticals. "Our regulatory and clinical teams led by Dr. Andrzej Chruscinski, Vice-President for Clinical and Scientific affairs, worked tirelessly with our expert advisors developing the protocols, and we are looking forward to the next stage of clinical development of FSD201. We believe FSD201 is a compelling drug candidate, and we are actively exploring opportunities for development partners and other synergistic collaborations that will maximize shareholder returns."

FSD201 is a proprietary formulation of ultra-micronized palmitoylethanolamide (PEA). FSD Pharma's successfully completed Phase 1 clinical trial showed FSD201 to be safe and well tolerated. This is especially important as chronic inflammatory diseases are the leading cause of death globally and the World Health Organization ranks chronic disease as the greatest threat to human health.[1] This immense problem has limited treatment options.[2] This is why FSD Pharma continues to work relentlessly to bring a new and safe inflammatory treatment option to market.

[1] Chronic Inflammation - StatPearls - NCBI Bookshelf (nih.gov); https://www.ncbi.nlm.nih.gov/books/NBK493173/
[2] 50 of 2021's best-selling pharmaceuticals | Drug Discovery; https://www.drugdiscoverytrends.com/50-of-2021s-best-selling-pharmaceuticals/#:~:text=(Look%20out%20for%20more%20insights,generated%20%2420.7%20billion%20in%20sales.

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, an ultra-micronized PEA, 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. Lucid-MS is a molecular compound identified for the potential treatment of neurodegenerative disorders.

Forward Looking Information

Certain statements contained herein are "forward-looking statements." Often, but not always, forward-looking statement can be identified by the use of words 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. Forward-looking statements contained in this press release include statements relating to the FDA and Health Canada Approval of IND for FSD Pharma to Proceed with Phase 2 Trial of FSD201 for Nociplastic Pain Associated with Idiopathic Mast Cell Activation Syndrome. FSD cannot give any assurance that such forward-looking statements will prove to have been correct. The reader is cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

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 is believed that the assumptions are reasonable in the circumstances, 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. Factors that may cause such material differences include without limitation: 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. 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) under the heading "Risk Factors." Any forward-looking statement contained in this release speaks only as of its date. The Company does not undertake to update any forward-looking statements, except to the extent required by applicable securities laws.

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