FSD Pharma Subsidiary Lucid Psycheceuticals Files for Patent On Novel Formulations of Palmitoylethanolamide, Presents Preclinical Toxicology Results at an International Symposium

TORONTO--(BUSINESS WIRE)--July 13, 2022--FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRE: 0K9A) ("**FSD Pharma**" or the "**Company**"), a life sciences holding company dedicated to building a portfolio of assets and biotech solutions, announced today that is wholly owned subsidiary, Lucid Psycheceuticals Inc. ("**Lucid**"), filed a provisional patent application on novel formulations of palmitoylethanolamide (PEA). The new patent application is based on the results of completed preclinical animal toxicology studies and phase 1 clinical trial using FSD201 (ultramicronized PEA), sponsored by FSD Pharma. Patent applications are important tools to protect intellectual property of the company for commercialization and value proposition for the shareholders.

FSD Pharma is diligently pursuing the clinical development of FSD201 for various indications. On May 31, 2022, the Company announced the submission of an Investigational New Drug application with the U.S. Food and Drug Administration ("FDA") and Health Canada detailing a planned Phase 2 clinical trial of FSD201 for the treatment of a yet-to-be-disclosed inflammatory disorder. FSD Pharma is fortifying its intellectual property position through additional novel formulations using PEA with superior biopharmaceutical profiles to serve patients in need.

FSD Pharma presented their preclinical toxicology results on FSD201 at the 32nd Annual Symposium of the International Cannabinoid Research Society held in Galway, Ireland on June 25-30, 2022, in a scientific peer setting. FSD Pharma and Lucid were represented at the conference by Dr. Lakshmi P. Kotra (CEO, Lucid Psycheceuticals), Dr. Andrzej Chruscinski (Vice-President, Clinical and Scientific Affairs, Lucid Psycheceuticals), and Dr. Mohammad Ebrahimzadeh (Scientist, Lucid Psycheceuticals). The poster presentation titled, "Preclinical Safety Pharmacology and Toxicology of FSD201, A Palmitoylethanolamide Composition" discussed the safety pharmacology and toxicokinetics of FSD201, which were completed by FSD Pharma for regulatory filings with the U.S. FDA. The poster presentation provided support for the clinical development of FSD201, revealing well-tolerated doses of FSD201 in two different animal species.

"New patent applications are a critical step for protecting our assets in the development of effective therapeutics targeting brain and inflammatory disorders," said Dr. Kotra. "Novel, high-quality treatments and intellectual property are important to us as an innovation-driven company, and I am very pleased with our team's performance to stay on target towards the key milestones in 2022, including the planned Phase 2 trial of FSD201."

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 of FSD Pharma, 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 of FSD Pharma, 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 related to the Company's subsidiary Lucid Psycheceuticals filing for a patent on novel formulations of PEA and presenting preclinical toxicology findings at a global symposium. 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.

Contacts

Zeeshan Saeed, Founder, President and Executive Co-Chairman of the Board, FSD Pharma Inc.
Zsaeed@fsdpharma.com
(416) 854-8884

For information: info@fsdpharma.com
Investor Relations: ir@fsdpharma.com
Website: www.fsdpharma.com