FSD Pharma submits its phase-1 Clinical Trial Application for Lucid-MS (Lucid-21-302) for first-in-human safety and tolerability investigation

Company Seeking to Initiate Phase 1 Clinical Trial for its First-in-Class Multiple Sclerosis Drug Candidate

TORONTO--(BUSINESS WIRE)--January 17, 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 the submission of the Company's Clinical Trial Application (CTA) for a planned Phase-1 clinical trial for Lucid-MS, a candidate for the treatment of Multiple Sclerosis (MS).

Lucid-MS is a first-in-class neuroprotective compound with a novel mechanism action which, in preclinical models, has shown to prevent myelin degradation (demyelination), a cause for MS and other neurodegenerative diseases. Preclinical evidence also showed that Lucid-MS promotes functional recovery in experimental animal models of MS. Lucid-MS has demonstrated excellent results in several animal models, as shown in a video available at: https://fsdpharma.com/our-science/.

"This is an exciting time for our company, shareholders, and most importantly for the MS community," said Dr. Lakshmi Kotra, CEO of Lucid Psycheceuticals, a wholly owned subsidiary of FSD Pharma. "Multiple Sclerosis is a debilitating disease without any cure, relegating patients and caregivers to significantly lower quality of life. There is an intense effort for disease-modifying treatments to address unmet needs especially for the treatment of progressive MS, and potentially that are non-immunomodulatory. Lucid-MS is a promising first-in-class agent with a novel mechanism of action with a potential to address progressive stages of the disease. Lucid-MS is non-immunomodulatory in its mechanisms of action based on current evidence. We are optimistic about the potential of Lucid-MS and we are eager to initiate this clinical trial taking this one step closer to the patients."

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.

Contacts

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

Investor Relations:
Email: ir@fsdpharma.com, info@fsdpharma.com
Website: www.fsdpharma.com