FSD Pharma Achieves Milestone in Completion of Dosing of Sentinel Subjects in First-in-Human Clinical Trial of Lucid-MS (Lucid-21-302) for Multiple Sclerosis

TORONTO--(BUSINESS WIRE)--April 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 for the treatment of challenging neurodegenerative, inflammatory and metabolic disorders, today announced completion of the first-in-human ("FIH") sentinel dosing of Lucid-21-302 ("Lucid-MS") in the Company's Phase I clinical trial evaluating its novel drug candidate as an orally-administered treatment for Multiple Sclerosis ("MS"). The sentinel dose was completed on Sunday, April 16, 2023.

"Dosing the sentinel subject is a major achievement for our team and culmination of more than a decade of very promising research by a seasoned development team passionate about changing the future treatment paradigm for patients dealing with the debilitating effects of MS," said Dr. Lakshmi Kotra, CEO of Lucid Psycheceuticals, a wholly owned subsidiary of FSD Pharma. "Current MS treatments are immunomodulatory and include repeated subcutaneous or intramuscular injections for treating the symptoms of MS. We envision a day where an oral medication will protect or even help repair myelin in the central nervous system, a hallmark feature of the disease. We are optimistic Lucid-MS has this type of paradigm-shifting potential and the sentinel dosing is a critical step in advancing this pipeline forward."

The FIH clinical trial is evaluating the safety and tolerability of Lucid-MS, a patented first-in-class New Chemical Entity ("NCE") and neuroprotective compound with a novel mechanism of action for the treatment of MS. Lucid-MS. In preclinical models, Lucid-MS has been shown to prevent myelin degradation (demyelination), a hall mark pathology feature of MS and other neurogenerative diseases characterized by damage to the myelin sheath surrounding nerve fibers in the central nervous system. Preclinical evidence has demonstrated Lucid-MS to promote functional recovery in experimental animal models of MS (https://fsdpharma.com/our-science/). Based upon current evidence, Lucid-MS is non-immunomodulatory, an important distinction in the potential for developing new, safe options for treating MS.

The Seriousness of MS

MS is a chronic inflammatory and degenerative disorder of the central nervous system (brain and spinal cord). Presentation of symptoms can be diverse, including fatigue, numbness and tingling, muscle spasms, blurred vision, dizziness, pain, mobility problems, cognitive impairment and decline, depression, anxiety, and more. Although current treatments reduce the relapse rate, there remains a significant unmet need to slow disease progression and address the progressive stages of MS, which LUCID-MS may address.

The MS Society (https://mssociety.ca/resources/news/article/atlas-of-ms-report-shows-28-million-people-worldwide-live-with-multiple-sclerosis) shows that someone in the world is

diagnosed with MS every five minutes. According to MS International Foundation (Atlas of MS 2020 – Epidemiology report found at www.msif.org/resource/atlas-of-ms-2020/), the number of people diagnosed worldwide with Multiple Sclerosis in 2020 is estimated at 2.8 million, up significantly from 2.3 million in 2013. The U.S. and Canada rank amongst the highest in the world in prevalence per capita, with 288 cases per 100,000 people and 250 cases per 100,000 people, respectively. MS can occur at any age, but the average age for diagnosis globally is 32 years. MS is also diagnosed in youths, with at least 30,000 children under the age of 18 (or ~1.5% of the total number of cases) living with the disease. MS is far more frequent in females (69% of cases) than in males (31% of cases). There currently is no cure for MS. Deaths attributed to MS are commonly caused by infection (e.g., respiratory, urinary tract-related); conditions associated with advanced disability and immobility (e.g., aspiration pneumonia, chronic respiratory disease). According to Allied Market Research, the global MS therapies market was valued at $22.99 billion in 2018 and will grow at a 2.5% compound annual growth rate to reach $28.0 billion by 2026 (www.alliedmarketresearch.com/multiple-sclerosis-market).

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 Psychss 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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