

FSD Pharma Receives Regulatory Clearance for Its Proposed Phase-1 Clinical Trial of Lucid-21-302 (Lucid-MS), First-in-Class Multiple Sclerosis Drug Candidate

TORONTO--(BUSINESS WIRE)--February 7, 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 announces the receipt of a No Objection Letter (“NOL”) from Health Canada regarding the Company’s proposed Phase 1 clinical trial of LUCID-21-302 (“Lucid-MS”), a novel drug candidate for the treatment of Multiple Sclerosis (“MS”). The NOL provides FSD Pharma with regulatory approval to move forward with the clinical trial in Canada.

The first-in-human clinical trial will evaluate the safety and tolerability of Lucid-MS, a neuroprotective compound with a unique mechanism of action for the treatment of MS. Lucid-MS is a patented New Chemical Entity (“NCE”) that has been the subject of more than 11 years of research and development. In preclinical models, Lucid-MS has been shown to prevent myelin degradation (demyelination), a known cause of MS and other neurodegenerative 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.

“There is an acute need today for effective, non-immunomodulatory, neuroprotective therapeutics, especially for the treatment of progressive stages of MS,” said Dr. Lakshmi Kotra, CEO of Lucid Psycheceuticals, a wholly owned subsidiary of FSD Pharma. “We are excited to receive the NOL regulatory clearance, and look forward to initiating the first clinical trial of this promising candidate as a critical steppingstone in our mission to develop novel therapeutics for the treatment of MS. We will continue to work with Health Canada and other regulators worldwide to complete clinical investigations as soon as we can.”

“Our drug development team worked hard to advance this pipeline into clinical stages,” added Dr. Andrzej Chruscinski, Vice-President, Clinical and Scientific Affairs at Lucid Psycheceuticals. “We continue to evaluate our clinical development strategy to advance Lucid-MS into next phases of development efficiently in collaboration with our expert advisors.”

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. 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 (<https://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 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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