



## **FSD Pharma announces Interim Results from First-in-Human Clinical Trial of Lucid-MS (Lucid-21-302) for Multiple Sclerosis. The Report Shows Compound to be Safe and Well Tolerated**

**Toronto, September 18, 2023** -- FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRA: OK9A) (“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 and metabolic disorders, today announced that an interim report has been received for the first-in-human (“FIH”) single ascending dose Phase I clinical trial evaluating the Company’s novel drug candidate Lucid-21-302 (“Lucid-MS”), an orally-administered treatment for Multiple Sclerosis (“MS”). This interim blinded report was issued on August 17, 2023 for the first 4 cohorts, with an addendum report describing the results of the fifth cohort due by the end of the month.

The report, issued by Biopharma Services Inc. as the clinical research organization under contract to FSD, states that “Lucid-21-302 was demonstrated to be safe and well-tolerated in single oral doses in healthy volunteers. Individual concentrations and PK parameters of Cohorts 1 to 4 are very encouraging for further development activity.”

“We are thrilled with the results described in this report, and consider this to be a major milestone for our team,” said Dr. Andrzej Chruscinski, Vice President Clinical and Scientific Affairs at Lucid Psycheceuticals, a wholly owned subsidiary of FSD Pharma. “We are looking forward to continuing the development of Lucid-MS for potential treatment of progressive MS, an indication where there is an unmet need for novel, non-immunomodulatory treatments.”

In Multiple Sclerosis, the brain, spinal cord, and optic nerves that make up the central nervous system (CNS) are attacked by immune system, and damage to CNS leads to the symptoms of MS. Secondary progressive multiple sclerosis is a course of the disease in which neurologic function worsens and disability increases, and typically follows the initial course of relapsing-remitting MS. According to estimates from the [National Multiple Sclerosis Society](#), 27–45 for every 100,000 people in the United States have SPMS. According to the [National Multiple Sclerosis Society](#), 10 to 15 percent of people with MS have primary progressive MS, an advanced disease course characterized by gradual worsening neurologic symptoms and an accumulation of disability. Clinically isolated syndrome, one of the 4 multiple sclerosis disease courses, is also due to demyelination, in addition to inflammation, and patients experience neurological symptoms due to damage to CNS. The current disease-modifying therapies work

primarily by reducing inflammation in the CNS but are not very effective for the treatment of nerve degeneration.

Dr. Lakshmi P. Kotra, CEO of Lucid Psycheceuticals said, “Our objective in this FIH study was to determine the safety, tolerability, and pharmacokinetic profile of Lucid-MS in humans and we seem to have been successful in meeting those goals. Development of novel, non-immunomodulatory therapies with new mechanisms of action is a very high priority for all stages of MS. We are inspired to expeditiously pursue the next stages of clinical development to bring such novel therapies for patients.”

## **About FSD Pharma**

FSD Pharma Inc. is a biotechnology company with two candidates in different stages of development. Lucid Psychss Inc., a wholly owned subsidiary, is focused on the research and development of its lead compounds, Lucid-MS and UNBUZZD™. Lucid-MS is a molecular compound identified for the potential treatment of neurodegenerative disorders. UNBUZZD™ is a proprietary formulation of natural ingredients, vitamins, and minerals to help with liver and brain function for the purposes of potentially quickly relieving from the effects of alcohol consumption, such as inebriation, and restoring normal lifestyle.

## **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](http://www.sedar.com)) and with the U.S. Securities and Exchange Commission on EDGAR ([www.sec.gov](http://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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