FSD Pharma Announces Its Australian Entity Receives Approval to Proceed With Phase 1 Clinical Trial of Lucid-201, a Candidate for the Potential Treatment of Major Depressive Disorder

TORONTO--(BUSINESS WIRE)--March 22, 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 that its Australian entity, FSD Pharma Australia Pty Ltd. received the certificate of approval from The Alfred Ethics Committee in Australia to proceed with a Phase 1 clinical trial of Lucid-201 ("Lucid-Psych") as a novel drug candidate for the potential treatment of Major Depressive Disorder ("MDD"). Lucid-Psych is being developed outside of Australia by Lucid Psycheceuticals, Inc., a wholly owned subsidiary of FSD Pharma, and in Australia by FSD Pharma Australia Pty Ltd

Lucid-Psych is a psychoactive molecule selected as a potential therapeutic for MDD based upon the compound's pharmaceutical and metabolic properties including employing machine learning algorithms, as well as for its potential proprietary position.

"Psychoactive molecules as new therapeutics for depression and other mental disorders represent some of the most exciting areas of clinical research in healthcare today," said Dr. Lakshmi Kotra, CEO of FSD Pharma Australia Pty Ltd. "Today's standard of care is prescribing antidepressants that merely mask the symptoms and are well documented to have a bevy of potential negative side effects. Hundreds of millions of people globally need new, safer, accessible and more effective options to redefine the front-line approach by getting to the root of the disorder and how it is currently treated. As we initiate the clinical stage for Lucid-Psych, our clinical team is optimistic that our novel drug candidate in a unique dosage form will be safe and tolerated." Dr. Kotra further added, "We are also very cognizant of mental health challenges faced by those suffering from neurodegenerative disorders, such as multiple sclerosis, Alzheimer's among others. As a company pursuing total brain health, we see Lucid-Psych a strategic fit for clinical development with our other pipeline programs."

Major Depressive Disorder, sometimes called clinical depression, is a serious mental health disorder categorized by feelings of sadness or worthlessness, depressed mood, lack of motivation, and anhedonia, or reduced interest in activities once considered enjoyable. MDD can be a chronic condition with multiple periods of regression and relapse over a lifetime. Different types of MDD include Seasonal Affective Disorder (SAD), Postpartum depression, psychotic depression, melancholic depression, and catatonic depression. Broadly speaking, the National Institute of Health considers depression one of the most common mental disorders in the United States.[1] An estimated 21.0 million adults in the U.S. had at least one major depressive episode in 2020, representing 8.4 percent of the country's adults. In the same year, an estimated 4.1 million adolescents aged 12 to 17 in the U.S. had at least one major depressive episode, representing 17.0 percent of people in the age group. According to Allied Market Research, the global antidepressant drugs market size was valued at $15.65 billion in 2020 and is projected to reach $21.0 billion by 2030.[2]

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.

[1] https://www.nimh.nih.gov/health/statistics/major-depression
[2] https://www.alliedmarketresearch.com/antidepressants-drugs-market

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