

# FSD Pharma Signs the Agreement With iGENu CRO To Conduct a Clinical Study To Assess the Safety and Pharmacokinetics of Multiple Ascending Doses of Lucid-21-302 (Lucid-MS) in Healthy Adults

**TORONTO, ON / ACCESSWIRE / March 27, 2024 / 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 announced that through its subsidiary, HUGE Biopharma Australia Pty Ltd., it entered into agreement with iGENu CRO Pty Ltd on March 26, 2024 to conduct "A Phase 1, Randomised, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study to Evaluate the Safety and Pharmacokinetics of Lucid-21-302 in Healthy Adult Participants".

"We are very pleased to formalize this agreement and to collaborate with iGENu to conduct this clinical study," said Zeeshan Saeed, Co-Chairman and CEO of FSD Pharma. "This clinical study builds on our prior Phase 1 study of Lucid-21-302 and represents an important next step in our mission to develop novel therapeutics for the treatment of MS."

Lucid-21-302 is a first-in-class, non-immunomodulatory, neuroprotective compound with a unique mechanism of action for the treatment of multiple sclerosis (MS). It is a patented New Chemical Entity that has shown in preclinical models to prevent 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. In a prior Phase 1 single ascending dose study, Lucid-21-302 was shown to be safe and well-tolerated in the dose range of 50-300 mg p.o. administered once to healthy adults, with no difference in pharmacokinetics between the fed and fasted states.

"Over the next several days and weeks, our R&D team will closely work with iGENu to start this clinical study swiftly." added Dr. Andrzej Chruscinski, Vice-President, Scientific and Clinical Affairs at FSD Pharma. "We are very eager to complete this clinical trial as efficiently as possible, and are encouraged by the strong data from the prior Phase 1 single ascending dose study supporting the safety and tolerability of Lucid-21-302."

## About FSD Pharma

FSD Pharma is a biopharmaceutical company dedicated to building a portfolio of innovative assets and biotech solutions for the treatment of challenging neurodegenerative and metabolic disorders and alcohol misuse disorders with drug candidates in different stages of development. Through its wholly-owned subsidiary, Lucid Psycheceuticals Inc. ("**Lucid**"), FSD is focused on the research and development of its lead compound, Lucid-MS (formerly Lucid-21-302) ("**Lucid-MS**"). Lucid-MS is a patented new chemical entity shown to prevent and reverse myelin degradation, the underlying mechanism of multiple sclerosis, in preclinical models. FSD Pharma has also licensed unbuzzd™, a proprietary formulation of natural ingredients, vitamins, and

minerals to help with liver and brain function for the purposes of quickly relieving individuals from the effects of alcohol consumption for use in the consumer recreational sector, to Celly Nutrition Corp. ("Celly Nu") and is entitled to a royalty on the revenue generated by Celly Nu from sales of products created using the technology rights granted under the licensing agreement. FSD Pharma continues its R&D activities to develop novel formulations for alcohol misuse disorders and continues the development of such treatments for use in the healthcare sector. FSD maintains a portfolio of strategic investments through its wholly-owned subsidiary, FSD Strategic Investments Inc., which represent loans secured by residential or commercial property.

### **Cautionary Note Regarding 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 and are based on certain assumptions that FSD Pharma has made in respect thereof as of the date of this press release, including those relating to future sales of Class B Shares under the ATM Offering, the offering price therefor and the use of proceeds thereof. 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 timing and ability to satisfy all applicable listing and regulatory requirements of the CSE and Nasdaq; the fact that the drug development efforts of the Company and Lucid are at a very early stage; the fact that preclinical drug development is uncertain, and the drug product candidates of the Company and Lucid 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 the Company and Lucid; 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 the Company and Lucid; the introduction of competing drugs that are safer, more effective or less expensive than, or otherwise superior to, the drug product candidates of the Company and Lucid; the initiation, conduct, and completion*

*of preclinical studies and clinical trials may be delayed, adversely affected or impacted by unforeseen issues; the potential inability to obtain adequate financing; the potential inability to obtain or maintain intellectual property protection for the drug product candidates of the Company and Lucid; the inability of the Company to sell under the ATM Offering or upon the terms outlined herein; the prices at which the Company may sell the Class B Shares in the ATM Offering; 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.sedarplus.ca](http://www.sedarplus.ca)) and with the SEC 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, 2022, the Prospectus and Registration Statement, each 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 CSE nor its regulation services provider accept responsibility for the adequacy or accuracy of this release.*

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