FSD Pharma Inc. Announces Termination of FSD-201 Phase 2 Clinical Trial

However, will continue to evaluate other potential commercial opportunities with FSD-201

TORONTO--(BUSINESS WIRE)--August 24, 2021--FSD Pharma Inc. (Nasdaq:HUGE) (CSE:HUGE) (FRA:0K9) (the "**Company**" or "**FSD**") announced today that it intends to terminate the Phase 2 clinical trial of ultra-micronized palmitoylethanolamide ("PEA"), or FSD-201, for use in treating COVID-19.

FSD-201 stabilizes mast cells and down-regulates the pro-inflammatory cytokines to effectuate an anti-inflammatory response; it is also known to target the CB2 receptors of the endocannabinoid system of the human body.

The Company has previously successfully completed a Phase 1 first-in-human safety and tolerability study for FSD-201 and the compound to be safe with no serious adverse side effects. In June 2020, the United States Food and Drug Administration (the "FDA") approved the submission of an Investigational New Drug Application ("IND") for the use of FSD-201 to treat COVID-19 and in September 2020, a randomized, controlled, double-blind, multicenter Phase 2 clinical study was approved by the FDA. The Company is working to complete and publish these findings in the near future.

As previously disclosed, following the May 14, 2021 annual general and special meeting of shareholders, the Company retained Bloom Burton Securities Inc. ("Bloom Burton") to undertake a review of its Phase 2 clinical program to assist the Company in determining its viability and, more broadly, evaluating the general current commercial viability of FSD-201. In particular, the Company was concerned with the pace of progress in advancing the Phase 2 clinical study during a period in which COVID-19 treatments evolved significantly and competitive products were being successfully advanced. Bloom Burton recently reported its findings and the Company concluded that, while there are potential commercial opportunities for FSD-201, specifically the treatment of COVID-19 by FSD-201 is unlikely to be commercially viable. Based on this information, the Company has elected to terminate the current Phase 2 clinical study in order to concentrate its resources on more commercially viable opportunities.

"We remain committed to fulfilling the strategic and operational goals outlined in our communications to shareholders prior to the May 14, 2021 shareholder meeting. Objectively evaluating the commercial viability of this Phase 2 study of FSD-201 was one of our immediate priorities. While we are disappointed that the Phase 2 study commenced under the Company's prior management was not productive, we are pleased that the independent review did support the belief that there are other viable commercial opportunities for FSD-201," said Zeeshan Saeed, the Company's President. "We will continue to explore these potential opportunities to advance the commercialization of FSD-201 and it's potential on the human endocannabinoid system," he added.

About FSD Pharma

FSD Pharma Inc. (www.fsdpharma.com) is a publicly-traded holding company.

FSD BioSciences, Inc., a wholly-owned subsidiary, is a specialty biotech pharmaceutical R&D company focused on developing multiple applications of its lead compound, ultramicro PEA by down-regulating the cytokines to effectuate an anti-inflammatory response.

Forward Looking Information

Certain statement contained herein are “forward-looking statements”. Often, but not always, forward-looking statement can be identified by the use of words such as “plans”, “expects”, “expected”, “scheduled”, “estimates”, “intends”, “anticipates” or “believes”, or variations of such words and phrases, or states that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved. Forward-looking statements contained in this press release include the comments made with respect to the Company’s clinical trial, the evaluation of the commercial viability of its principal drug compound, and the statements made by Zeeshan Saeed regarding the commercial opportunities the Company’s principal drug compound and other commercial opportunities and fulfilling strategic and operational goals outlined in prior communications to shareholders. FSD cannot give any assurance that such forward-looking statements will prove to have been correct. The reader is cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document.

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