FSD Pharma

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FSD Pharma says Phase 1 study finds micro-PEA "safe and well tolerated"

FSD Pharma Inc (NASDAQ:HUGE) (CSE:HUGE) announced Monday that a Phase 1 study of ultramicronized palmitoylethanolamide (PEA), or FSD201, found the drug "to be safe and well tolerated."

The company noted that mild and self-limiting side effects were reported and were deemed unlikely to be related to the study of the anti-inflammatory drug.

In addition, there were no abnormal laboratory findings or ECGs observed during the study and no serious adverse events were reported. And no subjects withdrew due to an adverse event and all eligible subjects completed all doses.

READ: FSD Pharma wins FDA nod to design Phase 2a clinical trial of its lead candidate micro-PEA to treat coronavirus patients

CEO Dr Raza Bokhari said the company will submit the top-line results from the randomized, double-blind, placebo-controlled study for publication in a peer-reviewed journal and to launch a Phase 2a proof-of-concept trial of FSD201 for the treatment of COVID-19.

The company said that severe COVID-19 disease caused by the SARS-CoV-2 virus is characterized by an "over-exuberant inflammatory response" that may lead to a cytokine storm and ultimately death. FSD Pharma is focused on developing FSD-201 for its anti-inflammatory properties to avoid the cytokine storm associated with acute lung injury in hospitalized COVID-19 patients.

"The US Food and Drug Administration recently gave the company permission to submit an Investigational New Drug application for the use of FSD201 to treat COVID-19," Bokhari said in a statement.

"We contacted the FDA after becoming aware that Italian physicians and scientists were advocating for use of ultramicronized PEA for patients suffering from symptoms of COVID-19, based on the drug's mechanism of action as a potent and safe anti-inflammatory agent that reduces the production of pro-inflammatory cytokines and may help mitigate a cytokine storm."

The single-site study was conducted at the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia and enrolled 48 healthy adult men and women.

The trial sequentially tested single ascending doses ranging from 600 milligrams (mg) to 2400 mg tablets and multiple ascending doses ranging from 600 mg to 1200 mg tablets administered twice daily for seven consecutive days. The single ascending dose subjects also were tested for food effect.

FSD Pharma said it is not making any express or implied claims that its product has the ability to eliminate, cure or contain COVID-19 (or the SARS-2 coronavirus) at this time.

Price:	3.64
Market Cap:	$53.59 m

1 Year Share Price Graph

Share Information

Code:		HUGE
Listing:		CSE
52 week	**High**	**Low**
	20.1	**3.35**
Sector:		**Pharma & Biotech**
Website:		**fsdpharma.com**

Company Synopsis:

FSD Pharma Inc. is a publicly-traded holding company, since May 2018. FSD Pharma BioSciences, Inc. , a wholly-owned subsidiary, is a specialty biotech pharmaceutical R&D company focused on developing over time multiple applications of its lead compound, ultramicronized-palmitoylethanolamide ("FSD201"), by down-regulating the cytokines to effectuate an anti-inflammatory response.

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