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Zynerba Pharmaceuticals

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Zynerba Pharmaceuticals CEO welcomes FDA approval of cannabinoid products

Last week, GW Pharmaceuticals PLC (NASDAQ:GWP) announced that Epidiolex, a cannabidiol oral medication for the treatment of seizures, is now available through a prescription in the US.

It is the first pharmaceutical formulation of a highly purified, plant-derived cannabidiol (CBD), a cannabinoid that lacks the high associated with marijuana, and is the first in a new category of anti-epileptic drugs. Epidiolex is an oral solution for seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. The drug was approved by the Food and Drug Administration on June 25, 2018,

The approval by the FDA of a cannabinoid product is a vital inflection point for companies in the pharmaceutical CBD space, the chief executive of Zynerba Pharmaceuticals (NASDAQ:ZYNE), Armando Anido, said.

"This approval is great achievement for GW Pharma and an important milestone for all companies in the pharmaceutical CBD space, as the FDA is very clearly in support of cannabinoid (CBD) products when developed according to their standards," Anido told Proactive Investors.

READ: Zynerba Pharmaceuticals anticipates data in late 2019 for its phase 3 cannabinoid drug
Anido said Zynerba is developing its own CBD product, ZYN002.

He said that while GW Pharmaceuticals is working on Dravet and Lennox-Gastaut syndromes, two rare pediatric epilepsy syndromes, Zynerba is conducting work in Fragile X Syndrome, a known genetic cause "of both inherited intellectual disability and autism spectrum disorder."

"The importance of their approval is that it speaks directly to the validity of CBD as a therapeutic compound supported by FDA," Anido explained.

He added the company is in the middle of a critical study for patients with Fragile X Syndrome. Data from tests are expected in the second half of 2019 and if the drug goes to market, it would "impact our bottom line very favorably."

The Zynerba CEO said the company's estimate of the market for Fragile X patients is approximately 71,000 patients in the US.

READ: GW Pharmaceuticals says first FDA approved cannabinoid medicine now available by prescription in US
While GW's CBD is extracted from cannabis, ZYN002 is manufactured pharmaceutically under the cGMP (current Good Manufacturing Practice) regulations enforced by the FDA.

Anido said manufacturing CBD through this method ensures consistent potency and efficient manufacturing without the cost, risks and logistical requirements of growing and harvesting cannabis themselves.

Price: US$3.89

Market Cap: US$68.57M

1 Year Share Price Graph

Share Information

Code:	ZYNE	
Listing:	NASDAQ	
52 week	**High**	**Low**
	12.98p	**2.82p**
Sector:	**Pharma & Biotech**	
Website:	**https://zynerba.com**	

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GW Pharma's CBD is administered orally and enters the system through the stomach while ZYN002 is applied directly to the skin and enters the bloodstream through the skin. Doing it this way results in lower incidence of gastrointestinal side effects such as nausea, diarrhea and vomiting.

Zynerba Pharmaceutical is a company seeking to develop next-generation cannabinoid therapeutics for rare and near-rare neuropsychiatric conditions in patients with high unmet medical needs.

The company is based in Devon, Pennsylvania.

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