

Cannibis Drug Found Effective Against Epilepsy

An experimental cannabis drug has produced promising results in a small study of children with hard-to-treat epilepsy, sending shares in its British maker GW Pharmaceuticals to an all-time high.

The company, which grows cannabis under license at a secret location in Britain, is developing a range of so-called cannabinoid medicines. It already sells Sativex for spasticity caused by multiple sclerosis across Europe.

The latest findings for its new product Epidiolex follow an assessment of 27 children and young adults with treatment-resistant epilepsy who were given the drug in two U.S. hospitals under an expanded access program.

Epidiolex is given as a strawberry-lime flavored syrup twice a day. The medicine contains the cannabinoid CBD but none of the psychoactive ingredient THC that makes marijuana smokers high.

GW said on Tuesday that results after 12 weeks of therapy in the open-label study were “encouraging,” with a reduction in seizure frequency of more than 50 percent. It now plans to start a Phase II/III clinical trial in the second half of the year.

Justin Gover, GW’s chief executive, said he expected Epidiolex would be ready for submission to U.S. and European regulators in 2016.

Epidiolex has been granted “orphan drug” status by the U.S. Food and Drug Administration, which may ease its path to market and also offers GW additional exclusivity.

The designation reflects the unmet need for new approaches to

help children with severe epilepsy syndromes such as Dravet and Lennox-Gastaut, where seizures often persist despite high doses of multiple anti-epileptic drugs.

Excitement over prospects for Epidiolex has been a driver for GW's shares, which have surged since the company tapped into a new U.S. shareholder base by listing on Nasdaq a year ago.

"It has become a central part of our valuation—there is no doubt about that," Gover said in an interview. "That reflects a number of reasons: the fact there is so much interest among physicians and patients, the fact it is an orphan development program and the fact we own all the commercial rights worldwide."

Shares in GW gained 15 percent to a record high of 430 pence by 1400 GMT.

Interest in cannabis has been spurred recently by the legalization of recreational marijuana shops in Colorado and Canada's move to create a federally regulated medical marijuana industry.

GW, however, distances itself from these developments by emphasizing its ability to extract key ingredients in cannabis for medical use, in the same way that pain-killing opioids have been developed from opium.

Its established product Sativex, which is given as an under-the-tongue spray, is currently available by prescription for MS spasticity in 11 countries and has received regulatory approval in an additional 13 countries.

Sativex is also in final-stage Phase III clinical development as a potential treatment of pain in people with advanced cancer.