



GW Pharmaceuticals and U.S. Subsidiary Greenwich Biosciences Announces the Unanimous Positive Result of FDA Advisory Committee Meeting for First Plant-Based Pharmaceutical Cannabidiol Treatment for Seizures in Patients with Two Rare, Severe Forms of Epile

April 19, 2018

LONDON and CARLSBAD, Calif., April 19, 2018 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) ("GW", "the Company" or "the Group"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, along with its U.S. subsidiary Greenwich Biosciences, today announced that the Peripheral and Central Nervous System Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) unanimously recommended supporting the approval of the New Drug Application (NDA) for the investigational cannabidiol oral solution (CBD), also known as Epidiolex®, for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome in patients two years of age and older. If approved, Epidiolex would be the first pharmaceutical formulation of purified, plant-based CBD, a cannabinoid lacking the high associated with marijuana, and the first in a new category of anti-epileptic drugs (AEDs). This public meeting was presented live through FDA's website.

LGS and Dravet syndrome, which develop in childhood, are devastating forms of epilepsy with high morbidity and mortality rates and a significant burden on families and caregivers. More than 90% of patients with LGS or Dravet syndrome have multiple seizures per day, which puts them at constant risk for falls and injury. Physicians who treat LGS and Dravet syndrome patients struggle to reduce the sheer volume of dangerous seizures with currently available therapies. If approved, Epidiolex would be the first-ever FDA-approved medicine for Dravet syndrome patients.

"We are pleased by the Advisory Committee's unanimous recommendation to approve Epidiolex, which would provide an important treatment option for patients with LGS and Dravet syndrome, two of the most severe and treatment-resistant forms of epilepsy," said Justin Gover, GW's Chief Executive Officer. "This favorable outcome marks an important milestone in our company's unwavering commitment to address the significant unmet need for patients with LGS and Dravet syndrome and our resolve to study Epidiolex under the highest research and manufacturing standards. We look forward to our ongoing discussions with the FDA as it continues to review the Epidiolex NDA."

During the meeting, the company presented the results of a robust clinical development program that included three randomized, controlled Phase 3 clinical trials and an open label extension study. In the Phase 3 studies, Epidiolex added to other antiepileptic therapies significantly reduced the frequency of seizures in patients with LGS and Dravet syndrome. The company's development program represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with LGS and Dravet syndrome. Epidiolex was generally well tolerated with most adverse events reported as mild or moderate.

"As a physician who treats LGS and Dravet syndrome, I know that patients and their families usually face significant difficulties getting seizures under control using existing therapies," said Elizabeth Thiele, MD, PhD, director of pediatric epilepsy at Massachusetts General Hospital, professor of Neurology at Harvard Medical School and a primary investigator for one of GW's and Greenwich's studies in LGS patients. "The results from these studies suggest that this pharmaceutical formulation of cannabidiol may provide hope for a new treatment option that may be effective for some patients."

FDA Advisory Committees are independent expert panels. Their votes are not binding but are considered by the FDA when deciding whether to approve a new medicine. The PDUFA (Prescription Drug User Fee Act) goal date for completion of the NDA review of the cannabidiol oral solution is June 27, 2018.

About Lennox-Gastaut Syndrome

The onset of LGS typically occurs between ages of 3 to 5 years and can be caused by a number of conditions, including brain malformations, severe head injuries, central nervous system infections, and genetic neuro-degenerative or metabolic conditions. In up to 30 percent of patients, no cause can be found. Patients with LGS commonly have multiple seizure types including drop and convulsive seizures, which frequently lead to falls and injuries, and non-convulsive seizures. Resistance to anti-epileptic drugs (AEDs) is common in patients with LGS. Most children with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviors.

About Dravet Syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the SCN1A sodium channels. Onset of Dravet syndrome occurs typically during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often body temperature related, severe, and long-lasting. Over time, patients with Dravet syndrome often develop multiple types of seizures, including tonic-clonic, myoclonic, and atypical absences and are prone to bouts of prolonged seizures including status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden unexpected death in epilepsy) is elevated in patients with Dravet syndrome. Additionally, the majority will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care. There are currently no FDA-approved treatments and nearly all patients continue to experience seizures and other medical needs throughout their lifetime.

About Epidiolex® (cannabidiol)

Epidiolex, GW's lead cannabinoid product candidate is a pharmaceutical formulation of purified cannabidiol (CBD), which is in development for the treatment of several rare childhood-onset epilepsy disorders. GW has submitted a New Drug Application with the FDA for Epidiolex as adjunctive

treatment for seizures associated with LGS and Dravet syndrome, which has been assigned a goal date of 27 June 2018 and, if approved, the medicine is expected to be available by prescription in the second half of 2018. GW has also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) with an expected decision date in early 2019. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex for the treatment of Dravet syndrome, LGS, Tuberous Sclerosis Complex (TSC) and infantile spasms (IS). Additionally, GW has received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare pediatric disease designation by FDA. The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for the treatment of LGS, Dravet syndrome, West syndrome and TSC. GW is currently evaluating additional clinical development programs in other orphan seizure disorders including Phase 3 trials in Tuberous Sclerosis Complex and Infantile Spasms.

About GW Pharmaceuticals plc and Greenwich Biosciences

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW, along with its U.S. subsidiary Greenwich Biosciences, is advancing an orphan drug program in the field of childhood-onset epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted regulatory applications in the U.S. and Europe for the adjunctive treatment of Lennox-Gastaut syndrome and Dravet syndrome. The Company continues to evaluate Epidiolex in additional rare epilepsy conditions and currently has ongoing clinical trials in Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States and for which the company is now planning a US Phase 3 trial. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, glioblastoma, and schizophrenia. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the timing, outcomes and protection of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of Epidiolex (cannabidiol) and the safety profile and commercial potential of Epidiolex. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion and uncertainties related to the regulatory process, and the acceptance of Sativex, Epidiolex and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the most recent Form 20-F filed on 4 December 2017. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Enquiries:

GW Pharmaceuticals plc

Stephen Schultz, VP Investor Relations (U.S.)

917 280 2424 / 401 500 6570

U.S. Media Enquiries:

Sam Brown Inc. Healthcare Communications

Christy Curran

615 414 8668

Mike Beyer

312 961 2502



Source: GW Pharmaceuticals plc