January 24, 2018

GW Pharmaceuticals and its U.S. Subsidiary Greenwich Biosciences Announce Publication of Landmark Epidiolex® (cannabidiol) Study in The Lancet

— First well-controlled clinical study of cannabidiol in Lennox-Gastaut syndrome, a rare, severe, form of childhood-onset epilepsy that is difficult to treat —

— Pharmaceutical formulation of cannabidiol significantly reduced drop seizure frequency in patients with poor seizure control despite the use of multiple anti-epileptic drugs —

LONDON and CARLSBAD, Calif., Jan. 24, 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, announced today that *The Lancet* has published results from a Phase 3 study of Epidiolex® (cannabidiol) in patients with Lennox-Gastaut syndrome (LGS).[1] Epidiolex, GW's lead product candidate and the potential first in a new category of anti-epileptic drugs (AEDs), is a pharmaceutical formulation of purified cannabidiol (CBD), a cannabinoid lacking euphoric side effects, which is being studied for the treatment of a number of rare, severe pediatric-onset epilepsy disorders. In this study, Epidiolex significantly reduced monthly drop seizure frequency compared to placebo in highly treatment-resistant patients when added to existing treatment. Treatment with Epidiolex was generally well tolerated, with a safety profile consistent with prior reported experience.

A New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for Epidiolex in the treatment of LGS and Dravet syndrome (another rare childhood-onset epilepsy) was accepted in December with an assigned PDUFA goal date of June 27th 2018 and, if approved, the medicine is expected to be available in the U.S. by prescription in the second half of 2018. A Marketing Authorisation Application (MAA) was submitted to the European Medicines Agency (EMA) in December 2017, with an expected decision in early 2019.

"Publication of this landmark study by *The Lancet* is an exciting achievement and marks the second time that Epidiolex data have been published in a highly prestigious journal, following last year's publication in *The New England Journal of Medicine*," said Justin Gover, GW's Chief Executive Officer. "These publications highlight the potential of Epidiolex to address the significant unmet need in LGS and Dravet syndrome, two very challenging epilepsy conditions, and we look forward to working with the FDA and EMA as they review our marketing applications for Epidiolex. We are absolutely focused on the goal of making this important new medicine available to appropriate patients and their caregivers as quickly as possible."

LGS is a rare, lifelong form of epilepsy that begins in childhood and is associated with a high mortality rate[2] and significant developmental delays.[3,4] LGS patients suffer from multiple types of seizures, including drop seizures which can result in falls and other injuries. Results from this study represent the only well-controlled clinical evaluation of a cannabinoid medication for this severe, drug-resistant condition.

"The publication of these positive results is an exciting milestone for the LGS community and we are encouraged that a new treatment option could soon be available," said Christina SanInocencio, executive director of the Lennox-Gastaut Syndrome Foundation. "Additional treatment options are desperately needed for patients who continue to struggle with uncontrolled seizures and these results offer much needed hope to those living with this debilitating condition."

"LGS is one of the most difficult types of epilepsy to treat and the majority of patients do not have an adequate response to existing therapies," said Elizabeth Thiele, MD, PhD, director of pediatric epilepsy at Massachusetts General Hospital, professor of Neurology at Harvard Medical School and lead author of the study publication. "These results show that Epidiolex may provide clinically meaningful benefits for patients with LGS."

The study randomized 171 patients (86 to CBD; 85 to placebo) ages two to 55 years (average age 15), with LGS whose seizures were not controlled by their current AED regimen, to receive either Epidiolex (20mg/kg/day) or placebo in addition to existing treatment. Conducted in 24 study centers in the United States and Europe, on average, patients were taking approximately three AEDs, having previously tried and discontinued an average of six other AEDs. At baseline, patients had

a median frequency of 74 drop seizures per month (drop seizures were defined as atonic, tonic or tonic-clonic seizures involving the entire body, trunk or head that led or could have led to a fall, injury, slumping in a chair or hitting the patient's head on a surface).

Over the 14-week treatment period (two-week dose escalation period followed by 12 weeks of maintenance), patients taking Epidiolex had a significantly greater median reduction in drop seizures compared to placebo (44 percent vs. 22 percent; p=0.0135), the study's primary endpoint. Sensitivity analyses confirmed that the treatment effect of CBD was established during the first month of treatment and was sustained over the entire treatment period.

Results from key secondary endpoints showed that significantly more patients on Epidiolex experienced a 50 percent or greater reduction in drop seizures compared to placebo (44 percent vs. 24 percent; p=0.0043) and total seizure frequency was significantly reduced with Epidiolex compared to placebo (median percent reduction of 41 percent vs. 14 percent; p=0.0005). CBD patients/caregivers were significantly more likely to report an improvement in overall condition with Epidiolex than placebo (58 percent vs. 34 percent; OR 2.54, 95% CI 1.5-4; p=0.0012) based on the Subject/Caregiver Global Impression of Change (S/CGIC) scale.

Epidiolex was generally well tolerated in the trial. The most common adverse events (AEs) (>10 percent) were diarrhea, somnolence, pyrexia, decreased appetite and vomiting. Overall, 86 percent of patients taking Epidiolex and 69 percent of patients taking placebo experienced an AE, and most were mild or moderate. Of those patients who experienced AEs, the events resolved by the end of the trial for 61 percent of Epidiolex patients and 64 percent of placebo patients.

Twenty patients on Epidiolex experienced serious AEs, including one fatal case of acute respiratory distress syndrome (considered unrelated by the Investigator), compared with four patients with serious AEs on placebo. Twelve patients taking Epidiolex discontinued treatment due to AEs compared with one patient taking placebo.

Across the Epidiolex development program, the most common reported adverse reactions are somnolence, decreased appetite, diarrhea, pyrexia, fatigue, lethargy, rash, nasopharyngitis, and pneumonia; dose-related reversible elevation of liver transaminases without elevation of bilirubin were also observed.

"Uncontrolled seizures significantly impact the lives of patients and their families and there is a tremendous need for new options in difficult-to-treat epilepsies such as LGS," said Philip Gattone, president and CEO, Epilepsy Foundation. "This randomized, controlled clinical study provides positive evidence of the potential role of cannabidiol in reducing seizures and we are excited about the possibility of a new treatment option for LGS."

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 Authorisation Application (MAA) to the European Medicines Agency (EMA) in December 2017 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, TSC and 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 epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted an NDA to the FDA for the adjunctive treatment of LGS and Dravet syndrome. The Company continues to evaluate Epidiolex in additional 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. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for gliobastoma, schizophrenia and epilepsy. 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 and outcomes 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.

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[1] Thiele EA, Marsh ED, French JA, et al. Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomized, double-blind placebo-controlled phase 3 trial. Published online January 24, 2018 http://dx.doi.org/10.1016/S0140-6736(18)30136-3.

[2] Autry AR, Trevathan E, Van Naarden Braun K, Yeargin-Allsopp M. Increased risk of death among children with Lennox-Gastaut syndrome and infantile spasms. *J Child Neurol*. 2010;25(4):441-447.

[3] LGS Foundation. About Lennox-Gastaut Syndrome. Available at http://www.lgsfoundation.org/aboutlgs. Accessed October 23, 2017.

[4] National Institute of Health. Lennox-Gastaut syndrome. Available at https://ghr.nlm.nih.gov/condition/lennox-gastaut-

syndrome#definition. Accessed October 23, 2017.

Photos accompanying this announcement are available at

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