GW Pharmaceuticals and U.S. Subsidiary Greenwich Biosciences Announce Publication in The New England Journal of Medicine of a Phase 3 Study of Epidiolex® (cannabidiol oral solution) in Lennox-Gastaut Syndrome

– First dose-ranging study comparing pharmaceutical formulation of cannabidiol to placebo as add-on therapy in Lennox-Gastaut syndrome, a rare, severe and difficult to treat form of childhood-onset epilepsy –

– Both doses significantly reduced drop seizure frequency in patients with poor seizure control despite the use of multiple anti-epileptic drugs –

London, UK, Carlsbad, CA, May 16, 2018 – 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 New England Journal of Medicine* has published results from a Phase 3 study of Epidiolex® (cannabidiol oral solution) in patients with Lennox-Gastaut syndrome (LGS), a rare, severe and difficult to treat form of childhood-onset epilepsy.[1] Epidiolex is a pharmaceutical formulation of highly purified cannabidiol (CBD), a cannabinoid lacking the high associated with marijuana. In this study, both evaluated doses of Epidiolex significantly reduced the monthly frequency of drop seizures compared to placebo in highly treatment-resistant patients when added to existing treatment.

"This publication in *The New England Journal of Medicine* marks the third time within a year that positive data for Epidiolex have been published by a top-tier, peer-reviewed journal, offering further evidence of the potential of Epidiolex as a new treatment option within the field of treatment-resistant, childhood-onset epilepsy," said Justin Gover, GW's Chief Executive Officer. "We are now in the latter stages of the FDA's review of the Epidiolex New Drug Application and look forward to a decision from FDA in late June. If approved, we expect to make this important new medicine available to patients with LGS and Dravet syndrome in the second half of the year."

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 pharmaceutical cannabinoid

medication for this severe, drug-resistant condition. Epidiolex is also being studied for the treatment of a number of other rare, severe childhood-onset epilepsy disorders.

"These positive data are important in that they provide further evidence of the promise of this investigational treatment in LGS, as well as information on its dosing range that can assist clinicians with prescribing decisions to address individual patient needs should this medicine be approved for use," said Orrin Devinsky, M.D., of NYU Langone Health's Comprehensive Epilepsy Center and lead author of the study. "The growing body of data which support the potential of this cannabidiol treatment in LGS and Dravet syndrome indicates that this treatment may offer meaningful benefit to these patients, who often do not have an adequate response to existing therapies."

"Positive study results, such as these, offer much needed hope for patients and their families living with this debilitating condition," said Christina SanInocencio, Executive Director of the Lennox-Gastaut Syndrome Foundation." New options are desperately needed and the LGS community is very excited about the potential of Epidiolex as a new, differentiated treatment option for patients for whom current treatments have failed to provide adequate benefit."

The study randomized 225 patients with LGS (73 to 10 mg/kg/day Epidiolex; 76 to 20 mg/kg/day Epidiolex; 76 to placebo) whose seizures were not controlled by their current anti-epileptic drug (AED) regimen, to receive either dose of Epidiolex or placebo in addition to existing treatment. As was disclosed in the study's top-line results, the average age of trial participants was 16 years (30 percent were 18 years or older). The study was conducted in 30 centers in the United States and Europe, and on average, patients were taking three concomitant AEDs, having previously tried and discontinued an average of six other AEDs. At baseline, patients had a median frequency of 85 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 or hitting the patient's head on a surface).

The primary efficacy endpoint of this trial was the percentage change from baseline in monthly drop seizure frequency during the treatment period (two-week dose escalation period followed by 12 weeks of maintenance) compared to the four-week baseline period before randomization. During the 14-week treatment period, patients taking both doses of Epidiolex, 10 mg/kg/day and 20 mg/kg/day, had significantly greater median reductions in monthly drop seizures of 37.2

percent (p=0.002 and 41.9 percent (p=0.005, respectively) compared with a 17.2 percent reduction for placebo. Sensitivity analyses confirmed that the treatment effect of Epidiolex was established during the first month of treatment (post-titration) and was sustained over the entire treatment period.

Results from key secondary endpoints showed that a significant number of patients receiving Epidiolex 10 mg/kg/day (36 percent) and Epidiolex 20 mg/kg/day (39 percent) experienced a 50 percent or greater reduction in monthly drop seizures compared with those taking placebo (14 percent, p=0.003 and p<0.001 respectively). In addition, patients/caregivers were significantly more likely to report an improvement in overall condition with both Epidiolex doses compared to placebo (p<0.05 for both comparisons) based on the Subject/Caregiver Global Impression of Change (S/CGIC) questionnaire.

In addition, the proportion of patients who experienced at least a 75 percent reduction from baseline in drop seizure frequency was higher in the 20 mg/kg/day Epidiolex group (25 percent) than in the 10 mg/kg//day Epidiolex group (11 percent) and both were higher when compared with those taking placebo (3 percent), p<0.001 and p=0.05, respectively.

Epidiolex was generally well tolerated in the trial. The pattern of adverse events (AEs) was consistent with that reported in previous Phase 3 studies. For this study across both dose groups, AEs in >10% were the following: somnolence, decreased appetite, diarrhea, upper respiratory infection, pyrexia, vomiting, nasopharyngitis, and status epilepticus. None of the cases of status epilepticus in the 10mg/kg group was deemed treatment related. Dose-related reversible elevation of liver transaminases without elevation of bilirubin were also observed, most occurring among patients receiving concomitant valproate with 20 mg/kg/day of Epidiolex.

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 with no FDA-approved treatments) was accepted for priority review in December 2017 with an assigned Prescription Drug User Fee Act (PDUFA) goal date of June 27, 2018. On April 19, 2018, the Peripheral and Central Nervous System Drugs Advisory Committee of the FDA unanimously recommended supporting the approval of the NDA. If approved, the medicine is expected to be available in the U.S. by prescription in the second half of 2018. In addition, a Marketing

Authorisation Application (MAA) was submitted to the European Medicines Agency (EMA) in December 2017, with an expected decision in early 2019.

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 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, 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-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 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]Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox–Gastaut Syndrome. N Engl J Med 2018;378;20:1888-97.

[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 April 9, 2018.

[4] National Institute of Health. Lennox-Gastaut syndrome. Available at https://ghr.nlm.nih.gov/condition/lennox-gastaut-syndrome#definition. Accessed April 9, 2018.