GW Pharmaceuticals Announces Positive Phase 3 Pivotal Trial Results for Epidiolex® (cannabidiol) in the Treatment of Lennox-Gastaut Syndrome

- Primary endpoint achieved with high statistical significance (p=0.0135) showing that Epidiolex treatment reduces drop seizures compared to placebo –

- Today's LGS data follows successful Phase 3 trial in Dravet syndrome announced in March 2016-

- Company to hold investor conference call today at 8:00 a.m. EDT/13:00 BST -

London, UK; 27 June 2016: GW Pharmaceuticals plc (Nasdaq: GWPH, AIM: "GWP," "GW," "the Company" or "the Group"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announces positive results of the first randomized, double-blind, placebo-controlled Phase 3 clinical trial of its investigational medicine Epidiolex® (cannabidiol or CBD) for the treatment of Lennox-Gastaut syndrome (LGS), a rare and severe form of childhood-onset epilepsy. In this trial, Epidiolex, when added as an adjunct to the patient's current treatment, achieved the primary endpoint of a significant reduction in the monthly frequency of drop seizures assessed over the entire 14-week treatment period compared with placebo (p=0.0135). This trial follows the announcement in March 2016 of positive results in a pivotal Phase 3 trial of Epidiolex for the treatment of Dravet syndrome. Epidiolex has Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LGS and Dravet syndrome.

"From a physician's perspective, the positive outcome in this trial of Epidiolex in patients with Lennox-Gastaut syndrome is very exciting. Lennox-Gastaut syndrome begins in early childhood, is particularly difficult to treat, and the vast majority of patients do not obtain an adequate response from existing therapies," stated Linda Laux, MD, Director of the Comprehensive Epilepsy Center at Ann & Robert H. Lurie Children's Hospital of Chicago and assistant professor of pediatrics, Northwestern University Feinberg School of Medicine and an investigator in the trial. "These data show that Epidiolex has the potential to provide a robust and clinically meaningful reduction in seizures in this highly treatment-resistant population together with an acceptable safety and tolerability profile, which is consistent with my previous clinical experience with Epidiolex. I am excited about the prospect of Epidiolex being made available on prescription in the future and believe it has the potential to make an important difference to the lives of many patients."

"We are delighted to announce positive results in this Phase 3 trial of Epidiolex in patients with Lennox-Gastaut syndrome, and particularly pleased that this result is consistent with our recent Phase 3 pivotal data for Epidiolex in Dravet syndrome. We believe that this result further demonstrates that Epidiolex offers the potential to be a new effective therapy within the field of treatment-resistant childhood-onset

epilepsies," stated Justin Gover, GW's Chief Executive Officer. "We now look forward to advancing Epidiolex towards the submission of an NDA with the FDA in the first half of 2017."

"Lennox-Gastaut syndrome is such a difficult form of epilepsy to treat. Additional safe and effective treatments are desperately needed for patients who continue to struggle with uncontrolled seizures," said Christina SanInocencio, Executive Director of the Lennox-Gastaut Syndrome Foundation. "We are thrilled with these positive results, which offer much needed hope and promise to those living with this debilitating condition."

Trial Overview and Result

Patients aged 2-55 years with a confirmed diagnosis of drug-resistant LGS currently uncontrolled on one or more concomitant anti-epileptic drugs (AEDs) were eligible to participate in this Phase 3, randomized, double-blind placebo-controlled trial. The trial randomized 171 patients into two arms, where Epidiolex 20mg/kg/day (n=86) or placebo (n=85) was added to current AED treatment. On average, patients were taking approximately 3 AEDs, having previously tried and failed an average of 6 other AEDs. The average age of trial participants was 15 years (34% were 18 years or older). The median baseline drop seizure frequency per month was 74.

The primary efficacy endpoint of this trial was a comparison between Epidiolex and placebo in the percentage change in the monthly frequency of drop seizures during the 14 week treatment period (2 week dose escalation period followed by 12 weeks of maintenance) compared to the 4 week baseline period before randomization. Drop seizures were defined as atonic, tonic and 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. During the treatment period, patients taking Epidiolex achieved a median reduction in monthly drop seizures of 44 percent compared with a reduction of 22 percent in patients receiving placebo, and the difference between treatments was statistically significant (p=0.0135).

A series of sensitivity analyses of the primary endpoint confirmed the robustness of this result. The difference between Epidiolex and placebo emerged during the first month of treatment and was sustained during the entire treatment period. Results from secondary efficacy endpoints reinforced the overall effectiveness observed with Epidiolex.

Epidiolex was generally well tolerated in this trial. Overall, 86 percent of all Epidiolex patients experienced an adverse event compared with 69 percent of patients on placebo. The most common adverse events (occurring in greater than 10 percent of Epidiolex-treated patients) were: diarrhea, somnolence, decreased appetite, pyrexia, and vomiting. Of those patients on Epidiolex who reported an adverse event, 78 percent reported it to be mild or moderate. Twenty patients on Epidiolex experienced a serious adverse event (nine of which were deemed treatment related) compared with four patients on placebo (one of which was deemed treatment related). Twelve patients on Epidiolex discontinued treatment due to adverse events compared with one patient on placebo. There was one death in the Epidiolex group, which was deemed unrelated to treatment. Of the patients who completed this trial, 100 percent have opted to continue into an open-label extension trial.

Further data will be presented in future publications and medical meetings.

In addition to this first Phase 3 trial of Epidiolex in LGS, GW is conducting a second Phase 3 dose-ranging trial of Epidiolex for the treatment of LGS, which is fully enrolled at 225 patients. This second trial has three treatment arms: Epidiolex 20mg/kg/day, 10mg/kg/day and placebo. GW expects to report top-line results from this trial towards the end of the third quarter of this year.

GW Clinical Trial Programs in Dravet Syndrome, Tuberous Sclerosis Complex and Infantile Spasms

In March 2016, GW announced positive results of the first pivotal Phase 3 trial of Epidiolex in Dravet syndrome. GW continues to enroll a second Phase 3 trial of Epidiolex in Dravet syndrome.

GW has commenced a Phase 3 trial of Epidiolex in Tuberous Sclerosis Complex and expects to initiate a Phase 3 trial of Epidiolex in infantile spasms in the fourth quarter of this year.

Investor Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast for analysts and investors to discuss the results from this initial Phase 3 trial today at 8:00 a.m. EDT /13:00 BST. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada), or 0800-756-3429 (toll free from the UK) or 201-689-8040 (international). Investors may also access a live audio webcast of the call via the investor relations section of the Company's website at http://www.gwpharm.com. A replay of the call will also be available through the GW website shortly after the call and will remain available for 90 days. Replay Numbers: (toll free): 1-877-660-6853, (international): 1-201-612-7415. For both dial-in numbers please use conference ID # 13639965.

About Lennox-Gastaut Syndrome

The peak 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 inherited 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 non-convulsive, convulsive and drop seizures, which frequently lead to falls and injuries. Drug resistance is one of the main features of LGS. Most children with LGS experience some degree of impaired intellectual functioning, as well as developmental delays and behavioral disturbances. It is estimated that there are approximately 14,000-18,500 patients with LGS in the United States and 23,000-31,000 patients with LGS in Europe.

About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is an oral pharmaceutical formulation of pure CBD, which is in development for the treatment of a number of rare childhood-onset epilepsy disorders. GW has conducted extensive pre-clinical research of CBD in epilepsy since 2007. This research has shown that CBD has significant anti-epileptiform and anticonvulsant activity using a variety of *in vitro* and *in vivo* models and reduced seizures in various acute animal models of epilepsy. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex for the treatment of Dravet syndrome, LGS,

Tuberous Sclerosis Complex and infantile spasms. Additionally, GW has received Fast Track Designation from the FDA and Orphan Designation from the European Medicines Agency for Epidiolex for the treatment of Dravet syndrome. GW is currently evaluating additional clinical development programs in other orphan seizure disorders.

About GW Pharmaceuticals plc

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 is advancing an orphan drug program in the field of childhood-onset epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, LGS and Tuberous Sclerosis Complex. GW successfully developed the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. GW has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, schizophrenia and epilepsy. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release may contain forward-looking statements that reflect GWs current expectations regarding future events, including statements regarding the therapeutic benefit, safety profile and commercial value of the Company's investigational drug Epidiolex, the development and commercialization of Epidiolex, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory submissions and approvals. 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 the GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex, Epidiolex, if approved, and other products which we may commercialize by consumer and medical professionals. A further list and description of risks, uncertainties and other risks associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission. 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.

References:

LGS Foundation: http://www.lgsfoundation.org

Epilepsia. 2014 Sep;55 Suppl 4:4-9. doi: 10.1111/epi.12567., *Lennox-Gastaut syndrome: a consensus approach to differential diagnosis*., Bourgeois BF[1], Douglass LM, Sankar R.

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