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GW Announces New Epidiolex® (CBD) Positive Phase 3 Data in Dravet Syndrome and Lennox-Gastaut Syndrome

- Posters Presented at American Epilepsy Society Annual Meeting -
- New data includes key secondary efficacy endpoints -

LONDON, Dec. 05, 2016 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) ("GW" or "the Company"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announced additional positive Epidiolex® (cannabidiol or CBD) Phase 3 data in poster presentations at the 70th Annual Meeting of the American Epilepsy Society. These data are from the positive pivotal Phase 3 study of Epidiolex in Dravet syndrome and the first pivotal Phase 3 study of Epidiolex in Lennox-Gastaut syndrome (LGS), both reported earlier this year.

"We are pleased to present key findings from two pivotal Phase 3 studies of Epidiolex and believe these additional positive data reinforce the robust nature of the results achieved in two of the most difficult-to-treat epilepsy patient populations," stated Justin Gover, GW's Chief Executive Officer. "We are making very good progress toward a NDA submission to the FDA as well as preparations for commercial launch and look forward to the opportunity to make this important new medicine available to patients as quickly as possible."

Highlights of Findings in Both Phase 3 Studies:

- Each pivotal Phase 3 study achieved the primary endpoint demonstrating a statistically significant difference between Epidiolex and placebo in seizure frequency reduction during the 14 week treatment period.
- In the 12-week maintenance period (excluding the initial dose escalation), the treatment effect increased for patients receiving Epidiolex and showed a greater level of statistical significance compared with placebo.
- Caregivers of patients receiving Epidiolex were significantly more likely to report an improvement in overall condition.
- A consistent separation between Epidiolex and placebo across all response rates was seen. In the LGS study, the drop seizure responder analysis showed a statistically significant separation between Epidiolex and placebo at the 50 percent seizure reduction threshold.
- Epidiolex efficacy was established relatively early in treatment.
- Epidiolex was generally well tolerated.

"These placebo-controlled studies demonstrate that Epidiolex provides clinically meaningful reductions in seizure frequency together with an acceptable safety and tolerability profile," stated Orrin Devinsky, M.D., of New York University Langone Medical Center's Comprehensive Epilepsy Center and Principal Investigator of the Dravet syndrome trial. "The epilepsy community has been eagerly anticipating the presentation of this high quality scientific data from the Epidiolex program at the American Epilepsy Society. My colleagues and I are excited at the future prospect of prescribing an appropriately standardized and tested pharmaceutical formulation of cannabidiol."

"Dravet syndrome and Lennox-Gastaut syndrome are diagnosed in early childhood and represent some of the most difficult types of epilepsy to treat. Nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime. These trial results show that Epidiolex offers much needed new hope for children and their families," stated Elizabeth Thiele, MD, PhD, Director of Pediatric Epilepsy at the Massachusetts General Hospital, Professor of Neurology at the Harvard Medical School and Principal Investigator of the LGS trial. "I very much look forward to the day when Epidiolex is available as a new prescription option for my patients."

The studies represented in the posters are the first randomized, double-blind, placebo-controlled studies to investigate the efficacy and safety of CBD added to concomitant antiepileptic drug (AED) therapy in Dravet syndrome and LGS. The following are links to the posters presented:

Phase 3 Trial in Lennox-Gastaut syndrome (click to access)
Phase 3 Trial in Dravet syndrome (Part A) (click to access)
Phase 3 Trial in Dravet syndrome (Part B) (click to access)

Copies of these posters will also be available on GW's corporate website in the Investor Relations section under presentations.

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 Dravet Syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic syndrome frequently associated with a genetic mutation in sodium channels. Onset of Dravet syndrome occurs during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often temperature related, severe, and long-lasting. Over time, people with Dravet syndrome can develop multiple types of seizures, including tonic-clonic, myoclonic, and atypical absences and are prone to bouts of prolonged seizures called status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden expected death in epilepsy) is elevated in people 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 have uncontrolled seizures and other medical needs throughout their lifetime.

About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is a liquid formulation of pure plant-derived CBD, which is in development for the treatment of a number of rare pediatric 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 has the ability to treat seizures in acute animal models of epilepsy with significantly fewer side effects than existing anti-epileptic drugs. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex in the treatment of both Dravet syndrome and Lennox-Gastaut syndrome. 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 epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 30 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 glioma, schizophrenia and epilepsy. In the United States, GW is operating as Greenwich Biosciences Inc. 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 approval. 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®, and other products 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.

Enquiries:

GW Pharmaceuticals plc
Stephen Schultz, VP Investor Relations (U.S.) 917 280 2424 / 401 500 6570

Sam Brown, Inc.
Amanda Foley 610-725-0725 / 610-585-9400

Primary Logo

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