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)
Existing and prospective investors are cautioned not to place undue reliance on the existing and prospective information contained in this press release, whether as a result of new information, future events or otherwise. 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 otherwise.
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

Source: GW Pharmaceuticals plc

News Provided by Acquire Media