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GW Pharmaceuticals Achieves Positive Results in Phase 2 Proof of Concept Study in Glioma

- GW intends to advance oncology research and development efforts -

LONDON, Feb. 07, 2017 (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, today announced positive top-line results from an exploratory Phase 2 placebo-controlled clinical study of a proprietary combination of tetrahydrocannabinol (THC) and cannabidiol (CBD) in 21 patients with recurrent glioblastoma multiforme, or GBM. GBM is a particularly aggressive brain tumor, with a poor prognosis. GW has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for THC:CBD in the treatment of glioma.

The study showed that patients with documented recurrent GBM treated with THC:CBD had an 83 percent one year survival rate compared with 53 percent for patients in the placebo cohort (p=0.042). Median survival for the THC:CBD group was greater than 550 days compared with 369 days in the placebo group. THC:CBD was generally well tolerated with treatment emergent adverse events leading to discontinuation in two patients in each group. The most common adverse events (three patients or more and greater than placebo) were vomiting (75%), dizziness (67%), nausea (58%), headache (33%), and constipation (33%). The results of some biomarker analyses are still awaited.

"The findings from this well-designed controlled study suggest that the addition of a combination of THC and CBD to patients on dose-intensive temozolomide produced relevant improvements in survival compared with placebo and this is a good signal of potential efficacy," said Professor Susan Short, PhD, Professor of Clinical Oncology and Neuro-Oncology at Leeds Institute of Cancer and Pathology at St James's University Hospital and principal investigator of the study. "Moreover, the cannabinoid medicine was generally well tolerated. These promising results are of particular interest as the pharmacology of the THC:CBD product appears to be distinct from existing oncology medications and may offer a unique and possibly synergistic option for future glioma treatment."

"We believe that the signals of efficacy demonstrated in this study further reinforce the potential role of cannabinoids in the field of oncology and provide GW with the prospect of a new and distinct cannabinoid product candidate in the treatment of glioma," stated Justin Gover, GW's Chief Executive Officer. "These data are a catalyst for the acceleration of GW's oncology research interests and over the coming months, we expect to consult with external experts and regulatory agencies on a pivotal clinical development program for THC:CBD in GBM and to expand our research interests in other forms of cancer."

The study, designed to evaluate a number of safety and efficacy endpoints, comprised an initial phase where the safety of THC:CBD in combination with dose-intense temozolomide (an oral alkylating agent that is a standard first-line treatment for GBM) was assessed in 2 cohorts of 3 patients each. Following a satisfactory independent safety evaluation, the study then entered a randomized placebo-controlled phase where 12 patients were randomized to THC:CBD as add-on therapy compared with 9 patients randomized to placebo (plus standard of care).

Beginning in 2007 and prior to initiating this study, GW conducted substantial pre-clinical oncologic research on several cannabinoids in various forms of cancer including brain, lung, breast, pancreatic, melanoma, ovarian, gastric, renal, prostate and bladder. These studies have resulted in approximately 15 publications and show the multi-modal effects of cannabinoids on a number of the key pathways associated with tumor growth and progression. Cannabinoids have been shown to promote autophagy (the process of regulated self-degradation by cells) via several distinct mechanisms, including acting on the AKT/mTOR pathway, an important intracellular signalling pathway that is overactive in many cancers.

In glioma, THC and CBD appear to act via distinct signalling pathways. The combination of THC and CBD showed good efficacy in various animal models of glioma, particularly when used in combination with temozolomide. Initial *in vitro* studies showed that the combined administration of THC and CBD led to a synergistic reduction in the viability of U87MG glioma cells when compared to the administration of each cannabinoid individually. The co-administration of temozolomide with THC and CBD had further synergistic effects, causing a significant reduction in cell viability. These pre-clinical studies justified the initiation of the Phase 2 clinical study.

GW's portfolio of intellectual property related to the use of cannabinoids in oncology includes a number of issued patents

and pending applications in both the U.S. and Europe. This portfolio is designed to protect the use of various cannabinoids individually or in combination, in the treatment of a variety of oncology-specific disorders and product formulations.

About GBM

Gliomas are tumors that arise from glial cells mainly in the brain but can also be found within the spinal cord. Within the category of Glioma there are multiple different tumor types. GBM is the most common Glioma and is one of the most common primary brain tumors, accounting for 15.6% of all primary brain tumors (Ostrom et al. 2013). They are also the most aggressive with only 28.4% of patients surviving one year and only 3.4% surviving to year five (Brodbelt et al. 2015). Studies of patients with high-grade gliomas showed that headache was the most common initial presenting symptom. These headaches can be persistent lasting more than six months and are often associated with other symptoms, including seizures, visual disturbances, cognitive impairment and nausea and vomiting depending on the location and growth rate of the tumor.

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® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in 31 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. 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 Sativex® and Epidiolex® and the safety profile and commercial potential of Sativex and 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 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 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 5 December 2016. 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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