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GW Pharmaceuticals Commences Phase 1b/2a Clinical Trial for the Treatment of Glioblastoma Multiforme (GBM)

-Study Features THC and CBD as the Primary Cannabinoids-

London, UK; 11 November 2013: GW Pharmaceuticals plc (Nasdaq: GWPH, AIM: GWP, "GW") a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announced today it has commenced a Phase 1b/2a clinical trial for the treatment of Recurrent Glioblastoma Multiforme (GBM).

Glioma describes any tumor that arises from the glial tissue of the brain. GBM is a particularly aggressive tumor that forms from abnormal growth of glial tissue. According to the *New England Journal of Medicine*, GBM accounts for approximately 50% of the 22,500 new cases of brain cancer diagnosed in the United States each year. Treatment options are limited and expected survival is a little over one year. GBM is considered a rare, or orphan, disease by the FDA and the European Medicines Agency, or EMA.

This study follows several years of pre-clinical research conducted by GW in the field of glioma which has demonstrated that cannabinoids inhibit the viability of glioma cells both *in vitro* and *in vivo*[i,ii] via apoptosis or programmed cell death, may also affect angiogenesis, and have demonstrated tumor growth-inhibiting action and an improvement in the therapeutic efficacy of temozolomide[1], a standard treatment for glioma. In addition, GW has shown tumor response to be positively associated with tissue levels of cannabinoids. GW has identified the putative mechanism of action for our cannabinoid product candidate, where autophagy and programmed cell death are stimulated via stimulation of the TRB3 pathway.

“We are very excited about moving this compound into further human study and the prospects of cannabinoids as new anti-cancer treatments. This is GW’s first clinical study of cannabinoids as a potential treatment to inhibit tumor growth,” stated Dr. Stephen Wright, Director of Research and Development at GW. “We believe this clinical program demonstrates the flexibility and broad application of GW’s cannabinoid platform to treat significant, unmet therapeutic needs.”

This study is a 20-patient, multicentre, two part study with an open-label phase to assess safety and tolerability of GW cannabinoids in combination with temozolomide, and a double blind, randomised, placebo-controlled phase with patients randomised to active or placebo, and with a primary outcome measure of 6 month progression free survival. The study objective is to assess the tolerability, safety and pharmacodynamics of a mixture of two principal cannabinoids, THC and CBD in a 1:1 allocation ratio, in combination with temozolomide in patients with recurrent GBM. Secondary endpoints include additional pharmacokinetic and biomarker analyses and additional measurable outcomes of tumor response.

References:

i. Parolaro D, Massi P, Rubino T, Monti E. Endocannabinoids in the immune system and cancer. Prostaglandins Leukot Essent Fatty Acids 2002;66(2-3):319-32.
ii. Guzman M. Cannabinoids: potential anticancer agents. Nat Rev Cancer 2003;3(10):745-55.

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 commercialized the world’s first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 22 countries. Sativex is also in Phase 3 clinical development as a potential treatment of pain in people with advanced cancer. This Phase 3 program is intended to support the submission of a New Drug Application for Sativex in cancer pain with the U.S. Food and Drug Administration and in other markets around the world. GW has established a world leading position in the development of plant-derived cannabinoid therapeutics and has a deep pipeline of additional clinical-stage cannabinoid product candidates targeting epilepsy (including an orphan pediatric epilepsy program), Type 2 diabetes, ulcerative colitis, glioma and schizophrenia. 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 our clinical goals, our plans for a clinical trial, the ability to conduct clinical trials sufficient to achieve positive completion, and the therapeutic and commercial value of the company's compounds. To the degree we are able to conduct clinical trials, we may have difficulty in enrolling candidates for testing and we may not be able to achieve the desired results. 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® 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, including the prospectus related to the NASDAQ offering filed by GW with the SEC on May 1, 2013. 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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