LONDON, Sept. 18, 2013 /PRNewswire/ -- GW Pharmaceuticals plc (Nasdaq: GWPH, AIM: GWP, "GW") announced today it has commenced a Phase 1 clinical trial of product candidate GWP42006 for the treatment of epilepsy.

Over the last five years, GW has conducted an extensive pre-clinical cannabinoid research program in the field of epilepsy in collaboration with the University of Reading in the United Kingdom .
This research has led to the emergence of a number of promising cannabinoid therapeutic candidates showing anti-epileptic effects. GWP42006, one of the most promising of those candidates, is a non-psychoactive cannabinoid extracted from specific chemotypes of the cannabis plant which has shown the ability to treat seizures in pre-clinical models of epilepsy with significantly fewer side effects than currently approved anti-epileptic drugs [1] .

"We are pleased to have advanced GWP42006 to first dose in man, a significant milestone in the development of this novel product candidate. The decision to progress into Phase 1 follows several years of highly promising pre-clinical research," stated Dr. Stephen Wright, Director of Research and Development at GW. "We believe that GWP42006 has the potential to become an important advance in the treatment of epilepsy, a condition for which there remains a substantial unmet medical need."

Dr. Ben Whalley, Senior Lecturer in Pharmacology at the Reading School of Pharmacy, said, "Our research collaboration with GW over the last several years has shown that GWP42006 not only exerts significant anticonvulsant effects in a wide range of preclinical models of seizure and epilepsy but is also better tolerated compared to existing anti-epileptic drugs. It is also noteworthy that GWP42006 appears to employ a different mechanism of action to currently available anti-epileptic treatments. Together, these findings fully support the exciting clinical development that is now underway and represent an important step towards a more effective and better tolerated treatment for epilepsy."

Separately, GW's activities in the field of epilepsy have expanded in recent months as a result of emerging interest among U.S. pediatric epilepsy specialists and patient organizations in the

potential role of a distinct cannabinoid product candidate, Cannabidiol (CBD), in treating intractable childhood epilepsy. Three expanded access INDs have recently been granted by the FDA to U.S. clinicians to allow treatment of a small number of pediatric epilepsy patients with a CBD formulation supplied by GW. These activities may generate initial evidence to add CBD as a further pipeline candidate for clinical evaluation in epilepsy.

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence surges of electrical activity in the brain resulting in unprovoked seizures. Epilepsy is estimated to affect 50 million people worldwide including, according to the Centers for Disease Control and Prevention, 2.2 million people in the United States. Drug therapy remains ineffective for seizure control in up to 30% of patients with epilepsy because either the drugs do not control the seizures or the patients cannot tolerate the side effects. Currently available drugs can cause significant side effects particularly affecting movement and cognition that can adversely affect the quality of life for epileptic patients.

1: Hill et al, *British Journal of Pharmacology*, September 2012;

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 cannabinoid product candidates, including two distinct compounds, GWP42004 and GWP42003, in Phase 2 clinical development for Type 2 diabetes and ulcerative colitis, respectively, and GWP42006 in Phase 1 clinical development for the treatment of epilepsy. For further information, please visit
www.gwpharm.com
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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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