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GW Pharmaceuticals Announces Preliminary Topline Results of Phase 2a Ulcerative Colitis Trial

- Trial data show promising signals of efficacy in patients who completed course of treatment -

- Data to be presented at R&D Day today commencing at 10:00 a.m. ET, 15:00 BST -

LONDON, Oct. 14, 2014 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) (AIM:GWP) ("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 preliminary topline results from a Phase 2a ulcerative colitis trial to be presented today at the Company's R&D Day event in New York City.

The Phase 2a pilot trial was a 10-week randomized, double-blind, placebo controlled study of GWP42003 extract, which features Cannabidiol (CBD) as the primary cannabinoid and which also contains Tetrahyrdocannabinol (THC) and other cannabinoid and non-cannabinoid components. The trial included 60 adult patients with ulcerative colitis who had not been able to gain remission from the condition despite first line treatment with salicylates, and in some cases immunosuppressive therapy.

GWP42003 was given as a twice daily oral capsule in a dose titration regimen with an upper target dose of 250mg twice daily. Due to the pilot nature of the study, and the small patient population, the significance value was set at p=0.1.

The primary endpoint of this study was the percentage of participants achieving remission quantified by the MAYO score and included a range of secondary measures to determine whether GWP42003 has a positive benefit for subjects on symptom control.

The study included 60 patients, of which 29 patients were randomised to the active treatment group, and 31 to the placebo group. During the early weeks of the study, more patients withdrew from the active treatment group than from the placebo treatment group so that the per protocol population (those that took the investigational medicine as intended) comprised only 17 patients on GWP42003 and 27 on placebo. Most of these withdrawals were due to minor THC-related adverse events such as dizziness. For this reason, GW believes that the results for the protocol compliant population are most relevant to the assessment of efficacy. The intent to treat population (ITT) includes those patients who were only exposed to GWP42003 for a short period, and therefore had little if any opportunity to benefit.

The primary endpoint of disease remission, as assessed by a Mayo score of 2 or less at the end of the study was achieved by 41% of the protocol-compliant patients on GWP42003 and 30% of patients on placebo (Odds Ratio 1.3, 95% CI 0.4 to 4.0 [NS]). This difference was not statistically significant in either protocol-compliant patients or the ITT population.

Among the secondary efficacy endpoints, for the protocol-compliant population, the Inflammatory Bowel Disease Questionnaire was significantly in favour of GWP42003, as was the Physician Assessment of Disease severity. At the end of the treatment period, in this per protocol group, the physician assessed 82% of the patients in the GWP42003 group as having normal or mild disease, compared with 52% in the placebo group. The Patient Global Impression of Change showed that 93% of the patients in the per protocol population regarded their condition as "improved," compared with 60% of the placebo group. Both these differences were statistically significant.

For the ITT population, the Patient Global Impression of Change and the total partial MAYO score change from baseline (this includes stool frequency, bleeding and physician global impression) were statistically significantly in favour of GWP42003.

All patients on GWP42003 reported at least 1 adverse event, compared with 77% of patients on placebo. Of the adverse events on drug, 90% were mild or moderate. There were no serious adverse events (SAEs) on GWP42003, while there were 4 SAEs on placebo (two of which were exacerbations of the ulcerative colitis). However, as stated above, 13 patients withdrew from the study due to adverse events on drug, compared with 7 on placebo. There were no deaths in the study.

"There is a substantial unmet need for an effective treatment in patients with mild to moderate ulcerative colitis who have failed to enter remission following first line therapy or relapse whilst taking maintenance therapy. In particular, both physicians and patients recognise the importance of avoiding steroids due to their side effect profile," stated Dr. Peter Irving Guy's Hospital, London, and Chief Investigator of the study. "These results provide promising evidence that GWP42003 may produce clinically relevant improvement in the severity of ulcerative colitis compared with placebo, in patients who complete a course of

treatment."

Dr. Stephen Wright, R&D Director at GW Pharmaceuticals, stated, "In patients who were able to take GWP42003 for a prolonged treatment period, these results provide good evidence for a therapeutic effect in the treatment of ulcerative colitis in patients who had previously failed to respond to first line therapy. The results support the further investigation of GWP42003 and have provided useful pointers as to how this further investigation should best be done. In addition, the relatively poor tolerability of the dosage form used in this study suggests that further reductions to the THC content may be helpful."

R&D Day Webcast and Conference Call

A live audio webcast and conference call of the R&D Day presentation will be available starting at 10:00 a.m. ET (15:00 BST). To participate in the conference call, please dial 888-669-0676 (toll free from the U.S. and Canada), or 862-255-5360 (international). Investors may also access a live audio webcast of the call via the investor relations section of the Company's website at http://www.gwpharm.com. A replay will be available soon after the live presentation.

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 27 countries outside the United States. Sativex is also in Phase 3 clinical development as a potential treatment of pain associated with advanced cancer. This Phase 3 program has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) and is intended to support the submission of a New Drug Application for Sativex in cancer pain with the FDA and in other markets around the world. GW has a deep pipeline of additional cannabinoid product candidates, including Epidiolex® in the treatment of childhood epilepsy, which has received Fast Track Designation from the FDA for Dravet syndrome as well as Orphan Drug Designations from the FDA in both the treatment of Dravet syndrome and Lennox-Gastaut syndrome. GW's product pipeline also includes compounds in Phase 1 and 2 clinical development for glioma, ulcerative colitis, type 2 diabetes, 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 the therapeutic benefit, safety profile and commercial value of the company's investigational drugs including GWP42003, the development and commercialization of such drug candidates, 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.

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