September 26, 2016

GW Pharmaceuticals Announces Second Positive Phase 3 Pivotal Trial for Epidiolex® (cannabidiol) in the Treatment of Lennox-Gastaut Syndrome

- Primary endpoint achieved in both Epidiolex doses with high statistical significance compared to placebo -

- Today's data represents the third positive Phase 3 pivotal trial for Epidiolex reported in 2016 -

- Data reinforce the potential of Epidiolex to be an important new medicine for patients who suffer from this treatment-resistant childhood-onset epilepsy -

- Company to hold investor conference call today at 8:00 a.m. EDT/13:00 BST -

LONDON, Sept. 26, 2016 (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, announces positive results of the second randomized, double-blind, placebo-controlled Phase 3 clinical trial of its investigational medicine Epidiolex® (cannabidiol or CBD) for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), a rare and severe form of childhood-onset epilepsy. In this trial, Epidiolex, when added to the patient's current treatment, achieved the primary endpoint for both dose levels with high statistical significance. During the treatment period, patients taking Epidiolex 20mg/kg/day achieved a median reduction in monthly drop seizures of 42 percent compared with a reduction of 17 percent in patients taking placebo (p=0.0047), and patients taking Epidiolex 10mg/kg/day achieved a median reduction in monthly drop seizures of 37 percent compared with a reduction of 17 percent in patients taking placebo (p=0.0016).

This trial follows the announcement in June 2016 of positive results in the first pivotal Phase 3 trial of Epidiolex for the treatment of seizures associated with LGS, and the March 2016 announcement of positive results in the treatment of seizures associated with Dravet syndrome. GW expects to submit a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) in the first half of 2017.

"The positive outcome in this second trial of Epidiolex in patients with Lennox-Gastaut syndrome demonstrates the effectiveness of this product in this particularly difficult to treat, childhood-onset epilepsy," stated Orrin Devinsky, M.D., of New York University Langone Medical Center's Comprehensive Epilepsy Center and principal investigator in the trial. "The data from the Epidiolex Dravet and LGS studies offers the prospect of an FDA-approved CBD medicine that shows both clinically meaningful seizure reduction and a consistent safety and tolerability profile. I believe Epidiolex has the potential to become an important new option within the field of treatment-resistant epilepsy."

"Today brings great news for the Lennox-Gastaut Syndrome community," said Christina SanInocencio, Executive Director of the Lennox-Gastaut Syndrome Foundation. "The announcement of a second set of positive results with Epidiolex is exciting as they offer much needed hope for patients and their families living with this debilitating condition where new treatment options are desperately needed."

"The Epilepsy Foundation is thrilled to learn about the recent preliminary results for an innovative new therapy from GW for LGS. LGS in so many cases is extremely difficult to treat, and is an incredible challenge for children and families. We feel a tremendous sense of urgency to stop seizures, and believe that the pursuit of new therapies offers hope to individuals who have no currently available therapy to effectively stop their seizures. The Epilepsy Foundation will continue to be a champion for GW's efforts to pursue this innovative new therapy as studies progress. We thank GW and all our partners who invest in a better tomorrow for people with epilepsy," stated Philip Gattone, President and Chief Executive Officer of the Epilepsy Foundation.

"We are very pleased to report this second positive Phase 3 trial in seizures associated with Lennox-Gastaut Syndrome. This is the third positive Phase 3 trial for Epidiolex reported in 2016. All three trials provide GW with robust evidence to support the efficacy and safety of Epidiolex. This latest trial also shows that Epidiolex likely has an effective dose range, allowing for dose flexibility to address individual patient needs. These compelling results make us more determined than ever to make this important new medicine available to patients who suffer from these treatment-resistant childhood-onset epilepsies," stated Justin Gover, GW's Chief Executive Officer.

Trial Overview and Result

Patients aged 2-55 years with a confirmed diagnosis of drug-resistant LGS currently uncontrolled on one or more concomitant anti-epileptic drugs (AEDs) were eligible to participate in this Phase 3, randomized, double-blind placebo-controlled trial. The trial randomized 225 patients into three arms, where Epidiolex 20mg/kg/day (n=76), Epidiolex 10mg/kg/day (n=73) or placebo (n=76) was added to current AED treatment. On average, patients were taking approximately three AEDs, having previously tried and discontinued an average of seven other AEDs. The average age of trial participants was 16 years (30 percent were 18 years or older). The median drop seizure frequency over the 4 week baseline period was 85.

The primary efficacy endpoint of this trial was a comparison between Epidiolex and placebo in the percentage change in the monthly frequency of drop seizures during the 14 week treatment period (two week dose escalation period followed by 12 weeks of maintenance) compared to the 4 week baseline period before randomization. Drop seizures were defined as atonic, tonic or tonic-clonic seizures involving the entire body, trunk or head that led or could have led to a fall, injury, slumping in a chair or hitting the patient's head on a surface.

During the treatment period, patients taking Epidiolex 20mg/kg/day achieved a median reduction in monthly drop seizures of 42 percent compared with a reduction of 17 percent in patients taking placebo (p=0.0047), and patients taking Epidiolex 10mg/kg/day achieved a median reduction in monthly drop seizures of 37 percent compared with a reduction of 17 percent in patients taking placebo (p=0.0016).

A series of sensitivity analyses of the primary endpoint for both dose groups confirmed the robustness of these results. In both dose groups, the difference between Epidiolex and placebo emerged during the first month of treatment and was sustained during the entire treatment period. Results from secondary efficacy endpoints in both dose groups reinforced the overall effectiveness observed with Epidiolex.

Epidiolex was generally well tolerated in this trial. The pattern of adverse events was consistent with that reported in the previous two Phase 3 studies. One patient on 10mg/kg Epidiolex discontinued treatment due to an adverse event compared with six patients on 20mg/kg and one patient on placebo.

Of the 84 percent of 10mg/kg patients who experienced an adverse event, 89 percent of them deemed it to be mild or moderate. Of the 94 percent of 20mg/kg patients who experienced an adverse event, 88 percent of them reported it to be mild or moderate. 72 percent of patients on placebo experienced an adverse event.

The most common adverse events (occurring in greater than 10 percent of Epidiolex-treated patients) in the 10mg/kg group were: somnolence, decreased appetite, upper respiratory infection, diarrhea, and status epilepticus. None of the cases of status epilepticus in the 10mg/kg group was deemed treatment-related. The most common adverse events (occurring in greater than 10 percent of Epidiolex-treated patients) in the 20mg/kg group were: somnolence, decreased appetite, diarrhea, upper respiratory infection, pyrexia, vomiting, and nasopharyngitis.

Thirteen patients on Epidiolex 10mg/kg experienced a serious adverse event (two of which were deemed treatment-related) compared with thirteen patients on 20mg/kg (five of which were deemed treatment-related) and eight patients on placebo (none of which were deemed treatment-related).

There were no deaths in this trial.

Of the patients who completed this trial, 99 percent have opted to continue into an open-label extension trial.

Further data will be presented in future publications and medical meetings.

Epidiolex New Drug Application (NDA)

Following the success of the first Dravet syndrome Phase 3 trial earlier this year, GW requested a pre-NDA meeting with the FDA to discuss a proposed Dravet syndrome NDA. This meeting took place in July 2016 and also included some discussion of data from the first Phase 3 LGS trial. As a result of this constructive meeting, GW believes the guidance received enables the Company's proposed filing strategy to submit a single NDA that includes Phase 3 data from one Dravet trial and two LGS trials, and which remains on track for a submission in the first half of 2017. Subject to satisfactory review, GW now anticipates a simultaneous decision on both indications and does not expect to wait for results from the second trial in Dravet syndrome prior to this submission.

In order to support GW's NDA, the Company expects to provide the FDA with data from ten Phase 1 and Phase 2 studies, as well as safety data in over 1,800 patients from both the expanded access program and pivotal programs, including over 450 patients with one year or more of Epidiolex continuous exposure. This data is in addition to the pivotal efficacy data.

Epidiolex has Orphan Drug Designation from the FDA for the treatment of LGS, Dravet syndrome, Tuberous Sclerosis Complex and Infantile Spasms.

GW Clinical Trial Programs in Dravet Syndrome, Tuberous Sclerosis Complex and Infantile Spasms

In March 2016, GW announced positive results of the first pivotal Phase 3 trial of Epidiolex in Dravet syndrome. GW continues to enroll a second Phase 3 trial of Epidiolex in Dravet syndrome and will report these results upon completion. GW has commenced a Phase 3 trial of Epidiolex in Tuberous Sclerosis Complex and expects to initiate a Phase 3 trial of Epidiolex in Infantile Spasms in the fourth quarter of this year.

Investor Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast for analysts and investors to discuss the results from this initial Phase 3 trial today at 8:00 a.m. EDT /13:00 BST. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada), or 0800-756-3429 (toll free from the UK) or 201-689-8040 (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 of the call will also be available through the GW website shortly after the call and will remain available for 90 days. Replay Numbers: (toll free): 1-877-660-6853, (international): 1-201-612-7415. For both dial-in numbers please use conference ID # 13646262.

About Lennox-Gastaut Syndrome

The peak onset of LGS typically occurs between ages of 3 to 5 years and can be caused by a number of conditions, including brain malformations, severe head injuries, central nervous system infections, and inherited degenerative or metabolic conditions. In up to 30 percent of patients, no cause can be found. Patients with LGS commonly have multiple seizure types including non-convulsive, convulsive and drop seizures, which frequently lead to falls and injuries. Drug resistance is one of the main features of LGS. Most children with LGS experience some degree of impaired intellectual functioning, as well as developmental delays and behavioral disturbances. Latest estimates are that there are more than 30,000 patients with LGS in the United States.

About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is an oral pharmaceutical formulation of CBD, which is in development for the treatment of a number of rare childhood-onset epilepsy disorders. GW has conducted extensive pre-clinical research of CBD in epilepsy since 2007. This research has shown that CBD has significant anti-epileptiform and anticonvulsant activity using a variety of in vitro and in vivo models and reduced seizures in various acute animal models of epilepsy. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex for the treatment of Dravet syndrome, LGS, Tuberous Sclerosis Complex and Infantile Spasms. Additionally, GW has received Fast Track Designation from the FDA and Orphan Designation from the European Medicines Agency for Epidiolex for the treatment of Dravet syndrome. GW is currently evaluating additional clinical development programs in other orphan seizure disorders.

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-onset epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, LGS and Tuberous Sclerosis Complex. GW successfully developed the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. GW 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 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 drug Epidiolex, the development and commercialization of Epidiolex, 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 submissions and approvals. 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, if approved, and other products which we may commercialize 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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