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GW Pharmaceuticals Receives Orphan Drug Designation from FDA for Cannabidiol for the Treatment of Tuberous Sclerosis Complex

LONDON, April 21, 2016 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) (AIM:GWP) ("GW" or "the Company"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for cannabidiol (CBD) for the treatment of Tuberous Sclerosis Complex (TSC). TSC is a rare genetic disorder, the most common symptom of which is epilepsy. Epilepsy occurs in around 80-90% of TSC patients and is a significant cause of morbidity and mortality. TSC is the third orphan indication that GW is targeting within its Epidiolex® (CBD) clinical development program, which includes four Phase 3 pivotal trials in Dravet syndrome and Lennox-Gastaut syndrome, both rare and catastrophic forms of childhood-onset epilepsy. On April 11, 2016, GW announced it has commenced a Phase 3 clinical trial of Epidiolex® as an adjunctive therapy for the treatment of seizures associated with TSC.

To obtain information about this clinical trial or eligibility criteria, the treating physician should contact: **medicaldirector@gwpharm.com**

About Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition - generally a disease or condition that affects fewer than 200,000 individuals in the U.S. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period for that drug and use, unless the applicant is unable to assure sufficient quantities of the drug or another applicant is able to demonstrate that its version of the drug is clinically superior.

About Tuberous Sclerosis Complex (TSC)

TSC is a genetic disorder that causes non-malignant tumors to form in many different organs, with the brain and skin being the most commonly affected tissues. There are approximately 50,000 in the United States and nearly 1 million people worldwide estimated to have TSC[1]. Epilepsy is the most common presenting symptom in TSC and is also the most common medical disorder in TSC. Up to 80 to 90% of individuals with TSC will develop epilepsy during their lifetime, with onset typically in childhood. The majority of children with TSC have onset of seizures during the first year of life, and up to one third of children with TSC will develop infantile spasms. Almost all seizure types can be seen in individuals with TSC, including tonic, clonic, tonic-clonic, atonic, myoclonic, atypical absence, partial, and complex partial. The seizures are often severe, and up to two-thirds of TSC patients do not respond adequately to available medical therapies. There are significant co-morbidities associated with TSC including cognitive impairment, autism spectrum disorders, and neurobehavioral disorders in individuals with TSC. [2]

References:
1: http://www.tsalliance.org/pages.aspx?content=585
2: http://www.medscape.com/viewarticle/495644

About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is a liquid formulation of pure plant-derived CBD, which is in development for the treatment of a number of rare pediatric 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 has the ability to treat seizures in acute animal models of epilepsy with significantly fewer side effects than existing anti-epileptic drugs. To date, GW has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for Epidiolex in the treatment of Dravet syndrome, Lennox-Gastaut syndrome and TSC. 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 commercialized 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 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 and Tuberous Sclerosis Complex. GW has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, type 2 diabetes, 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 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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