

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Month of April, 2016

Commission File Number: 001-35892

GW PHARMACEUTICALS PLC

(Translation of registrant's name into English)

Sovereign House
Vision Park
Histon
Cambridge CB24 9BZ
United Kingdom
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes

No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes

No

Other Events

On April 11, 2016, GW Pharmaceuticals plc issued a press release announcing that it has commenced a Phase 3 clinical trial of Epidiolex® (cannabidiol or CBD) as an adjunctive therapy for the treatment of seizures associated with Tuberous Sclerosis Complex (TSC), a rare genetic disorder, the most common symptom of which is epilepsy. The press release is attached as Exhibit 99.1 and is incorporated by reference herein. The information contained in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Exhibits

99.1 Press Release dated April 11, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GW Pharmaceuticals plc

By: /s/ Adam George

Name: Adam George

Title: Chief Financial Officer

Date: April 11, 2016



GW Pharmaceuticals Initiates Phase 3 Pivotal Study in Tuberous Sclerosis Complex

London, UK, 11 Apr 2016: 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 it has commenced a Phase 3 clinical trial of Epidiolex® (cannabidiol or CBD) as an adjunctive therapy for the treatment of seizures associated with Tuberous Sclerosis Complex (TSC), 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 indication that GW is targeting within its Epidiolex 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 March 14, 2016, GW announced positive results from the first of these pivotal trials in Dravet syndrome.

“We are pleased to announce the start of this pivotal clinical trial of Epidiolex in TSC, which follows the recent positive results from our trial in patients with Dravet syndrome. Our decision to evaluate Epidiolex in TSC is based on findings from the physician-led Epidiolex expanded access program, which found that TSC patients reported reductions in seizure activity,” stated Justin Gover, GW’s Chief Executive Officer. “With the commencement of this trial, GW’s Epidiolex development program now encompasses three rare epilepsy indications with pivotal trials fully underway. GW is committed to establishing Epidiolex as a new therapy to address the significant unmet need among patients who have few treatment options.”

“In patients with TSC, epilepsy is common, presents early and can become more difficult to treat over time. The results of our open-label study of Epidiolex in children with TSC have been very encouraging and we are excited to begin this important placebo-controlled clinical trial,” stated Elizabeth Thiele, MD, PhD, Director, Pediatric Epilepsy Program at Massachusetts General Hospital, Director, Herscot Center for Tuberous Sclerosis Complex and Professor of Neurology, Harvard Medical School and Principal Investigator of the trial. “As one of the largest TSC treatment centers in the country, our focus has always been on finding new and innovative solutions that improve the lives of people living with TSC.”

At the 69th Annual Meeting of the American Epilepsy Society in December 2015, safety and efficacy data on 10 patients diagnosed with TSC from the physician-led open-label Epidiolex expanded access program were presented by Massachusetts General Hospital for Children (Geffrey *et al* 2015) on Epidiolex treatment of refractory epilepsy in these patients. The percent of patients who reported a 50% or greater reduction in seizures were 50%, 50%, 40%, 60% and 66% at 2, 3, 6, 9, and 12 months of treatment with Epidiolex, respectively. Side effects were seen in five patients (50%) and most were resolved with anti-epileptic drug or CBD dose adjustment.

This single Phase 3 dose-ranging trial is a 16-week comparison of Epidiolex versus placebo in a total of approximately 200 patients, aged one to 65, to assess its safety and efficacy as an adjunctive antiepileptic treatment. The primary measure of this trial is the percentage change from baseline in seizure frequency during the treatment period. Primary endpoint seizures include focal motor seizures with or without impairment of consciousness or awareness and generalized convulsive seizures. Several additional efficacy and safety secondary outcome measures will be analysed. Following completion of the study, patients may be eligible to receive Epidiolex through a long term open-label extension study.

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

About Tuberous Sclerosis Complex (TSC)

Tuberous Sclerosis Complex (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 TSC¹. 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 tuberous sclerosis complex, 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 both Dravet syndrome and Lennox-Gastaut syndrome. 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 GW's 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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