GW Pharmaceuticals receives positive CHMP opinion for EPIDYOLEX™ (cannabidiol oral solution) for the treatment of seizures in patients with two rare, severe forms of childhood-onset epilepsy

July 26, 2019

If approved cannabidiol oral solution will be the first plant-derived cannabis-based medicine to be approved in Europe for the treatment of any form of epilepsy

GW's cannabidiol oral solution contains highly purified, plant-derived cannabidiol (CBD), a cannabinoid lacking the "high" associated with cannabis

LONDON and CARLSBAD, Calif., July 26, 2019 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH) ("GW", "the Company" or "the Group"), the world leader in discovering, developing and commercialising cannabinoid prescription medicines, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending marketing authorisation of EPIDYOLEX™ (cannabidiol oral solution) for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. The European Commission (EC) is expected to make a final decision on the marketing authorisation application (MAA) in approximately two months.

"Today's positive CHMP opinion for EPIDYOLEX™ marks a major milestone for patients, and their families, battling to control two of the most severe and life-threatening forms of childhood onset epilepsy. Cannabidiol oral solution is the first in a new class of epilepsy medicines and the first plant-derived cannabis-based medicine to be submitted for European regulatory review, representing a historic breakthrough," said Justin Gover, GW's Chief Executive Officer. "We are excited by the potential to bring patients and physicians a rigorously tested and evaluated cannabis-based medicine with a documented safety and efficacy profile, manufactured to the highest standards and approved by a medicines regulator."

"This is a significant milestone for patients with LGS and Dravet syndrome as there remains a severe unmet medical need for these rare, lifelong forms of epilepsy," said Professor Martin Brodie, President, International Bureau for Epilepsy. "Today's positive opinion brings hope to both patients and their families of a treatment option which has the potential to better control seizures and notably improve quality of life."

"In my clinic, I often see patients with these highly treatment-resistant epilepsies who have tried and failed existing therapies. These patients and their families face a long and challenging road and very few achieve adequate seizure control," said Dr Antonio Gil-Nagel Rein, Director of the Epilepsy Programme, Ruber International Hospital, Madrid. "Based on numerous clinical trials and the scrutiny of the European medicines regulator, this medicine has the potential to make a real difference to the lives of many patients."

The CHMP's positive opinion is based on results from four randomised, controlled Phase 3 trials. These studies incorporate data from more than 714 patients with either LGS or Dravet syndrome, two forms of epilepsy with high morbidity and mortality rates, which place a significant burden on families and caregivers. Many patients with LGS or Dravet syndrome have multiple seizures per day, which puts them at ongoing risk of falls and injury. Despite current anti-epileptic drug treatment, both of these severe forms of epilepsy remain highly treatment-resistant.[1,2,3]

GW's cannabidiol oral solution was approved by the U.S. Food and Drug Administration (FDA) in June 2018 under the trade name EPIDIOLEX ® for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age or older.

The EC has the authority to approve medicines for use in the 28 countries of the European Union, alongside Norway, Iceland and Liechtenstein.

1: Bourgeois, B. F., Douglass, L. M. and Sankar, R. (2014), Lennox-Gastaut syndrome: A consensus approach to differential diagnosis. Epilepsia, 55: 4-9. Doi:10.1111/epi.12567.

2. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Lancet Neurol. 2009;8(1):82-93.

3. Dravet C. The core Dravet syndrome phenotype. Epilepsia. 2011;52 Suppl 2:3-9.

ADDITIONAL INFORMATION

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

Founded in 1998, GW is a UK-based global biopharmaceutical company focused on discovering, developing and commercialising novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. In June 2018 GW, along with its U.S. subsidiary Greenwich Biosciences, received U.S. FDA approval for EPIDIOLEX® (cannabidiol oral solution) for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. GW developed the world's first plant-derived cannabinoid prescription medicine, Sativex® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in more than 25 countries around the world. The Company has a deep pipeline of additional cannabinoid product candidates, which includes compounds in Phase 1, 2 and 3 trials for epilepsy, autism, glioblastoma, and schizophrenia.

About EPIDIOLEX®/EPIDYOLEX ™(cannabidiol oral solution)

EPIDIOLEX®/EPIDYOLEX™ (cannabidiol oral solution), the first prescription, plant-derived cannabis-based medicine approved by the FDA for use in the U.S., is an oral solution which contains highly purified cannabidiol (CBD). The medicine is for the treatment of seizures associated with Lennox-

Gastaut syndrome (LGS) and Dravet syndrome in patients two years of age or older and is the first in a new class of anti-epileptic medications with a novel mechanism of action. GW submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for EPIDYOLEX™ in December 2017, which was accepted for review in February 2018. GW received Orphan Drug Designation from the EMA for the treatment of seizures associated with LGS, Dravet syndrome, and Tuberous Sclerosis Complex (TSC).

About Dravet syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the sodium channel gene *SCN1A*. Onset of Dravet syndrome occurs typically during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often body temperature related, severe, and long-lasting. Over time, patients with Dravet syndrome often develop multiple types of seizures, including tonic-clonic, myoclonic and atypical absences and are prone to bouts of prolonged seizures including status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden unexpected death in epilepsy) is elevated in patients with Dravet syndrome. Additionally, the majority of patients will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care.

About Lennox-Gastaut syndrome (LGS)

The 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 genetic neuro-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 drop and convulsive seizures, which frequently lead to falls and injuries, and non-convulsive seizures. Resistance to anti-epileptic drugs (AEDs) is common in patients with LGS. Most patients with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviours.

Forward-looking statements

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of EPIDIOLEX®/EPIDYOLEX™ (cannabidiol oral solution) and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines. 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 GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion and uncertainties related to the regulatory process, and the acceptance of EPIDIOLEX®/EPIDYOLEX™, Sativex® and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the most recent Form 10-K filed on 29 November 2018. 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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