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GW Pharmaceuticals Submits Marketing Authorisation Application in Europe for Epidiolex® (cannabidiol) in the treatment of Lennox-Gastaut syndrome and Dravet syndrome

LONDON and CARLSBAD, Calif., Dec. 29, 2017 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) ("GW" or "the Company"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, today announced it has submitted its Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Epidiolex® (cannabidiol or CBD) as adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two highly treatment-resistant forms of childhood-onset epilepsy. GW has received Orphan Designations from the EMA for Epidiolex for the treatment of LGS, Dravet syndrome, and recently, West syndrome and Tuberous Sclerosis Complex. In October 2017, GW completed the submission of its rolling Epidiolex New Drug Application (NDA) to the United States Food and Drug Administration (FDA), also for seizures associated with LGS and Dravet syndrome. This NDA has been accepted by the FDA for Priority Review.

"This MAA submission marks another major milestone for the Epidiolex program and is an important next step toward providing this potential new treatment option globally," stated Justin Gover, CEO of GW Pharmaceuticals. "GW is committed to making Epidiolex available to patients in Europe that struggle with the burden of living with LGS and Dravet syndrome, both very difficult to treat and devastating conditions. We continue to build a commercial infrastructure in Europe in anticipation of future approval and launch."

The MAA for Epidiolex is supported by data from three Phase 3 safety and efficacy studies, each of which met their primary endpoint. Epidiolex was generally well tolerated in these trials. The MAA includes safety data on approximately 1,500 patients, with approximately 400 patients on continuous therapy for more than one year. Approximately 26% of the Epidiolex patients from the Phase 3 pivotal program came from European sites. Beyond pivotal safety and efficacy data, the MAA includes a comprehensive clinical pharmacology, pre-clinical and toxicology package.

About Lennox-Gastaut Syndrome

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 children with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviors.

About Dravet Syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the SCN1A sodium channels. 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 will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care. There are currently no FDA-approved treatments and nearly all patients continue to experience seizures and other medical needs throughout their lifetime.

About Epidiolex® (cannabidiol)

Epidiolex, GW's lead cannabinoid product candidate is a pharmaceutical formulation of purified cannabidiol (CBD), which is in development for the treatment of several rare childhood-onset epilepsy disorders. GW has submitted a New Drug Application with the FDA for Epidiolex as adjunctive treatment for seizures associated with LGS and Dravet syndrome with an expected approval and launch in 2018. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex

for the treatment of Dravet syndrome, LGS, TSC and IS. Additionally, GW has received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare pediatric disease designation by the FDA. The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for the treatment of LGS, Dravet syndrome, West syndrome and TSC. GW is currently evaluating additional clinical development programs in other orphan seizure disorders including Phase 3 trials in Tuberous Sclerosis Complex and Infantile Spasms.

About GW Pharmaceuticals plc and Greenwich Biosciences

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, along with its U.S. subsidiary Greenwich Biosciences, is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted an NDA to the FDA for the adjunctive treatment of LGS and Dravet syndrome. The Company continues to evaluate Epidiolex in additional epilepsy conditions and currently has ongoing clinical trials in Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for gliobastoma, schizophrenia and epilepsy. For further information, please visit www.gwpharm.com.

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® (cannabidiol) and the safety profile and commercial potential of Epidiolex. 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 Sativex, Epidiolex 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 20-F filed on 4 December 2017. 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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