EPIDIOLEX® (cannabidiol) Oral Solution – the First FDA-approved Plant-derived Cannabinoid Medicine – Now Available by Prescription in the U.S.

November 1, 2018

- Medication indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, two rare, severe childhood-onset epilepsies -

- Comprehensive support program available for eligible patients -

LONDON and CARLSBAD, Calif., Nov. 01, 2018 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH, "GW," "the Company" or "the Group"), the world leader in the development and commercialization of cannabinoid prescription medicines, along with its U.S. subsidiary Greenwich Biosciences, announced today that EPIDIOLEX® (cannabidiol) oral solution CV is now available in the U.S. for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. EPIDIOLEX, which was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018, is the first prescription pharmaceutical formulation of highly purified, plant-derived cannabidiol (CBD), a cannabinoid lacking the high associated with marijuana, and the first in a new category of anti-epileptic drugs.

"We are delighted to announce that EPIDIOLEX is now available by physician prescription as a new treatment option for patients with LGS and Dravet syndrome, two of the most difficult-to-treat forms of childhood-onset epilepsy," said Justin Gover, Chief Executive Officer of GW Pharmaceuticals. "Because these patients have historically not responded well to available seizure medications, there has been a dire need for new therapies that aim to reduce the frequency and impact of seizures. We are committed to ensuring that these patients can access this novel cannabinoid medicine that has been thoroughly studied in clinical trials, manufactured to assure quality and consistency, and is eligible to be covered by insurance for appropriate patients."

The company has introduced a comprehensive patient support program called EPIDIOLEX Engage™, which is designed to help patients who have been prescribed EPIDIOLEX gain access to therapy. The program offers patient/caregiver-focused education and resources to help lower out-of-pocket costs or provide product at no cost for eligible patients. More information can be found at EPIDIOLEX.com.

"EPIDIOLEX is a much-needed new treatment option for patients with LGS, a rare and severe form of childhood-onset epilepsy that typically persists into adulthood," said Christina SanInocencio, Executive Director of the Lennox-Gastaut Syndrome Foundation. "Despite the use of multiple epilepsy treatments, the majority of LGS patients continue to have life-long, debilitating seizures and our community welcomes the availability of a new, first-in-class treatment option."

"We are very pleased that EPIDIOLEX -- the first medication to be approved by the FDA for patients with Dravet syndrome -- is now available," said Mary Anne Meskis, Executive Director of the Dravet Syndrome Foundation. "Our community has long desired a medication specifically approved for the treatment of seizures associated with Dravet syndrome, and the availability of EPIDIOLEX is an important milestone for patients and caregivers whose lives are significantly impacted by this catastrophic, lifelong form of epilepsy."

The EPIDIOLEX clinical development program included three randomized, controlled Phase 3 clinical trials and an open-label extension study. The Phase 3 studies have been published in *The New England Journal of Medicine*[1,[2]] and *Lancet*[3]. EPIDIOLEX added to other antiepileptic therapies significantly reduced the frequency of drop seizures in patients with LGS and convulsive seizures in patients with Dravet syndrome. The most common adverse reactions that occurred in EPIDIOLEX-treated patients were somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor quality sleep; and infections. The company's development program represents the only well-controlled clinical development program of a cannabinoid medication leading to FDA approval for patients with LGS and Dravet syndrome.

EPIDIOLEX was developed by GW Pharmaceuticals and will be marketed in the U.S. by its subsidiary, Greenwich Biosciences. For more information on EPIDIOLEX, visit www.EPIDIOLEX.com.

About EPIDIOLEX® (cannabidiol) oral solution
EPIDIOLEX, the first prescription, plant-derived cannabinoid medicine in the United States and the first in a new class of anti-epileptic medications, is a pharmaceutical formulation of highly purified cannabidiol (CBD) now FDA approved for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. GW has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for EPIDIOLEX with an expected decision date in the first quarter of 2019. GW has received Orphan Drug Designation from the FDA for EPIDIOLEX for the treatment of seizures associated with tuberous sclerosis complex (TSC). The Company has also received Orphan Designation from the EMA for EPIDIOLEX for the treatment of seizures associated with LGS, Dravet syndrome, and TSC. GW is currently conducting an additional Phase 3 clinical development program in the treatment of seizures associated with TSC.

Important Safety Information & Indications
What is the Most Important Information I Should Know About EPIDIOLEX?
Do not take if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX.
EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

- loss of appetite, nausea, vomiting

- fever, feeling unwell, unusual tiredness
- yellowing of the skin or the whites of the eyes (jaundice)
- itching
- unusual darkening of the urine
- right upper stomach area pain or discomfort

EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.

Like other antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any signs of depression or anxiety, thoughts about suicide or self-harm, feelings of agitation or restlessness, aggression, irritability, or other unusual changes in behavior or mood, especially if they are new, worse, or worry you.

Take EPIDIOLEX exactly as your healthcare provider tells you. Do not stop taking EPIDIOLEX without first talking to your healthcare provider. Stopping a seizure medicine suddenly can cause serious problems.

What Else Should I Know When Taking EPIDIOLEX?
The most common side effects of EPIDIOLEX include sleepiness, decreased appetite, diarrhea, increase in liver enzymes, feeling very tired and weak, rash, sleep problems, and infections. EPIDIOLEX may affect the way other medicines work, and other medicines may affect how EPIDIOLEX works. Do not start or stop other medicines without talking to your healthcare provider. Tell healthcare providers about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products.

EPIDIOLEX is a federally controlled substance (CV) because it has a low potential for abuse. Keep EPIDIOLEX in a safe place to prevent theft, misuse, or abuse.

What Additional Information Applies to Women?
If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby. You and your healthcare provider will have to decide if you should take EPIDIOLEX while you are pregnant.

If you become pregnant while taking EPIDIOLEX, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry (by calling 1-888-233-2334). The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy.
Because many medicines like EPIDIOLEX are passed into breast milk, talk to your healthcare provider about the best way to feed your baby while taking EPIDIOLEX.

What is EPIDIOLEX?
EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

It is not known if EPIDIOLEX is safe and effective in children under 2 years of age.

Please refer to the EPIDIOLEX Medication Guide and Instructions for Use for additional important information.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.
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, has 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. The Company has submitted a regulatory application in Europe for the adjunctive treatment of seizures associated with LGS and Dravet syndrome. The company continues to evaluate EPIDIOLEX in additional rare epilepsy conditions and currently has an ongoing clinical trial in tuberous sclerosis complex (TSC). 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 and for which the company is now planning a U.S. Phase 3 trial. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, glioblastoma, and schizophrenia. 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 commercial launch of EPIDIOLEX, 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) oral solution 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. An additional 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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[1] Devinsky O, Cross JH, Laux L, et al. Trial of cannabidiol for drug-resistant seizures in the Dravet syndrome. *N Engl J Med* 2017;376;2011-20.

[2] Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox–Gastaut Syndrome. *N Engl J Med* 2018;378;20:1888-97.

[3] Thiele EA, Marsh ED, French JA, et al. Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomized, double-blind placebo-controlled phase 3 trial. *Lancet* 2018;391;10125:1085-1096.

A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/b420c8be-627c-47b3-8248-0af55a60aa23