



## **GW Pharmaceuticals and U.S. Subsidiary Greenwich Biosciences to Present Data on EPIDIOLEX® (cannabidiol) Oral Solution at the American Epilepsy Society Annual Meeting**

November 19, 2018

### **Meeting Highlights Include over 20 Posters and Virtual Tour of the Epidiolex Manufacturing Process**

LONDON and CARLSBAD, Calif., Nov. 19, 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 results from completed Phase 3 trials of EPIDIOLEX® (cannabidiol) oral solution CV, as well as new pre-clinical and Phase 1 cannabinoid research, will be presented at the American Epilepsy Society (AES) Annual Meeting, November 30-December 4, 2018, in New Orleans, Louisiana. EPIDIOLEX is FDA-approved and available by prescription in the U.S. for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age and older.

At AES, scientific posters will include first-time presentations of data from the EPIDIOLEX Phase 3 pivotal trials in LGS and Dravet syndrome; reports from the Expanded Access Program (EAP); presentation of Phase 1 and 2 studies and collaborative pre-clinical research.

GW/Greenwich will also host an exhibit booth as well as an Innovation Pavilion where AES attendees can learn about the Company's CBD growing and manufacturing processes through a virtual tour of its facilities in the United Kingdom. The Pavilion will also include presentations about the EPIDIOLEX clinical trial program.

"Following the recent launch of EPIDIOLEX, the first prescription pharmaceutical formulation of CBD, we are excited to share with the epilepsy community at AES our latest clinical data, including long-term safety and efficacy of CBD in LGS and Dravet syndrome, as well as a new virtual experience of the growing and manufacturing process for this first-in-class anti-epilepsy drug," said Justin Gover, GW's Chief Executive Officer.

Meeting activities include:

### **Exhibit (Booth #401)**

*Saturday, December 1 – Monday, December 3*

### **Innovation Pavilion: Growing Innovation (Pavilion D)**

*Saturday, December 1 and Sunday, December 2*

- **Virtual Reality Experience**

**Saturday 2:30-4:30 PM; Sunday 10 AM-2:30 PM**

Virtual reality tour of the EPIDIOLEX growing and manufacturing process.

- **The history and science behind EPIDIOLEX® (cannabidiol) CV**

**Saturday 1-2 PM; Sunday 3-4 PM**

Hear the story of Greenwich Biosciences' long-standing dedication to advancing cannabinoid science, and see the data that led to the FDA approval of EPIDIOLEX. There will also be an interactive Q&A session.

- **Nurses' Reception**

**Saturday 5-6 PM**

An evening reception for nurses and nurse practitioners with information on patient education and support resources.

### **Scientific Exhibition**

*Monday, December 3*

- **EPIDIOLEX®: The Only FDA-approved Cannabidiol Treatment**

**8-11 AM, Room 277**

Presentation of the most recent safety and efficacy data on EPIDIOLEX.

### **Data Presentations**

#### **Phase 3 and Long-term EPIDIOLEX data**

- Cannabidiol (CBD) Reduces Seizure Frequency in Patients with Dravet Syndrome Who Had No Response to Prior Medications: Subgroup Analysis of Phase 3 Study – Wilfong et al (Saturday, Dec. 1, Poster #1.295)

- Time to Onset of Efficacy of Cannabidiol (CBD) During Titration in Patients with Lennox–Gastaut Syndrome (LGS) and Dravet Syndrome (DS) Enrolled in 3 Randomized Controlled Trials – Privitera et al (Saturday, Dec. 1, Poster #1.296)
- Long-term Safety and Efficacy of Add-on Cannabidiol (CBD) Treatment in Patients with Lennox Gastaut Syndrome (LGS) in an Open-label Extension (OLE) Trial – Patel et al (Saturday, Dec. 1, Poster #1.298)
- Effect of SCN1A Mutation Type on Cannabidiol (CBD) Response in Patients with Dravet Syndrome: Subgroup Analysis of Phase 3 Trial – Zuberi et al (Saturday, Dec. 1, Poster #1.299)
- Long-Term Safety and Efficacy of Add-on Cannabidiol (CBD) Treatment in Patients with Dravet Syndrome (DS) in an Open-Label Extension (OLE) Trial (GWPCARE5) – Scheffer et al (Saturday, Dec. 1, Poster #1.470)

#### **Pharmacokinetic Data**

- A Phase 1 Single Ascending Dose, Multiple Dose, and Food Effect Trial in Healthy Volunteers – VanLandingham et al (Saturday, Dec. 1, Poster #1.300)

#### **Drug-drug interactions**

- A Phase 1 Investigation into the Potential Effects of Cannabidiol on CYP3A4 Mediated Drug Drug Interactions in Healthy Volunteers – Morrison et al (Saturday, Dec. 1, Poster #1.297)
- Exploration of the Potential for Plasma Protein Binding Displacement and Drug-Drug Interactions of Valproate in Combination with Cannabidiol – Tayo et al (Saturday, Dec. 1, Poster #1.453)

#### **Mechanism of action**

The Proposed Multimodal Mechanism of Action of Cannabidiol in Epilepsy: Modulation of Intracellular Calcium and Adenosine-Mediated Signaling – Nichol et al (Sunday, Dec. 2, Poster #2.462)

#### **Collaborator and expanded access program abstracts**

More than a dozen posters from the expanded access program and pre-clinical research collaborations will be presented during sessions on Saturday, Sunday and Monday.

#### **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 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](http://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 and is available by prescription in the U.S. 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<sup>®</sup> (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](http://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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