



## **GW Pharmaceuticals Announces Receipt of Notices of Allowance by the United States Patent and Trademark Office (USPTO) for Five New Epidiolex® (cannabidiol) Patents**

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LONDON and CARLSBAD, Calif., March 13, 2018 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq:GWPH) ("GW," "the Company" or "the Group"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, along with its U.S. subsidiary Greenwich Biosciences, today announced receipt of Notices of Allowance for five new Epidiolex® patent applications that will be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) if the NDA for Epidiolex is approved. Once issued, these patents are set to expire in 2035. One or more patents may be eligible for additional patent term through patent term adjustment and/or regulatory exclusivities.

"The allowance of these important patent applications confirms GW's innovative science and leadership in developing cannabinoid-based medicines and provides meaningful additional exclusivity for Epidiolex," stated Justin Gover, GW's Chief Executive Officer. "We have numerous additional patent applications under prosecution at the USPTO and will continue to work to expand our patent portfolio as we innovate and develop new Epidiolex formulations and additional products."

Exemplary claims from the allowed patent applications are as follows:

### **US 15/449,084**

A method of reducing seizure frequency in a patient suffering from a treatment-resistant childhood-onset epilepsy selected from Lennox-Gastaut syndrome or Dravet syndrome and who was previously treated with clobazam, comprising administering CBD and clobazam to the patient in need thereof, wherein the dose of clobazam used in combination with the CBD is reduced relative to the dose of clobazam administered to the patient prior to treatment with the CBD, wherein the CBD has a purity of at least 98 percent (w/w) CBD and comprises not more than 0.15 percent (w/w) THC.

### **US 15/449,124**

A method of reducing seizure frequency in a patient with a treatment-resistant epilepsy, which is Lennox-Gastaut syndrome, comprising administering to the patient in need thereof clobazam and CBD, wherein the purity of the CBD is at least 98 percent (w/w) CBD and comprises not more than 0.15 percent (w/w) THC, wherein the dose of the CBD is at least 10 mg/kg/day.

### **US 15/449,185**

A method of reducing seizure frequency in a patient with a treatment-resistant epilepsy, which is Dravet syndrome, comprising administering to the patient in need thereof clobazam and CBD, wherein the purity of the CBD is at least 98 percent (w/w) CBD and comprises not more than 0.15 percent (w/w) THC, wherein the dose of the CBD is at least 10 mg/kg/day.

### **US 15/449,204**

A method of reducing convulsive seizure frequency in a patient with a treatment-resistant epilepsy, which is Lennox-Gastaut syndrome, comprising administering to the patient in need thereof CBD, wherein the CBD has a purity of at least 98 percent (w/w) CBD and comprises not more than 0.15 percent (w/w) THC, wherein the dose of the CBD is at least 10 mg/kg/day.

### **US 15/449,177**

A method of reducing convulsive seizure frequency in a patient with a treatment-resistant epilepsy, which is Dravet syndrome, comprising administering to the patient in need thereof CBD, wherein the CBD has a purity of at least 98 percent (w/w) CBD and comprises not more than 0.15 percent (w/w) THC, wherein the dose of the CBD is at least 10 mg/kg/day.

GW has submitted regulatory applications in both the U.S. and Europe for Epidiolex in the treatment of seizures associated with Lennox-Gastaut Syndrome and Dravet syndrome, two rare, severe infantile-onset, drug-resistant epilepsy syndromes. The Food and Drug Administration (FDA) has set a PDUFA goal date of June 27, 2018. Epidiolex is expected to receive New Chemical Entity exclusivity and Orphan Drug exclusivity in the US. The FDA has granted Orphan Drug Designation for the use of Epidiolex for seizures associated with the following severe infantile-onset, drug-resistant epilepsy syndromes: Dravet syndrome, Lennox-Gastaut syndrome, 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-onset epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted regulatory applications in the U.S. and Europe for the adjunctive treatment of Lennox-Gastaut syndrome and Dravet syndrome. The Company continues to evaluate Epidiolex in additional rare 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 and for which the company is now planning a US 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 clinical trials, the timing, outcomes and protection 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.*

## Enquiries:

### GW Pharmaceuticals plc

Stephen Schultz, VP Investor Relations (U.S.)

917 280 2424 / 401 500 6570

## U.S. Media Enquiries:

### Sam Brown Inc. Healthcare Communications

Christy Curran

615 414 8668



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