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GW Pharmaceuticals Announces Epidiolex® Receives Orphan Drug Designation from the European Medicines Agency for the Treatment of Lennox-Gastaut Syndrome

LONDON, March 29, 2017 (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, today announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation to GW's investigational product Epidiolex® (cannabidiol or CBD) in the treatment of Lennox-Gastaut Syndrome (LGS), a treatment-resistant, debilitating childhood-onset epilepsy.

"Following two positive Phase 3 trials of Epidiolex in patients with LGS, GW is committed to pursuing registration of Epidiolex in Europe in order to provide these patients access to an approved prescription CBD medicine," stated Justin Gover, GW's Chief Executive Officer. "In addition to preparing to submit a New Drug Application with the U.S. Food and Drug Administration in the middle of 2017, we are also planning a submission to the EMA shortly afterwards."

In addition to this Orphan Drug Designation by the EMA in LGS, GW has also previously been granted Orphan Drug Designation by the EMA for Epidiolex in the treatment of Dravet syndrome. In the U.S., GW has received Orphan Drug Designation from the FDA for Epidiolex in the treatment of LGS, Dravet syndrome, Tuberous Sclerosis Complex, and Infantile Spasms, each of which are severe infantile-onset, drug-resistant epilepsy syndromes. Additionally, GW has received Fast Track Designation from the FDA for Epidiolex in the treatment of Dravet syndrome.

The EMA orphan drug designation is a status assigned to a medicine intended for use against a rare condition (prevalence of the condition in the European Union must not be more than 5 in 10,000) and allows a pharmaceutical company to benefit from incentives offered by the EU to develop a medicine for the treatment, prevention or diagnosis of a disease that is life threatening or a chronically debilitating rare disease.

About GW Pharmaceuticals plc

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 is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, 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 31 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 glioma, 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 the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products in development, the clinical benefits of Epidiolex® 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 of 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 5 December 2016. 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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