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GW Pharmaceuticals Reacquires Full Rights to Develop and Commercialize Sativex® in U.S.

- Previous License Agreement with Otsuka Terminated -

LONDON, Dec. 13, 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 announces the termination of its previous license agreement with Otsuka Pharmaceutical Co., Ltd. in relation to Sativex® (nabiximols) in the U.S. As a result, GW has now reacquired full ownership of the development and commercialization rights to the product in the U.S. market without making any upfront payment to Otsuka. GW has agreed to make contingent milestone payments to Otsuka, the first of which would become due upon FDA approval of Sativex and thereafter additional payments would become due upon the achievement of certain annual sales thresholds of Sativex in the United States.

"We are pleased to have amicably reached this agreement with Otsuka, which enables GW to develop, seek approval for, and commercialize Sativex in the United States," stated Justin Gover, GW's CEO. "We have previously conducted several positive Phase 2 and 3 trials for Sativex and believe that this product represents an important new late-stage pipeline opportunity for GW in the U.S. market."

Sativex is an oromucosal spray of a formulated extract that contains the principal cannabinoids cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC) in a 1:1 ratio. Sativex is currently approved in 29 countries outside the U.S. for the treatment of spasticity in patients with multiple sclerosis. GW and Otsuka originally signed a licensing agreement in 2007 under which GW granted Otsuka an exclusive license to develop and market Sativex in the U.S. The two companies conducted a clinical trials program in the treatment of cancer pain, in which the trials did not meet the primary endpoint.

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 glioblastoma, 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 Sativex® (nabiximols) and the safety profile and commercial potential of Sativex. 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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