GW Pharmaceuticals and U.S. Subsidiary Greenwich Biosciences to Present Data on Epidiolex® (cannabinoid oral solution) at the 2018 American Academy of Neurology Annual Meeting

April 12, 2018

Long-Term Safety and Efficacy Data in Patients with Lennox-Gastaut Syndrome and Dravet Syndrome to be Presented

LONDON, April 12, 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 that the Company will present data from the pivotal Phase 3 trials of Epidiolex® (cannabinoid oral solution) in Lennox-Gastaut syndrome (LGS) and Dravet syndrome, along with other supportive data, at the American Academy of Neurology (AAN) Annual Meeting, April 21-27, 2018, in Los Angeles, California.

Highlights of the data to be presented include:

- Long-term safety and efficacy data in patients with LGS and Dravet syndrome
- Safety and efficacy outcomes by time in Phase 3 LGS studies
- Exposure-response analysis in Phase 3 LGS studies
- Results from a study evaluating the abuse potential of purified cannabidiol oral solution
- Analyses of the direct cost burden associated with LGS and Dravet syndrome in the U.S.

“We look forward to sharing additional findings from our Epidiolex clinical program with the broader neurology community at AAN and expect that the significant continued flow of data should be supportive for neurologists as they grow their understanding of our medicine,” said Justin Gover, GW’s Chief Executive Officer. “With regulatory applications for Epidiolex accepted for review in both the U.S. and Europe, and an expected U.S. launch in the second half of this year, this is a very exciting time for our Company and those awaiting this new potential treatment option.”

Sunday, April 22, 2018
Poster Session P1
11:30 a.m. - 5:30 p.m. PT

- Poster 264: Long-term Safety and Efficacy of Cannabidiol Oral Solution in Patients with Lennox-Gastaut Syndrome (LGS): Results from Open-label Extension Trial (GWPCARE5)
- Poster 271: Exposure-Response Analysis of Cannabidiol Oral Solution for the Treatment of Lennox–Gastaut Syndrome
- Poster 266: A Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Abuse Potential of Purified Cannabidiol Oral Solution in Subjects with a History of Recreational Polydrug Use

Monday, April 23
Session S19: Epilepsy/Clinical Neurophysiology (EEG) II
3:30 p.m. - 5:30 p.m. PT

- Presentation 003 (3:54 p.m. - 4:06 p.m. PT): Maintenance of Long-Term Safety and Efficacy of Cannabidiol Oral Solution Treatment in Dravet Syndrome (DS): Results of the Open-Label Extension (OLE) Trial (GWPCARE 5)
- Presentation 006 (4:30 p.m. - 4:42 p.m. PT): Cannabidiol Oral Solution Treatment Effect and Adverse Events (AEs) by Time in Patients (Pts) with Lennox-Gastaut Syndrome (LGS): Pooled Results from 2 Trials

Monday, April 23
Poster Session P2
11:30 a.m. - 7:00 p.m. PT

- Poster 277: A Role of GPR55 in the Anti-Epileptic Properties of Cannabidiol

Friday, April 27
Poster Session P6
11:30 a.m. - 5:00 p.m. PT

- Poster 272: The Direct Cost Burden of Illness of Lennox-Gastaut Syndrome in the US
- Poster 290: The Direct Cost Burden of Illness of Dravet Syndrome in the US

Friday, April 27
Session SS3: Epilepsy/Clinical Neurophysiology (EEG) III
3:30 p.m. - 5:30 p.m. PT

- Presentation 004 (4:06 p.m. - 4:18 p.m. PT): Antiseizure Properties of Cannabidiol Oral Solution are Attenuated in the Absence of TRPV1 Receptors

About Epidiolex® (cannabinoid)
Epidiolex, GW’s lead cannabinoid product candidate is a pharmaceutical formulation of purified cannabidiol (CBD), which is in development for the treatment of...
several rare childhood-onset epilepsy disorders. GW has submitted a New Drug Application with the FDA for Epidiolex as adjunctive treatment for seizures associated with LGS and Dravet syndrome, which has been assigned a goal date of 27 June 2018 and, if approved, the medicine is expected to be available by prescription in the second half of 2018. GW has also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) with an expected decision date in early 2019. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex for the treatment of Dravet syndrome, LGS, TSC and IS. Additionally, GW has received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare pediatric disease designation by FDA. The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for the treatment of LGS, Dravet syndrome, West syndrome and TSC. GW is currently evaluating additional clinical development programs in other orphan seizure disorders including Phase 3 trials in 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.

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 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.

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