GW Pharmaceuticals plc and Its U.S. Subsidiary Greenwich Biosciences, Inc. Announce That EPIDIOLEX® (cannabidiol) Oral Solution Has Been Descheduled And Is No Longer A Controlled Substance

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- Descheduling will enable prescribing free of the previous Schedule V requirements -

CARLSBAD, Calif., April 06, 2020 (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 platform, along with its U.S. subsidiary Greenwich Biosciences, Inc., announced today that it has received notification from the United States Drug Enforcement Administration (DEA) confirming that EPIDIOLEX® (cannabidiol) is no longer subject to the Controlled Substances Act (CSA). This change takes effect immediately.

"This notification from DEA fully establishes that EPIDIOLEX, the only CBD medicine approved by FDA, is no longer a controlled substance under the federal Controlled Substances Act," said Justin Gover, GW's Chief Executive Officer. "We would like to thank DEA for confirming the non-controlled status of this medicine. Importantly, the descheduling of EPIDIOLEX has the potential to further ease patient access to this important therapy for patients living with Lennox-Gastaut Syndrome and Dravet syndrome, two of the most debilitating forms of epilepsy."

EPIDIOLEX, which was launched in the United States on November 1, 2018 after approval by FDA for the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) or Dravet syndrome in patients two years of age or older, is the first prescription pharmaceutical formulation of highly purified, plant-derived cannabidiol (CBD), and the first in a new category of anti-epileptic drugs.

Following FDA approval, EPIDIOLEX was initially placed in Schedule V of the CSA. Following receipt of this DEA notification, GW has filed a post-approval supplement with FDA to remove Schedule V designation from EPIDIOLEX.

DEA's letter means that all federal controlled-substance restrictions have been removed for EPIDIOLEX. The Company will now begin the process of implementing these changes at the state level and through the EPIDIOLEX distribution network. Once this process is completed in each state, prescriptions for EPIDIOLEX, like other non-controlled medicines, will be valid for one year and can be easily transferred between pharmacies. The descheduling of EPIDIOLEX also enables physicians to prescribe this breakthrough medicine free of the requirements of state prescription drug monitoring programs.

The most common adverse reactions that occurred in EPIDIOLEX-treated patients were somnolence, decreased appetite, diarrhea, transaminase elevations, fatigue, malaise, and asthenia, rash, insomnia, sleep disorder and poor-quality sleep, and infections. The medicine is marketed in the United States by Greenwich Biosciences, the U.S. subsidiary of GW Pharmaceuticals plc. More information, including the product label, can be found at Epidiolex.com.

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. The Company's lead product, EPIDIOLEX ® (cannabidiol) oral solution, is commercialized in the U.S. by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. This product has received approval in the European Union under the tradename EPIDYOLEX®. The Company has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to expand the indication for Epidiolex to include seizures associated with Tuberous Sclerosis Complex (TSC), for which it has reported positive Phase 3 data, and is carrying out a Phase 3 trial in Rett syndrome. The Company has a deep pipeline of additional cannabinoid product candidates, in particular nabiximols, for which the Company is advancing multiple late-stage clinical programs in order to seek FDA approval in the treatment of spasticity associated with multiple sclerosis and spinal cord injury, as well as for the treatment of PTSD. The Company has additional cannabinoid product candidates in Phase 2 trials for autism and schizophrenia. For further information, please visit www.gwpharm.com.

About EPIDIOLEX® (cannabidiol) oral solution

EPIDIOLEX® (cannabidiol) oral solution, a pharmaceutical formulation of highly purified cannabidiol (CBD), is the first in a new class of anti-epileptic medications with a novel mechanism of action, and the first prescription, plant-derived cannabis-based medicine approved by the U.S. Food and Drug Administration (FDA). In the U.S., Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. A supplemental New Drug Application (sNDA) has been submitted to the FDA for the treatment of seizures associated with tuberous sclerosis complex (TSC). Epidiolex has received approval in the European Union under the tradename EPIDYOLEX® for adjunctive use in conjunction with clobazam to treat seizures associated with LGS and Dravet syndrome. Epidiolex/Epidyolex has received Orphan Drug Designation from the FDA and the EMA for the treatment of seizures associated with Dravet syndrome, LGS and TSC, each of which are severe childhood-onset, drug-resistant syndromes.

Forward-looking statements

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the timing and outcomes of regulatory decisions. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from

those projected herein and depend on a number of factors, including the risks and uncertainties which can be found in GW's filings with the U.S. Securities and Exchange Commission. 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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