GW Pharmaceuticals and Greenwich Biosciences Submit Supplemental New Drug Application to U.S. FDA for Epidiolex® (cannabidiol) for the Treatment of Tuberous Sclerosis Complex

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LONDON and CARLSBAD, Calif., Feb. 03, 2020 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the science, development, and commercialization of cannabinoid prescription medicines, along with its U.S. subsidiary Greenwich Biosciences, Inc., announced today that it has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for Epidiolex® (cannabidiol) oral solution, CV. The sNDA seeks to expand the Epidiolex label to include the treatment of seizures associated with Tuberous Sclerosis Complex (TSC), a rare genetic condition. Epidiolex is currently approved in the U.S. to treat seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome and has been granted Orphan Drug Designation from the FDA for the treatment of TSC.

"The submission of this sNDA for Epidiolex is an important step towards the prospect of offering a new treatment option for those patients with TSC who battle difficult-to-treat seizures," said CEO, Justin Gover. "Having already obtained approval for Epdiolex in the treatment of seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome, this submission is based on positive Phase 3 data showing that Epidiolex reduced TSC-associated seizures, which include both focal and generalized seizures types. We look forward to working with the FDA toward an expected approval later this year."

TSC is a condition that causes mostly benign tumors to grow in vital organs of the body including the brain, skin, heart, eyes, kidneys and lungs[1] and is a leading cause of genetic epilepsy.[2] TSC is typically diagnosed in childhood. More than 60% of individuals with TSC do not achieve seizure control[4] with standard treatments.

The sNDA is supported by data from a Phase 3 safety and efficacy study, results of which were recently presented at the American Epilepsy Society 2019 annual meeting. The study met its primary endpoint with patients treated with Epidiolex 25 mg/kg/day experiencing a significantly greater reduction from baseline in TSC-associated seizures compared to placebo (49% vs 27%; p=0.0009). Results for the 50 mg/kg/day dose group were similar, with seizure reductions of 48% from baseline vs 26.5% for placebo (p=0.0018). All key secondary endpoints were supportive of the effects on the primary endpoint. The safety profile observed was consistent with findings from previous studies, with no new safety risks identified.

About Tuberous Sclerosis Complex (TSC)
Tuberous sclerosis complex (TSC) is a rare genetic condition that affects approximately 40-80 thousand individuals in the U.S. and nearly one million people worldwide.[3] At least two children born each day will develop TSC, with an estimated prevalence of one in 6,000 newborns.[5] The condition causes mostly benign tumors to grow in vital organs of the body including the brain, skin, heart, eyes, kidneys and lungs[4] and is a leading cause of genetic epilepsy.[5] TSC often occurs in the first year of life with patients suffering from either focal seizures or infantile spasms[1] and is associated with an increased risk of autism and intellectual disability.[6] The severity of the condition can vary widely. In some children the disease is very mild, while others may experience life-threatening complications.[6]

Seizures are present in about 85% of patients with TSC.[1,2,3] More than 60% of individuals with TSC do not achieve seizure control[4] with standard treatments such as antiepileptic drugs, epilepsy surgery, ketogenic diet, or vagus nerve stimulation[2] compared to 30-40% of individuals with epilepsy who do not have TSC who are drug resistant.[7,8]

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, CV, 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, CV

EPIDIOLEX® (cannabidiol) oral solution, CV, 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.

Important Safety Information
Important safety information for Epidiolex is available at Epidiolex.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®/EPIDYOLEX® (cannabidiol) oral solution CV and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines. 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 EPIDIOLEX®/EPIDYOLEX®, Sativex® 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. 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
Mike Beyer 312 961 2502

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[2] TS Alliance Website. https://www.tsalliance.org/. Accessed November 19, 2019.
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