GW Pharmaceuticals receives positive CHMP opinion for EPIDYOLEX® (cannabidiol) for use as treatment of seizures associated with Tuberous Sclerosis Complex

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– If approved by the European Commission (EC), the label for EPIDYOLEX® will expand to include a third indication in Europe –

LONDON, Feb. 26, 2021 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH) ("GW", "the Company" or "the Group"), a world leader in discovering, developing and delivering regulatory approved cannabis-based medicines, today announces that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion on the Company's Type II variation application for EPIDYOLEX® (cannabidiol) as an adjunctive treatment of seizures associated with Tuberous Sclerosis Complex (TSC), for patients two years of age and older.

TSC is a condition that causes mostly benign tumours to grow in vital organs of the body, including the brain, skin, heart, eyes, kidneys and lungs, and in which epilepsy is the most common neurological feature. TSC is typically diagnosed in childhood.[1]

"Epilepsy is reported in more than 90% of individuals with Tuberous Sclerosis Complex (TSC), and over 60% of those with seizures associated with TSC do not respond to standard anti-epileptic medicines.[2,3] Today's positive CHMP opinion brings us one step closer to a potentially life-improving new treatment option for these patients for whom EPIDYOLEX may be appropriate," said Justin Gover, GW's Chief Executive Officer. "This decision represents another important step for GW as we look to expand the medicine's label in Europe. If approved, this represents the third licensed indication for GW's medicine, broadening patient access to this rigorously tested cannabis-based medicine."

Professor Helen Cross, Honorary Consultant in Paediatric Neurology at Great Ormond Street Hospital for Children NHS Foundation Trust, said, "This debilitating disease affects tens of thousands of patients in Europe, many of whom may benefit from alternative treatment options to achieve adequate seizure control. This decision, and the clinical data supporting the use of EPIDYOLEX in this challenging condition, offers real hope to the patients, their parents and physicians that battle this condition and the seizures it brings every day."

Carla Fladrowski and Micaela Rozenberg, Co-Chairs of the European Tuberous Sclerosis Complex Association, added, "The lives of individuals with TSC and their families are seriously impacted by drug-resistant epilepsy; TSC Associations together are therefore resolute in their search for successful therapies to help manage a condition that is so difficult to control. We are extremely hopeful of the potential benefits that this desperately needed new treatment option could bring to our community, including the positive impact it could have not only on quality of life but also the burden of the disease itself."

The CHMP's positive opinion is based on data from a positive Phase 3 safety and efficacy study evaluating 25 mg/kg/day of GW's cannabidiol (oral solution). The study met its primary endpoint, which was the reduction in seizure frequency compared to baseline of cannabidiol vs placebo, with seizure reduction of 49% in patients taking cannabidiol 25 mg/kg/day compared with 24% for placebo (p=0.0009). 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.

Dr. Volker Knappertz, GW's Chief Medical Officer, said, "We are delighted to have been able to demonstrate the potential EPIDYOLEX has in treating seizures associated with TSC through this regulatory review and in our conversations with the CHMP. We now look forward to working with the European Commission to gain approval for this label expansion to broaden access to this medicine across the thousands of European patients who need new treatment options."

The CHMP's recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for use in the 27 countries of the European Union (EU) alongside Norway, Iceland and Liechtenstein. The EC is expected to make a final decision on the Type II Variation Application in approximately two months.

GW's cannabidiol (oral solution) was originally approved by the EMA and received marketing authorisation in September 2019 under the trade name EPIDYOLEX® as an adjunctive therapy for seizures associated with Lennox-Gastaut Syndrome (LGS) or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older.

ADDITIONAL INFORMATION

About GW Pharmaceuticals plc
GW Pharmaceuticals (GW), and U.S. subsidiary Greenwich Biosciences, is a UK-based global biopharmaceutical company that has established a world-leading position in cannabinoid science and medicine. Founded over two decades ago in response to significant unmet patient need, patients remain our key focus and improving their quality of life, our motivation. GW's pioneering work has led to the regulatory approval of world first, potentially life improving, cannabis-based medicines. Our continued dedication has resulted in the treatment of thousands of patients with our medicines around the world. For further information, please visit www.gwpharm.co.uk

About EPIDIOLEX®/EPIDYOLEX® (cannabidiol)
EPIDIOLEX®/EPIDYOLEX® (cannabidiol), the first prescription, plant-derived cannabis-based medicine approved by the U.S. Food and Drug Administration (FDA) for use in the U.S. and the European Commission (EC) for use in Europe, is an oral solution which contains highly purified cannabidiol (CBD). In the U.S., EPIDIOLEX® is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome or Tuberous Sclerosis Complex (TSC) in patients one year of age and older. 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 in patients two years and older. In September 2020, EPIDYOLEX® was approved by the Australian Therapeutic Goods Administration (TGA) for use in Australia for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older. EPIDYOLEX® has received Orphan Drug Designation from the European Medicines Agency (EMA) for the treatment of seizures associated TSC.

About Tuberous Sclerosis Complex (TSC)

Tuberous Sclerosis Complex (TSC) is a rare genetic condition that has an estimated prevalence in the EU of 10 in 100,000.[4] The condition causes mostly benign tumours to grow in vital organs of the body including the brain, skin, heart, eyes, kidneys and lungs and is a leading cause of genetic epilepsy.[1,5] TSC often occurs in the first year of life with patients suffering from either focal seizures or infantile spasms. It is associated with an increased risk of autism and intellectual disability.[1] The severity of the condition can vary widely. In some children the disease is very mild, while others may experience life-threatening complications.[6]

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