



## **GW Pharmaceuticals receives European Commission approval for EPIDYOLEX® (cannabidiol) for the treatment of seizures associated with tuberous sclerosis complex**

April 20, 2021

*– Tuberous sclerosis complex (TSC) represents a third indication for GW's cannabidiol in Europe –*

*– TSC causes epilepsy in up to 85% of patients, and up to 60% of those patients do not respond to standard anti-epileptic medicines<sup>1,2,3</sup> –*

LONDON, April 20, 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 Commission (EC) has approved the Type II variation application for EPIDYOLEX® (cannabidiol) as an adjunctive treatment of seizures associated with TSC, for patients two years of age and older. This approval, which represents the third indication for GW's cannabidiol in Europe, paves the way for the expanded launch of the medicine across Europe.

"This is an exciting moment for patients, and their families, who are affected by this debilitating disease and may benefit from this treatment. This approval is the result of the continued dedication of GW and the physician and patient communities to address this serious unmet medical need," said Justin Gover, GW's Chief Executive Officer. "We now look forward to working with each European member state to make EPIDYOLEX® available to appropriate patients across Europe, as quickly as possible."

Dr. Volker Knappertz, GW's Chief Medical Officer, said, "We are excited by the news of this approval by the European Commission and the benefits EPIDYOLEX could bring to the community. The clinical data supporting EPIDYOLEX in TSC provides hope of a better quality of life for patients. This medicine provides more choice for physicians managing seizures associated with TSC and has the potential to benefit the thousands of patients who do not respond to the current standard of care."

Professor Alexis Arzimanoglou, Coordinator of the European Reference Network for Rare and Complex Epilepsies ERN EpiCARE (University Hospitals of Lyon, France), added, "Those suffering from TSC and those involved in their care will welcome this European approval. Given the demonstrated efficacy and safety profile of EPIDYOLEX, this important development could offer a much-needed treatment option to those most in need."

The approval is based on data from a positive Phase 3 safety and efficacy study evaluating 25 mg/kg/day of GW's cannabidiol. 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 27% 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.

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.<sup>4</sup>

GW's cannabidiol was originally approved by the European Medicines Agency (EMA) in September 2019 under the tradename 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.

The EC decision is valid in all 27 countries of the European Union, alongside Norway, Iceland and Liechtenstein.

### **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](http://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, and for adjunctive use to treat seizures associated with TSC, 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 LGS, Dravet syndrome, and Tuberous Sclerosis Complex (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.<sup>5</sup> 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.<sup>4,5</sup> The onset of epilepsy in TSC often occurs in the first year of life with patients initially suffering from predominantly focal seizures or infantile spasms. It is associated with an increased risk of autism and intellectual disability.<sup>1</sup> The severity of the condition can vary widely. In some children the disease is very mild, while others may experience life-threatening complications.<sup>6,7</sup>

#### **Enquiries**

All investor and media enquiries [publicrelations@gwpharm.com](mailto:publicrelations@gwpharm.com)

#### **GW Pharmaceuticals plc**

Scott Giacobello, Chief Financial Officer +1 760 795 2200

#### **UK, EU and ex-U.S. media enquiries**

FTI Consulting  
Michael Trace / Ben Atwell +44 (0)203 727 1000

#### **U.S. media enquiries**

Kristen Cardillo, Corporate Communications +1 760 579 6628

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