# GW Pharmaceuticals receives positive NICE recommendation for EPIDYOLEX® (cannabidiol) oral solution for the treatment of seizures in patients with two rare, severe forms of childhood-onset epilepsy

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*GW also welcomes the positive guideline recommendation for Sativex® (nabiximols) for the treatment of spasticity due to multiple sclerosis as part of NICE's evaluation of cannabis-based medicinal products (CBMPs)*

*Cannabidiol oral solution and nabiximols are the first and only plant-derived cannabis-based medicines to be routinely reimbursed on the NHS*

LONDON and CARLSBAD, Calif., Nov. 10, 2019 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH) ("GW", "the Company" or "the Group"), world leader in discovering, developing and commercialising cannabinoid prescription medicines, today announces that two of its medicines, EPIDYOLEX (cannabidiol) oral solution and Sativex (nabiximols), have been recommended by the UK's National Institute for Health and Care Excellence (NICE) to receive routine reimbursement from NHS England.

This represents the first-time any plant-derived cannabis-based medicine has been recommended by NICE for use on the NHS. Cannabidiol oral solution is recommended 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. Nabiximols, reviewed as part of NICE's evaluation of cannabis-based medicinal products (CBMPs), has been considered cost effective for the treatment of spasticity due to multiple sclerosis.

"This is a momentous occasion for UK patients and families who have waited for so many years for rigorously tested, evidenced and regulatory approved cannabis-based medicines to be reimbursed by the NHS," said Chris Tovey, GW's Chief Operating Officer. "This is proof that cannabis-based medicines can successfully go through extensive randomised placebo-controlled trials and a rigorous NICE evaluation process to reach patients. I am hugely proud of the entire GW team for achieving this milestone in the country where the company was founded and where both of these medicines were developed and are manufactured."

Commenting on the NICE recommendation for cannabidiol oral solution, Dr Rhys Thomas, Consultant Neurologist at the Royal Victoria Hospital in Newcastle, said: "This is a significant moment for adults and children with the most difficult to treat epilepsies. NICE's recommendation of cannabidiol oral solution follows a period of great anticipation and enthusiasm for patients and their clinicians. The European Medicines Agency (EMA) licence and availability through the NHS is welcome as we badly need additional effective treatments for Dravet and Lennox Gastaut syndromes."

"We welcome the addition of cannabidiol oral solution as a new medicine to add to the Dravet syndrome treatment armamentarium. Dravet syndrome is a devastating condition and having a new treatment option offers potential new hope to patients and their families searching for better seizure control," said Galia Wilson, Chair, Dravet Syndrome UK. "Many families come to us asking about the potential of cannabis-based medicines, particularly cannabidiol (CBD), and we are thrilled that one is now available on the NHS."

When added to other anti-epileptic therapies, GW's cannabidiol oral solution significantly reduced the frequency of seizures in patients with LGS and Dravet syndrome. The most common adverse reactions that occurred in patients treated with the medicine were somnolence, decreased appetite, diarrhoea, pyrexia, fatigue and vomiting. GW's development programme represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with refractory epilepsy.

GW's cannabidiol oral solution was approved by the EMA and received marketing authorisation in September 2019 under the trade name EPIDYOLEX as an adjunctive therapy for seizures associated with LGS or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older. Following this approval, GW has been working with the relevant bodies in the UK, Germany, Spain, France and Italy to secure reimbursement ahead of the anticipated launch of the medicine in these countries.

The inclusion of nabiximols in NICE guidelines comes as part of the comprehensive evaluation of the clinical and cost-effectiveness of CBMPs. Nabiximols has been approved by medicines regulators in more than 25 countries around the world. Nabiximols was approved in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2010 and is marketed in the UK by GW's commercial partner, Bayer.

**About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.**
Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercialising novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW's lead product, EPIDIOLEX (cannabidiol oral solution) is commercialised in the US 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 Europe under the tradename EPIDYOLEX. The Company continues to evaluate EPIDIOLEX in additional rare conditions including Tuberous Sclerosis Complex (TSC) and Rett syndrome. GW commercialised the world's first plant-derived cannabinoid prescription medicine, 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 advancing a late stage programme in order to seek FDA approval. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, autism, glioblastoma, and schizophrenia. For further information, please visit www.gwpharm.com.

**About EPIDIOLEX®/EPIDYOLEX® (cannabidiol) oral solution**
EPIDIOLEX®/EPIDYOLEX® (cannabidiol), the first prescription, plant-derived cannabis-based medicine approved by the FDA for use in the U.S., is an oral solution which contains highly purified cannabidiol (CBD). The medicine is for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older and is the first in a new class of anti-epileptic medications with a novel

mechanism of action. EPIDYOLEX received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in July 2019 and the European Commission (EC) granted the marketing authorisation on 23 September 2019 for adjunctive use in conjunction with clobazam. The medicine was granted an Orphan Drug Designation from the EMA for the treatment of seizures associated with LGS, Dravet syndrome, and Tuberous Sclerosis Complex (TSC).

**About Sativex® (nabiximols)**
Sativex® (nabiximols), the first cannabinoid medicine derived from the cannabis plant, is an oromucosal spray which contains a complex mixture of cannabinoids, including delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) and specific minor cannabinoids and other non-cannabinoid components. Nabiximols is approved in over 25 countries around the world for the treatment of spasticity due to multiple sclerosis (MS) in people who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Nabiximols is currently licensed to Almirall in Europe (excluding the UK), to Bayer in the UK and Canada, Neopharm in Israel, IDS Medical in UAE, Al-Mojil in Kuwait, Ipsen in Latin America (excluding Mexico and Islands of Caribbean), and Emerge Healthcare in New Zealand and Australia.

**About Dravet syndrome**
Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the sodium channel gene *SCN1A*. Onset of Dravet syndrome typically occurs during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often body temperature related, severe, and long-lasting. Over time, patients with Dravet syndrome often develop multiple types of seizures, including tonic-clonic, myoclonic and atypical absences and are prone to bouts of prolonged seizures including status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden unexpected death in epilepsy) is elevated in patients with Dravet syndrome. Additionally, the majority of patients will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care.

**About Lennox-Gastaut syndrome (LGS)**
The onset of LGS typically occurs between the ages of 3 to 5 years and can be caused by a number of conditions, including brain malformations, severe head injuries, central nervous system infections and genetic neuro-degenerative or metabolic conditions. In up to 30 percent of patients, no cause can be found. Patients with LGS commonly have multiple seizure types including drop and convulsive seizures, which frequently lead to falls and injuries, and non-convulsive seizures. Resistance to anti-epileptic drugs (AEDs) is common in patients with LGS. Most patients with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviours.

**About Multiple Sclerosis (MS)**
Multiple sclerosis (MS) is a chronic neurological condition characterized by progressive and disabling loss of motor and sensory nervous system functions. In Europe, the prevalence rate of MS is estimated to be 83 per 100,000 and is most commonly diagnosed between the ages of 20 and 40, although it can affect younger and older people too. In the UK, it affects around 100,000 people. Spasticity related to MS is an involuntary increase in muscle tone affecting more than 80% of MS patients across their disease evolution, and being moderate or severe in one third of them despite physiotherapy and first line drug treatments. The burden of spasticity grows as the MS evolves. When the muscle is moved externally, there is more resistance to this movement than there normally would be and the muscle feels stiff or rigid. Increased muscle tone also means that muscles are slow to relax, and this causes stiffness. Spasticity, beyond the continuous stiffness, may also cause muscles to jerk suddenly in an uncontrolled way.

**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 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.*


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