GW Pharmaceuticals announces that EPIDYOLEX® (cannabidiol) has been reclassified by the UK Home Office as a Schedule 5 drug

June 23, 2020

GW's cannabis-based medicine rescheduled following approval by the European Medicines Agency (EMA) and an independent assessment by the Advisory Council on the Misuse of Drugs (ACMD)

Burden on patients, their families and healthcare professionals eased due to the reduction in controlled drug requirements

LONDON, June 24, 2020 (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 UK Home Office has reclassified EPIDYOLEX (cannabidiol) as a Schedule 5 drug. This change will take effect immediately in all four of the constituent nations of the UK – with Northern Ireland enacting separate legislation[1] – and sees the medicine move from Schedule 2 to Schedule 5 under the Misuse of Drugs Regulations 2001.

"The decision to move EPIDYOLEX to a low level of control is an important one for patients, their families, healthcare professionals, pharmacists and the NHS as a whole – reducing costs and ensuring the medicine can be dispensed more easily," said Chris Tovey, GW's Chief Operating Officer. "The extensive pre-clinical and clinical data that GW developed to support the medicine's approval by regulatory authorities was pivotal to this important schedule change, and we would like to thank the MHRA, ACMD and Home Office for scrutinising this data and making this change in such a short timeframe. We remain committed to expanding the high-quality evidence base for cannabis-based medicines and securing further regulatory approvals because doing so is in the interests of patients and healthcare professionals and can support further rescheduling."

The ACMD and its Technical Committee recommended the schedule change to Kit Malthouse MP, Minister of State for Crime and Policing, on 29 January 2020. This followed the submission of a written dossier and oral presentation from the MHRA, which drew on the substantial data package developed by GW as part of the medicine's review and subsequent approval by the regulatory authorities in September 2019. The medicine is approved in the EU for adjunctive therapy of seizures associated with Lennox Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, for patients from 2 years of age and older.

In its recommendation to the Minister, the ACMD cited the "low risk of abuse potential, low risk of dependency and low risk of diversion" as reasons for the reclassification from a schedule 2 controlled drug to a schedule 5 controlled drug.[2] The ACMD also cautioned that GW's medicine is "distinct from other commercially available CBD containing supplements that have not sought marketing authorisation as a medicine" and that the schedule change therefore applies exclusively to EPIDYOLEX.

The recommendation was accepted by the Minister on 22 April 2020 and secondary legislation was tabled to enact the change on 3 June 2020.[3] GW's medicine is now exempt from virtually all controlled drug requirements.[4] Patients and their families will now have greater flexibility on the quantity of medicine they can receive and be able to benefit from repeat prescriptions, thereby potentially reducing travel to hospital pharmacies, whilst healthcare professionals and pharmacists will benefit from reduced controls around the storage and reporting requirements that exist for medicines under Schedule 2.

1. HM Government, The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2020, Statutory Rules of Northern Ireland, 2020 No.104, http://www.legislation.gov.uk/nisr/2020/104/introduction/made
2. Advisory Council on the Misuse of Drugs, Advice on Epidyolex (2020), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/861607/ACMD_advice_Epidyolex.pdf
3. Kit Malthouse, Letter responding to the ACMD on Epidyolex scheduling and definition under the Misuse of Drugs Regulations 2001 (2020), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/882901/Epidyolex_scheduling_and_definition_under_the_Misuse_of_Drugs_Regulations_2001.pdf
4. National Institute for Health and Care Excellence, British National Formulary. Controlled drugs and dependence, Regulations and classification (2020), https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html

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 medicines. 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 changing, cannabis-based medicines. Our continued dedication has resulted in the treatment of thousands of patients with our medicines in the UK and 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 Medicines Agency's (EMA) for use in Europe, is an oral solution which contains highly purified cannabidiol (CBD). The medicine received approval in Europe in September 2019 for the adjunctive treatment of seizures associated with

Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older in conjunction with clobazam. GW's cannabidiol has received Orphan Drug Designation from the FDA and the EMA for the treatment of seizures associated with Dravet syndrome and LGS, both of which are severe childhood-onset, drug-resistant syndromes.

Enquiries

All investor and media enquiries	publicrelations@gwpharm.com

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

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

Investor Relations

Stephen Schultz, VP Investor Relations, GW	+1 917 280 2424 / +1 401 500 6570

U.S. media enquiries

Sam Brown Inc Healthcare Communications	
Christy Curran	+1 615 414 8668
Mike Beyer	+1 312 961 2502