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Press Release

Hikma launches Clobazam Oral Suspension and Clobazam Tablets

London, 10 December 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) announces that Hikma Pharmaceuticals USA Inc., formerly known as West-Ward Pharmaceuticals Corp., has launched Clobazam Oral Suspension, 2.5mg/mL, and Clobazam Tablets, 10mg and 20mg, the generic equivalent to Onfi®.[1]

Hikma's Clobazam is a benzodiazepine indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.

According to IQVIA, US sales of Clobazam Oral Suspension were approximately $260 million and of Clobazam Tablets were approximately $601 million in the 12 months ending September 2018.

Brian Hoffmann, President, Generics Division, said, "We are very excited to add Clobazam Oral Suspension and Clobazam Tablets to our product portfolio. This will be among the first generics available on the market and we are pleased to improve patients' access to this important medicine."

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[1] Onfi® is a registered trademark of Lundbeck Inc.

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About Hikma

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We're a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner in the MENA region, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit www.hikma.com.

Important Safety Information for Clobazam Oral Suspension and Clobazam Tablets:

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

See Clobazam Oral Suspension full Prescribing Information and Clobazam Tablets full Prescribing Information for complete boxed warning.

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma and death.

- **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

Contraindication: Hypersensitivity
Clobazam is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.

Risks from Concomitant Use with Opioids (see Boxed Warning)
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe clobazam concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use and follow patients closely for signs and symptoms of respiratory depression and sedation. Advise both patients and caregivers about the risks of respiratory depression and sedation when clobazam is used with opioids.

Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants
Clobazam has a CNS depressant effect. Caution patients and their caregivers against simultaneous use with other CNS depressant drugs or alcohol and that the effects of other CNS depressant drugs or alcohol may be potentiated.

Somnolence or Sedation
Clobazam causes somnolence and sedation. In clinical trials, somnolence or sedation was reported at all effective doses and was dose-related. In general, somnolence and sedation begin within the first month of treatment and may diminish with continued treatment. Monitor patients for somnolence and sedation, particularly with concomitant

use of other CNS depressants. Caution patients against engaging in hazardous activities that require mental alertness, such as operating dangerous machinery or motor vehicles, until the effect of clobazam is known.

Withdrawal Symptoms
Abrupt discontinuation of clobazam should be avoided. As with all antiepileptic drugs (AEDs), withdraw clobazam gradually to minimize the risk of precipitating seizures, seizure exacerbation or status epilepticus. Withdrawal symptoms (e.g., convulsions, psychosis, hallucinations, behavioral disorder, tremor and anxiety) occurred following abrupt discontinuation of clobazam; the risk of withdrawal symptoms is greater with higher doses. The more severe withdrawal symptoms have usually been limited to patients who received excessive doses over an extended period of time, followed by an abrupt discontinuation used over an extended period of time. Generally milder withdrawal symptoms (e.g., dysphoria, anxiety and insomnia) have been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic doses for several months.

Serious Dermatological Reactions
Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam in both children and adults during the post-marketing period. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the first 8 weeks of treatment initiation or when re-introducing therapy. Discontinue clobazam at the first sign of rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

Physical and Psychological Dependence
Carefully monitor patients with a history of substance abuse when receiving clobazam or other psychotropic agents because of the predisposition of such patients to habituation and dependence. In clinical trials, cases of dependency were reported following abrupt discontinuation of clobazam. The risk of dependence increases with increasing dose and duration of treatment.

Suicidal Behavior and Ideation
AEDs, including clobazam, increase the risk of suicidal thoughts or behavior in patients. Inform patients, their caregivers and families of the risk and advise them to monitor and report any emergence or worsening of depression, any unusual changes in mood or behavior or the emergence of suicidal thoughts, behavior or thoughts of self-harm. If these symptoms occur, consider whether it may be related to the AED or illness, because epilepsy itself can increase these risks.

Pregnancy, Registry and Nursing Mothers
Based on animal data, clobazam may cause fetal harm and should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. Advise a pregnant woman and women of childbearing age of the potential risk to a fetus.

- Encourage patients to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit http://www.aedpregnancyregistry.org/.
- Clobazam is excreted in human milk. Instruct patients to notify their physician if they are breast feeding or intend to breast feed during therapy and counsel nursing mothers to observe their infants for lethargy, poor sucking and somnolence. Because of the potential for serious adverse reactions in nursing infants from clobazam, advise patients to discontinue nursing or discontinue the drug.

Adverse Reactions
The most commonly observed adverse reactions reported in an LGS randomized, double-blind, placebo-controlled, parallel group clinical trial of patients who received clobazam as adjunctive therapy (≥10% in any treatment group and at least 5% greater than placebo, respectively) were somnolence or sedation (32% vs. 15%), somnolence (25% vs. 12%), pyrexia (17% vs. 3%), lethargy (15% vs. 5%), aggression (14% vs. 5%), drooling (14% vs. 3%), irritability (11% vs. 5%), ataxia (10% vs. 3%) and constipation (10% vs. 0%).

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Overdosage
Overdose and intoxication with benzodiazepines may lead to CNS depression, associated with drowsiness, confusion and lethargy, possibly progressing to ataxia, respiratory depression, hypotension, and, rarely, coma or death. The risk of a fatal outcome is increased in cases of combined poisoning with other CNS depressants, including opioids and alcohol.

For more information, please see Clobazam Oral Suspension full Prescribing Information and Clobazam Tablets full Prescribing Information for complete boxed warning, including Boxed Warning, regarding risks from concomitant use with opioids; the Medication Guide and the Instructions for Use.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch, or call 1-800-FDA-1088.

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