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Press Release

Hikma launches Dalfampridine Extended-release Tablets

London, 19 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 Dalfampridine Extended-release Tablets, 10 mg, the generic therapeutic equivalent to Ampyra®.[1] Dalfampridine Extended-release Tablets are indicated to help improve walking in adult patients with multiple sclerosis as demonstrated by an increase in walking speed.

In September 2018, the United States Court of Appeals for the Federal Circuit upheld the United States District Court for the District of Delaware's decision to invalidate all remaining Ampyra® patents. Hikma was one of the first ANDA applicants to submit an ANDA with a Paragraph IV certification challenging the validity of patents listed for Ampyra® tablets, 10 mg, and therefore is eligible for 180 days of generic drug exclusivity. Of the 10 first-filers, Hikma was one of two generic manufacturers who did not settle with Acorda Therapeutics.

In its 2017 annual report, Acorda Therapeutics reported that US sales of Ampyra® were approximately $543 million in 2017, 10 percent higher than 2016.

Brian Hoffmann, President, Generics Division, said, "We are very pleased to be launching Dalfampridine Extended-release Tablets, a life-enhancing medicine for people with multiple sclerosis. This product highlights our ability to successfully litigate patent-protected Paragraph IV products, improving patient access to high-quality, affordable medicines."

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Enquiries

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[1] Ampyra® is a registered trademark of Acorda Therapeutics, 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.

Indication for Dalfampridine Extended-release Tablets, 10 mg

Dalfampridine Extended-release Tablets are indicated to improve walking in adults with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Important Safety Information for Dalfampridine Extended-release Tablets, 10 mg

IMPORTANT SAFETY INFORMATION

- Dalfampridine Extended-release Tablets are contraindicated in patients with history of seizure, moderate or severe renal impairment (creatinine clearance [CrCl] ≤50 mL/min) or history of hypersensitivity to dalfampridine or 4-aminopyridine.
- Dalfampridine can cause seizures. The risk of seizures increases with increasing doses. Permanently discontinue dalfampridine if seizure occurs. In the post-marketing period seizures have been reported. The majority of seizures occurred at the recommended dose and in patients without a history of seizures, and generally within days to weeks of starting therapy.
- Dalfampridine has not been evaluated in patients with history of seizures or with evidence of epileptiform activity on an electroencephalogram (EEG), as these patients were excluded from clinical trials. The risk of seizures in patients with epileptiform activity on an EEG is unknown, and could be substantially higher than that observed in clinical studies.
- Avoid concomitant use of dalfampridine with other forms of 4-aminopyridine (4-AP, fampridine) since the active ingredient is the same. Instruct patients to discontinue use of any product containing 4-aminopyridine prior to initiating treatment with dalfampridine in order to reduce the potential for dose-related adverse reactions.
- Dalfampridine can cause anaphylaxis and severe allergic reactions. Signs and symptoms have included respiratory compromise, urticarial, and angioedema of the throat and or tongue. If an anaphylactic or other serious allergic reaction occurs, permanently discontinue dalfampridine.
- Dalfampridine is eliminated through the kidneys primarily as unchanged drug. The risk of seizures in patients with mild renal impairment (CrCl 51–80 mL/min) is unknown, but dalfampridine plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures. Estimated CrCl should be known before initiating dalfampridine and monitored at least annually during treatment.
- The most common adverse reactions (incidence ≥ 2% and at a rate greater than placebo) for dalfampridine were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia and pharyngolaryngeal pain.

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- The risk of adverse reactions, including seizures, and discontinuations because of adverse reactions were more frequent with increasing dalfampridine doses. There is no evidence of additional benefit at doses greater than 10 mg twice daily.
- Concomitant use with OCT2 inhibitors (eg, cimetidine) may cause increased exposure to dalfampridine and potential risk of seizures.
- There are no adequate and well-controlled studies of dalfampridine in pregnant women. Dalfampridine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- It is not known if dalfampridine passes into breast milk. A decision should be made whether to discontinue dalfampridine or to discontinue nursing, taking into consideration the importance of dalfampridine to the mother.
- Safety and effectiveness of dalfampridine in patients younger than 18 years of age have not been established.
- Clinical studies of dalfampridine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Because elderly patients are more likely to have decreased renal function, it is important to know the estimated CrCl before initiating dalfampridine.
- Overdose has been reported and in some instances, patients developed status epilepticus, requiring intensive supportive care and were responsive to standard therapy for seizures.

Please see the Full Prescribing Information for Dalfampridine Extended-release Tablets. Additional information on Hikma US products is available on www.hikma.com/us.

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.

Manufactured by: West-Ward Columbus Inc., Columbus, OH 43228