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Press Release

Hikma launches generic version of Northera®

London, 2 March 2021 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces it has received FDA approval for and launched Droxidopa Capsules, the generic equivalent to Northera®[1] through its US affiliate, Hikma Pharmaceuticals USA Inc. The company has launched 100mg, 200mg and 300mg doses.

Droxidopa is indicated for the treatment of orthostatic dizziness and light-headedness in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of droxidopa should be assessed periodically.

According to IQVIA, US sales of Droxidopa Capsules, 100mg, 200mg and 300mg, were approximately $353 million in the 12 months ending November 2020.

Brian Hoffmann, President of Generics said, “We are pleased to launch Droxidopa Capsules and to be among the first wave of generics, making this important drug available to customers and patients in the US. We are committed to diversifying our portfolio through delivering on our pipeline and bringing new products to market, helping us to improve patients’ access to high-quality and affordable generic medicines around the world.”

- ENDS -

Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050
uk-investors@hikma.uk.com

Steve Weiss
David Belian
US Communications and Public Affairs

+1 732 720 2830/ +1 732 788 8279
+1 732 720 2814/+1 848 254 4875
uscommunications@hikma.com

About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P, BBB-/stable Fitch and Ba1/stable Moody's)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are 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

[1] Northera® is a registered trademark of LundbeckNA Ltd.

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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 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, 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 Droxidopa Capsules, 100mg, 200mg and 300mg:

WARNING: SUPINE HYPERTENSION
Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue droxidopa.

CONTRAINDICATIONS
Droxidopa is contraindicated in patients who have a history of hypersensitivity to the drug or its ingredients.

WARNINGS AND PRECAUTIONS

- **Supine Hypertension**

Droxidopa therapy may cause or exacerbate supine hypertension in patients with neurogenic orthostatic hypertension. Advise patients to elevate the head of the bed when resting or sleeping. Monitor blood pressure, both in the supine position and in the recommended head-elevated sleeping position. Reduce the dose or discontinue droxidopa if supine hypertension persists. If supine hypertension is not well managed, droxidopa may increase the risk of cardiovascular events, particularly stroke.

- **Hyperpyrexia and Confusion**

Post marketing cases of a symptom complex resembling neuroleptic malignant syndrome (i.e., hyperthermia, muscle rigidity, involuntary movements, mental status changes, altered consciousness) have been reported with droxidopa use during postmarketing surveillance. The early diagnosis of this condition is important for appropriate management. Observe patients carefully when the dosage of droxidopa is changed or when concomitant levodopa is reduced abruptly or discontinued, especially if the patient is receiving neuroleptics.

- **Ischemic Heart Disease, Arrhythmias and Congestive Heart Failure**

Droxidopa may exacerbate existing ischemic heart disease, arrhythmias and congestive heart failure. Carefully consider this potential risk before initiating therapy in patients with these conditions.

- **Allergic Reactions**

Hypersensitivity reactions, some requiring emergency treatment, have been reported during postmarketing surveillance. If a hypersensitivity reaction occurs, discontinue droxidopa and initiate appropriate therapy.

- **Immunologic**
  This product contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although overall incidence of tartrazine sensitivity in the general population is low, it is frequently seen in patients who have aspirin hypersensitivity.

- **Lactation**
  There is no information regarding the presence of droxidopa or its active metabolite(s) in human milk, the effects of droxidopa on the breastfed child, nor the effects of droxidopa on milk production/excretion. Because of the potential for serious adverse reactions in animal data, including reduced weight gain in breastfed infants, advise a woman not to breastfeeding during treatment with droxidopa.

ADVERSE REACTIONS

- The most common adverse reactions (>5% and ≥3% difference compared to placebo) were headache, dizziness, nausea, and hypertension.

- In the long-term, open-label extension studies, the most commonly reported adverse events were falls, urinary tract infections, headache, syncope and dizziness.

The following adverse reactions are described in more detail in the Warnings and Precautions section of the full Prescribing Information:

- Supine Hypertension
- Hyperpyrexia and Confusion
- May exacerbate existing ischemic heart disease, arrhythmias and congestive heart failure

The safety of droxidopa is based on 2 placebo-controlled studies 1 to 2 weeks in duration, an 8-week placebo-controlled study and 2 long-term, open-label extension studies.

For more information about adverse reactions, see the full Prescribing Information.

Monitoring

- Therapeutic/Efficacy

Improvement in symptoms of neurogenic orthostatic hypotension (eg, orthostatic dizziness, lightheadedness) is indicative of efficacy.

- Toxic

Monitor supine blood pressure (and with head elevated) prior to and during treatment. More frequent monitoring is required with dosage increases

DRUG INTERACTIONS

- **Drugs That Increase Blood Pressure**

Administering droxidopa in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension.

- **Parkinson's Medications**

Dopa-decarboxylase inhibitors may require dose adjustments for droxidopa.

- **Non-Selective MAO Inhibitors**

The concomitant use of selective MAO-B inhibitors was permitted in the droxidopa clinical trials. Based on mechanism of action, however, non-selective MAO inhibitors and linezolid should be avoided, as there is a potential for increased blood pressure when taken with droxidopa.

USE IN SPECIFIC POPULATIONS

- **Pregnancy**

There are no available data on the use of droxidopa in pregnant women and risk of major birth defects or miscarriage.

- **Lactation**

There is no information regarding the presence of droxidopa or its active metabolite(s) in human milk, the effects of droxidopa on the breastfed child or the effects of droxidopa on milk production/excretion.

- **Pediatric Use**

The safety and effectiveness of droxidopa in pediatric patients have not been established.

- **Geriatric Use**

In clinical trials, no overall differences in safety were observed between patients 75 years and older and younger patients. However, greater sensitivity of some older individuals to droxidopa cannot be ruled out.

- **Renal Impairment**

Clinical experience with droxidopa in patients with severe renal function impairment (GFR <30 mL/min) is limited; therefore, dosing recommendations cannot be provided for these patients.

DOSAGE AND ADMINISTRATION

- **Dosage**

Initial, 100 mg orally 3 times daily scheduled: upon arising in the morning, at midday, and in late afternoon at least 3 hours before bedtime. Titrate as needed in increments of 100 mg 3 times daily every 24 to 48 hours; MAX dose, 1800 mg/day. Efficacy beyond 2 weeks of treatment not established

- **Administration**

Oral route: Swallow capsule whole and take consistently either with or without food

- **Storage**

Store capsules at room temperature between 20 and 25 degrees C (68 and 77 degrees F)

For more information, please see the full Prescribing Information, including the Boxed Warning.

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

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