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Press Release

Hikma launches Icosapent Ethyl Capsules

London, 5 November, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Icosapent Ethyl Capsules, 1gm, in the US through its US affiliate, Hikma Pharmaceuticals USA Inc.

Following an earlier than expected favorable court ruling, Hikma has accelerated the launch of its Icosapent Ethyl Capsules in order to quickly provide patients with access to this important medicine. Initially, Hikma will be releasing limited quantities to ensure a consistent supply for customers. The Company is working to scale up manufacturing and increase availability as soon as possible.

“Hikma’s launch of this important medicine for US patients and healthcare providers once again underscores our ability to put better health, within reach, every day for millions of people who rely on our medicines," said Brian Hoffmann, President of Hikma Generics. "Today's launch demonstrates Hikma's ability to successfully challenge patents and launch complex products, bringing greater value to our customers and patients."

Hikma’s FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Hikma’s product is not approved for any other indication for the reference listed drug VASCEPA®.

- ENDS -

Enquiries

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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

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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 8,600 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 Icosapent Ethyl Capsules, 1gm:

CONTRAINDICATIONS
Icosapent ethyl is contraindicated in patients with known hypersensitivity (eg, anaphylactic reaction) to icosapent ethyl or any of its components.

WARNINGS AND PRECAUTIONS

- **Atrial Fibrillation/Flutter**

In a double-blind, placebo-controlled trial, icosapent ethyl was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.

- **Potential for Allergic Reactions in Patients With Fish Allergy**

It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to icosapent ethyl. Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions and advise them to discontinue use and seek medical attention if any reactions occur.

- **Bleeding**

In a double-blind, placebo-controlled trial, icosapent ethyl was associated with an increased risk (12% vs 10%) of bleeding. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.

ADVERSE REACTIONS
The following important adverse reactions are described in the full Prescribing Information for Icosapent Ethyl capsules:

- Atrial Fibrillation or Atrial Flutter
- Potential for Allergic Reactions in Patients With Fish Allergy
- Bleeding

Common adverse reactions (incidence ≥3% on icosapent ethyl and ≥1% more frequent than placebo) included musculoskeletal pain, peripheral edema, constipation, gout and atrial fibrillation.

In hypertriglyceridemia trials, adverse reactions reported with icosapent ethyl (incidence ≥1% more frequent than placebo) included arthralgia and oropharyngeal pain.

DRUG INTERACTIONS

- **Increased Bleeding Risk With Anticoagulants and Antiplatelet Agents**

Monitor patients receiving icosapent ethyl and concomitant anticoagulants and/or antiplatelet agents for bleeding.

USE IN SPECIFIC POPULATIONS

- **Lactation**

Lactating women receiving oral omega-3 fatty acids for supplementation have resulted in higher levels of omega-3 fatty acids in human milk. There are no data on the effects of omega-3 fatty acid ethyl esters on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for icosapent ethyl and any potential adverse effects on the breastfed child from icosapent ethyl or from the underlying maternal condition.

- **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

- **Hepatic Impairment**

In patients with hepatic impairment, alanine aminotransferase and aspartate aminotransferase levels should be monitored periodically during therapy with icosapent ethyl.

INDICATIONS AND USAGE

Icosapent ethyl is indicated:

- as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

Limitations of use

The effect of icosapent ethyl on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

For more information, please see the full Prescribing Information and Medication Guide.

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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