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Press Release

# Hikma launches Mitomycin for Injection, USP

**London, 29 January 2019** – 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 Mitomycin for Injection, USP, 20mg and 40mg.

Hikma's Mitomycin for Injection, USP is not recommended as single-agent, primary therapy. It has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Mitomycin is not recommended to replace appropriate surgery and/or radiotherapy.

According to IQVIA, US sales of Mitomycin for Injection were approximately $43 million in the 12 months ending November 2018.

Riad Mechlaoui, President of Injectables said, "We are excited to add Mitomycin for Injection to our oncology portfolio in the US, improving patients' access to this important medicine. This demonstrates the successful execution of our strategy to expand our portfolio in key therapeutic areas."

This new product introduction expands Hikma's broad US offering of more than 90 injectable products and further solidifies our position as one of the top three suppliers of generic injectable products to US hospitals.

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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 Mitomycin for Injection, USP, 20mg and 40mg:**

**WARNING**

**Mitomycin should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.**

**Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of mitomycin.**

**Hemolytic Uremic Syndrome (HUS) a serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia, thrombocytopenia, and irreversible renal failure, has been reported in patients receiving systemic mitomycin. The syndrome may occur at any time during systemic therapy with mitomycin as a single agent or in combination with other cytotoxic drugs; however, most cases occur at doses ≥ 60 mg of mitomycin. Blood product transfusion may exacerbate the symptoms associated with this syndrome.**

**The incidence of the syndrome has not been defined.**

WARNINGS AND PRECAUTIONS

Mitomycin is contraindicated in patients who have demonstrated a hypersensitive or idiosyncratic reaction to it in the past as well as in patients with thrombocytopenia, coagulation disorder, or an increase in bleeding tendency due to other causes.

The following warnings and precautions should be taken when administering Mitomycin for Injection, USP:

- Patients be must be observed carefully during and after treatment.
- Advise patients of the potential toxicity of this drug.
- Safe use of mitomycin in pregnant women has not been established.
- It is recommended that women receiving mitomycin not breast feed because of the potential for serious adverse events.
- Acute shortness of breath and severe bronchospasm have been reported following administration of vinca alkaloids in patients who had previously or simultaneously received mitomycin.
- Respiratory distress syndrome may occur. Caution should be exercised using only enough oxygen to provide adequate arterial saturation since oxygen itself is toxic to the lungs.
- Follow proper handling and disposal of anticancer drugs.

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The following adverse reactions have been reported: bone marrow toxicity, integument and mucous membrane toxicity, renal toxicity, pulmonary toxicity, hemolytic uremic syndrome, and cardiac toxicity.

Acute side effects of mitomycin were fever, anorexia, nausea, and vomiting.

Other adverse events include: headache, blurred vision, confusion, fatigue, thrombophlebitis, diarrhea, and pain. Malaise and asthenia have been reported in postmarketing surveillance. Bladder fibrosis/contraction has been reported with intravesical administration (not an approved route of administration).

**For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.**

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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