hikma.

Press Release

Hikma launches Cisplatin Injection

London, 26 July 2019 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's, stable / BB+ S&P, positive) the multinational pharmaceutical company, has launched Cisplatin Injection, 1mg/mL in 50mL and 100mL vials, in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.[1]

Cisplatin Injection is indicated as therapy to be employed as follows:

- **Metastatic Testicular Tumors**
  - In established combination therapy with other approved chemotherapeutic agents in patients with metastatic testicular tumors who have already received appropriate surgical and/or radiotherapeutic procedures.

- **Metastatic Ovarian Tumors**
  - In established combination therapy with other approved chemotherapeutic agents in patients with metastatic ovarian tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination consists of Cisplatin Injection and cyclophosphamide. Cisplatin Injection, as a single agent, is indicated as secondary therapy in patients with metastatic ovarian tumors refractory to standard chemotherapy who have not previously received Cisplatin Injection therapy.

- **Advanced Bladder Cancer**
  - Cisplatin Injection is indicated as a single agent for patients with transitional cell bladder cancer which is no longer amenable to local treatments, such as surgery and/or radiotherapy.

According to IQVIA, US sales of Cisplatin Injection, 1mg/mL in 50mL and 100mL, were approximately $5 million in the 12 months ending May 2019.

Hikma is the third largest US supplier of generic injectable medicines by volume, with a growing portfolio of over 100 products. Today one in every six injectable generic medicines used in US hospitals is a Hikma product.

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[1] Hikma Pharmaceuticals USA Inc. was formerly known as West-Ward Pharmaceuticals Corp.

Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal	+44 (0)20 7399 2760/ +44 7776 477050
EVP, Strategic Planning and Global Affairs	uk-investors@hikma.uk.com
Steven Weiss	+1 732 720 2830/ +1 732 788 8279
Senior Director, Communications and Public Affairs	sweiss@hikma.com

About Hikma

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'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 8,400 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 Cisplatin Injection, 1mg/mL in 50mL and 100mL vials:

BOXED WARNING

Cisplatin injection 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.

Cumulative renal toxicity associated with cisplatin is severe. Other major dose-related toxicities are myelosuppression, nausea, and vomiting.

Ototoxicity, which may be more pronounced in children, and is manifested by tinnitus, and/or loss of high frequency hearing and occasionally deafness, is significant.

***Anaphylactic-like* reactions to cisplatin have been reported. Facial edema, bronchoconstriction, tachycardia, and hypotension may occur within minutes of cisplatin administration. Epinephrine, corticosteroids, and antihistamines have been effectively employed to alleviate symptoms (see warnings and adverse reactions sections).**

Exercise caution to prevent inadvertent cisplatin overdose. Doses greater than 100 mg/m2/cycle once every 3 to 4 weeks are rarely used. Care must be taken to avoid inadvertent cisplatin overdose due to confusion with carboplatin or prescribing practices that fail to differentiate daily doses from total dose per cycle.

CONTRAINDICATIONS

Cisplatin is contraindicated in patients with pre-existing renal impairment. Cisplatin should not be employed in myelosuppressed patients, or in patients with hearing impairment.

Cisplatin is contraindicated in patients with a history of allergic reactions to cisplatin or other platinum-containing compounds.

Warning and Precautions

The following warnings and precautions should be taken when administering Cisplatin Injection:

- Cisplatin produces cumulative nephrotoxicity which is potentiated by aminoglycoside antibiotics.
- At the recommended dosage, cisplatin should not be given more frequently than once every 3 to 4 weeks.
- Elderly patients may be more susceptible to nephrotoxicity, myelosupression, and peripheral neuropathy.
- Loss of motor function has been reported.
- Anaphylactic-like reactions have also been reported.
- Can cause ototoxicity which is cumulative and may be severe.
- Pediatric patients receiving cisplatin should have audiometric testing at baseline, prior to each subsequent dose of drug and for several years post therapy.
- Cisplatin can cause fetal harm when administered to a pregnant woman. Patients should be advised to avoid becoming pregnant.
- Patients receiving cisplatin should not breastfeed.
- Injection site reactions may occur during administration.
- The development of acute leukemia coincident with the use of cisplatin has been reported.
- Plasma levels of anticonvulsant agents may become subtherapeutic during cisplatin therapy.
- Peripheral blood counts should be monitored weekly. Liver function should be monitored periodically. Neurologic examination should also be performed regularly.
- Cisplatin is known to be substantially excreted by the kidney and is contraindicated in patients with pre-existing renal impairment. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and renal function should be monitored.
- Caution should be exercised to prevent inadvertent overdosage with cisplatin.
- Aluminum reacts with cisplatin injection, causing precipitate formation and a loss of potency.
- Cisplatin Injection is administered by slow intravenous infusion. Cisplatin Injection should not be given by rapid intravenous injection.

ADVERSE REACTIONS

The following adverse reactions have been reported: nephrotoxicity, ototoxicity, myelosuppression, leukopenia, thrombocytopenia, anemia, fever, infection, nausea, and vomiting. Diarrhea has also been reported.

Other toxicities have been reported such as vascular toxicities coincident with the use of cisplatin in combination with antineoplastic agents, hypomagnesemia, hypocalcemia, hyponatremia, hypokalemia, and hypophosphatemia. Hyperuricemia has been reported to occur at approximately the same frequency as the increases in BUN and serum creatinine. Neurotoxicity, usually characterized by peripheral neuropathies, loss of taste, seizures, leukoencephalopathy, reversible posterior leukoencephalopathy syndrome (RPLS), and muscle cramps have been reported. Ocular toxicities include optic neuritis, papilledema, cerebral blindness, blurred vision and altered color perception have been reported. Anaphlylactic-like reactions, consisting of facial edema, wheezing, tachycardia, and hypotension have been reported. Transient elevations of liver enzymes, especially SGOT, as well as bilirubin, have been reported. Other events such as cardiac abnormalities, hiccups, elevated serum amylase, rash, alopecia, malaise, asthenia, dehydration, and local soft tissue toxicity have been reported.

For additional information, please refer to the Package Insert for full prescribing information, including the Boxed Warning.

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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