hikma.

Press Release

Hikma launches 100th injectable medicine in US with introduction of Vancomycin Hydrochloride for Injection, USP

London, 1 May 2019 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) the multinational pharmaceutical company, today launched its 100th injectable medicine in the United States with the introduction of Vancomycin Hydrochloride for Injection, USP, 5g, 10g and 750mg, through its US affiliate, Hikma Pharmaceuticals USA Inc.[1]

"Vancomycin Hydrochloride for Injection is an essential antibiotic used by hospitals to treat patients who have failed to respond to a number of other antibiotics, and it's another important addition to our growing US portfolio," said Dan Motto, Executive Vice President, Commercial and Development, Injectables. "This launch marks a great milestone – Hikma's 100th injectable medicine in the US – and it demonstrates our commitment to providing doctors and hospitals with a broad range of high-quality medicines needed to treat the current and future needs of patients."

Hikma's Vancomycin Hydrochloride for Injection, USP is indicated for:

- the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (β-lactam-resistant) staphylococci;
- patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins, and for infections caused by Vancomycin-susceptible organisms that are resistant to other antimicrobial drugs;
- initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly;
- the treatment of staphylococcal endocarditis. Its effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin and skin structure infections. When staphylococcal infections are localized and purulent, antibiotics are used as adjuncts to appropriate surgical measures;

and has been:

- reported to be effective alone or in combination with an aminoglycoside for endocarditis caused by *S. viridans* or *S. bovis.* For endocarditis caused by enterococci (e.g., *E. faecalis*), has been reported to be effective only in combination with an aminoglycoside;
- reported to be effective for the treatment of diphtheroid endocarditis;
- used successfully in combination with either rifampin, an aminoglycoside, or both in early-onset prosthetic valve endocarditis caused by *S. epidermidis* or diphtheroids.

Specimens for bacteriologic cultures should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to Vancomycin.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Injection, USP and other antibacterial drugs, Vancomycin Hydrochloride for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

The parenteral form of Vancomycin Hydrochloride may be administered orally for treatment of antibiotic-associated pseudomembranous colitis produced by C. difficile and for staphylococcal enterocolitis. Parenteral administration of

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

Vancomycin Hydrochloride alone is of unproven benefit for these indications. Vancomycin is not effective by the oral route for other types of infection.

According to IQVIA, US sales of Vancomycin Hydrochloride for Injection, USP, 5g, 10g and 750mg were approximately $247 million in the 12 months ending February 2019.

“Our portfolio of 100 injectable medicines now covers many vital, large and growing therapeutic areas including oncology, anti-infectives, anaesthesia and pain management,” continued Mr. Motto. “We are expecting to launch 15 additional products this year, further strengthening Hikma’s position as a top manufacturer and supplier in the US generic injectable market with a strong portfolio that can’t easily be replicated.”

“Our customers prefer to work with manufacturers that have a large product portfolio and a long record of successful FDA inspections,” said Riad Mechlaoui, Hikma’s President of Injectables. “Over the years Hikma has established a strong reputation for quality products and reliability. We have made significant investments to build flexible manufacturing capabilities allowing us to shift capacity to where it is needed most, and enabling us to quickly address changing market demands, including US drug shortage situations as they arise.”

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

-- ENDS –

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

FTI Consulting

Ben Atwell/Andrew Ward	+44 (0)20 3727 1000

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 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.

hikma.

Important Safety Information for Vancomycin Hydrochloride for Injection, USP, 5g, 10g, and 750mg:

WARNINGS AND PRECAUTIONS

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

- A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents of this pharmacy bulk package are intended for use by a pharmacy admixture service for addition to suitable parenteral fluids in the preparation of admixtures for intravenous infusion. **FURTHER DILUTION IS REQUIRED. NOT FOR DIRECT INFUSION.**
- Mixtures of solutions of Vancomycin and beta-lactam antibiotics have been shown to be physically incompatible. The likelihood of precipitation increases with higher concentrations of Vancomycin. It is recommended to adequately flush the intravenous lines between the administration of these antibiotics. It is also recommended to dilute solutions of Vancomycin to 5 mg/mL or less.
- Although intravitreal injection is not an approved route of administration for Vancomycin, precipitation has been reported after intravitreal injection of Vancomycin and Ceftazidime for endophthalmitis using different syringes and needles. The precipitates dissolved gradually, with complete clearing of the vitreous cavity over two months and with improvement of visual acuity.
- Vancomycin Hydrochloride for Injection should be administered in a diluted solution over a period of not less than 60 minutes to avoid rapid-infusion-related reactions.
- Monitor renal function in all patients, especially patients with underlying renal impairment, patients with co-morbidities that predispose to renal impairment, and patients receiving concomitant therapy with a drug known to be nephrotoxic.
- *Clostridium difficile associated diarrhea* (CDAD) has been reported with use of nearly all antibacterial agents. Careful observation of the patient is essential.
- Hemorrhagic occlusive retinal vasculitis, including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of Vancomycin during or after cataract surgery.
- Reversible neutropenia has been reported in patients receiving Vancomycin Hydrochloride for Injection.
- Must be given by a secure IV route of administration.
- Infusion-related events may be minimized by the administration of Vancomycin as a 60-minute infusion prior to anesthetic induction.
- Prescribing Vancomycin Hydrochloride for Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- Concomitant administration of Vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing and anaphylactoid reactions.
- Vancomycin should be given to a pregnant woman only if clearly needed.
- Caution should be exercised when Vancomycin Hydrochloride for Injection is administered to a nursing woman.
- Confirm desired Vancomycin serum concentrations in pediatric patients.
- Patients should be counseled that antibacterial drugs including Vancomycin Hydrochloride for Injection should only be used to treat bacterial infections.

Vancomycin Hydrochloride for Injection is contraindicated in patients with known hypersensitivity to this antibiotic.

The following adverse reactions have been reported: anaphylactoid reactions, flushing of the upper body, acute kidney injury, pseudomembranous colitis symptoms, hearing loss, vertigo, reversible neutropenia, inflammation at the injection site, drug fever, nausea, chills, rashes, and vasculitis. Chemical peritonitis has been reported following intraperitoneal administration.

Postmarketing reports include skin and subcutaneous tissue disorders, drug rash with eosinophilia and systemic symptoms (DRESS).

Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased Vancomycin clearance. To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center.

For additional information, please refer to the Package Insert for the vial and the Package Insert for the pharmacy bulk pack for full prescribing information, available on www.hikma.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

Manufactured by:
HIKMA FARMACÊUTICA (PORTUGAL) S.A.
Estrada do Rio da Mó nos.8, A/B
2705-906 Terrugem SNT
Portugal

Distributed by:
WEST-WARD
A HIKMA COMPANY
Eatontown, NJ 07724 USA

Document Identification Number: WW30336