Lupin Gets USFDA Nod for Single-Dose Dalbavancin Injection to Treat Bacterial Skin Infections

Mumbai: Lupin Limited has received approval from the United States Food and Drug Administration (USFDA) for its New Drug Application (NDA) for Dalbavancin Injection, 500 mg/5 mL (100 mg/mL), single-dose vial, through the 505(b)(2) regulatory pathway. The product is approved for single-dose regimen use only.

Lupin's Dalbavancin Injection is a liquid formulation containing dalbavancin, the active ingredient in AbbVie's Dalvance® (dalbavancin) 500 mg base/vial. The ready-to-dilute formulation is designed to simplify product preparation.

The injection is indicated as a single-dose regimen for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adult and pediatric patients caused by designated susceptible strains of Gram-positive microorganisms.

Contraindications

Dalbavancin Injection is contraindicated in patients with known hypersensitivity to dalbavancin.

Warnings and Precautions

The USFDA-approved prescribing information highlights the following warnings and precautions:

Hypersensitivity Reactions: Serious hypersensitivity, including anaphylactic reactions and skin reactions, have been reported in patients treated with dalbavancin. If an allergic reaction occurs, treatment should be discontinued and appropriate therapy initiated. Patients with known hypersensitivity to glycopeptides should be carefully monitored.

Infusion-Related Reactions: Dalbavancin Injection is administered intravenously over a total infusion period of 30 minutes to minimise the risk of infusion-related reactions. Rapid intravenous infusion may cause flushing of the upper body, urticaria, pruritus, rash and/or back pain. Stopping or slowing the infusion may help resolve these reactions.

Hepatic Effects: Elevations in alanine aminotransferase (ALT) levels have been reported in clinical trials involving dalbavancin.

Clostridioides difficile Infection: Clostridioides difficile infection (CDI) has been reported with nearly all systemic antibacterial agents, including dalbavancin. Patients who develop diarrhoea should be evaluated for CDI.

Development of Drug-Resistant Bacteria: Prescribing dalbavancin in the absence of a proven or strongly suspected bacterial infection, or a prophylactic indication, is unlikely to benefit patients and may increase the risk of developing drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions, occurring in more than 4% of adult patients treated with dalbavancin, were nausea, headache and diarrhoea. Among pediatric patients, pyrexia was the most common adverse reaction, occurring in more than 1% of patients.

Suspected adverse reactions can be reported to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or to the USFDA at 1-800-FDA-1088.

Use in Special Populations

Pregnancy and Lactation: There are no adequate and well-controlled studies of dalbavancin use in pregnant women. In pregnant rats, dalbavancin exposure at 3.5 times the human dose resulted in delayed fetal maturation and increased fetal loss.

There are no available data on the presence of dalbavancin or its metabolite in human milk, its effects on breastfed children or its impact on milk production. Dalbavancin is excreted in the milk of lactating rats and is likely to be present in human milk.

Renal Impairment: In adult patients with creatinine clearance (CLcr) below 30 mL/min who are not receiving regularly scheduled haemodialysis, the recommended dalbavancin dosage is 1,125 mg as a single dose. No dosage adjustment is recommended for adult patients receiving regularly scheduled haemodialysis, and the drug may be administered regardless of the timing of dialysis.

The safety and effectiveness of dalbavancin for treating ABSSSI have been established in pediatric patients from birth to below 18 years of age. However, there is insufficient information to recommend dosage adjustments for pediatric patients below 18 years with CLcr below 30 mL/min/1.73 m^2.

Geriatric Use: The efficacy and tolerability of dalbavancin were similar to those of the comparator across age groups. Its pharmacokinetics were not significantly affected by age, and no dosage adjustment is required based on age alone.

However, dalbavancin is substantially excreted by the kidneys, and elderly patients may be at greater risk of adverse reactions due to impaired renal function. Therefore, care should be taken when selecting the dosage for this age group.

Hepatic Impairment: No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh Class A). Caution is advised when prescribing dalbavancin to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C), as data in these populations are unavailable.

Lupin Limited is a global pharmaceutical company headquartered in Mumbai, India, with a presence across India, the US, other developed markets and emerging markets. Its products are distributed in more than 100 markets worldwide.

The company's diversified portfolio includes generics, complex generics, specialty medicines and biosimilars. Lupin has a strong presence in the US and Indian markets across key therapeutic areas, including cardiovascular, respiratory, diabetes, gastrointestinal and women's health.

The company operates 15 manufacturing facilities and six research centres, supported by a workforce of more than 26,000 professionals. It also continues to expand its healthcare ecosystem through diagnostics, digital health, patient-support programmes and disease management initiatives, with sustainability forming a key part of its business strategy.

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