November 25, 2026

National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051
Symbol: LUPIN

BSE Limited
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
Mumbai - 400 001

Scrip Code: Equity - 500257

Subject: Disclosure pursuant to Regulation 30 of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

We are pleased to enclose a Press Release titled "Lupin Receives Approval from U.S. FDA for Dalbavancin Injection for Single-dose Regimen Use".

The same is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

AMIT KUMAR GUPTA

Digitally signed by AMIT KUMAR GUPTA
DN: c=IN, st=Maharashtra, 2.5.4.20=472cf02f52d2a7e5959c43b4659bdca28c8f26a9398bb3583 5a169f2a257229a3, postalCode=400705, street=C701 Shivdarshan CHS Ltd Sector 16 Plot No5 Navi Mumbai, pseudonym=d3e468db830354fe6afdf62a7cb7aaaae, title=7875, serialNumber=de9bbd80d8994e4be9f0dd239914e6eba7e782d70 2 87df06aad1994f0b523fa08a, o=Personal, cn=AMIT KUMAR GUPTA
Date: 2026.11.25 21:22:03 +05'30'

AMIT KUMAR GUPTA
COMPANY SECRETARY & COMPLIANCE OFFICER
(ACS -15754)

Encl.: a/a.

Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPCIN

Lupin Receives Approval from U.S. FDA for Dalbavancin Injection for Single-dose Regimen Use

Mumbai, India, Naples, FL, November 25, 2026: Global pharma major, Lupin Limited (Lupin) today announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its New Drug Application for Dalbavancin Injection, 500 mg/ 5 mL (100 mg/mL) single-dose vial via the 505(b)(2) pathway. The product is approved for single-dose regimen use only.

Lupin's Dalbavancin Injection, 500 mg/5 mL single dose vial is a liquid formulation of dalbavancin, the active ingredient in Dalvance® (dalbavancin) 500 mg base/vial of AbbVie and provides a ready-to-dilute formulation designed to simplify preparation.

Lupin's Dalbavancin Injection, 500 mg/5 mL single dose vial 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.

IMPORTANT SAFETY INFORMATION

Contraindications

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

Warnings and Precautions

- **Hypersensitivity Reactions:** Serious hypersensitivity (anaphylactic) and skin reactions have been reported in patients treated with dalbavancin for injection. If an allergic reaction to Dalbavancin injection occurs, discontinue treatment with Dalbavancin injection and institute appropriate therapy for the allergic reaction. Carefully monitor patients with known hypersensitivity to glycopeptides.
- **Infusion-Related Reactions:** Dalbavancin injection is administered via intravenous infusion, using a total infusion time of 30 minutes to minimize the risk of infusion-related reactions. Rapid intravenous infusion of Dalbavancin injection can cause flushing of the upper body, urticaria, pruritus, rash, and/or back pain. Stopping or slowing the infusion may result in cessation of these reactions.
- **Hepatic Effects:** Alanine aminotransferase (ALT) elevations with dalbavancin for injection treatment were reported in clinical trials.
- ***Clostridioides difficile* Infection:** *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including dalbavancin. Evaluate if diarrhea occurs.
- **Development of drug-resistant bacteria:** Prescribing Dalbavancin 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.

Press Release

BSE: 500257 NSE: LUPIN REUTERS: LUPIN.BO BLOOMBERG: LPCIN

Adverse Reactions

The most common adverse reactions occurring in more than 4% of adult patients treated with dalbavancin for injection were nausea, headache, and diarrhea. The most common adverse reaction that occurred in more than 1% of pediatric patients was pyrexia.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Use in Special Populations

Pregnancy and Lactation: There are no adequate and well-controlled studies with dalbavancin use in pregnant women. In pregnant rats, dalbavancin at 3.5 times the human dose on an exposure basis resulted in delayed fetal maturation and increased fetal loss. There are no data on the presence of dalbavancin or its metabolite in human milk, the effects on the breast-fed child, or the effects 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) less than 30 mL/min who are not receiving regularly scheduled hemodialysis, the recommended dosage regimen of dalbavancin is 1,125 mg, administered as a single dose No dosage adjustment is recommended for adult patients receiving regularly scheduled hemodialysis, and dalbavancin can be administered without regard to the timing of hemodialysis. The safety and effectiveness of dalbavancin for treating ABSSSI have been established in pediatric patients from birth to <18 years of age. There is insufficient information to recommend dosage adjustment for pediatric patients younger than 18 years with CLcr less than 30 mL/min/1.73m^2.

Geriatric use: The efficacy and tolerability of dalbavancin for injection were similar to comparator regardless of age. The pharmacokinetics of dalbavancin for injection were not significantly altered with age; therefore, no dosage adjustment is necessary based on age alone. Dalbavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Hepatic impairment: No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh Class A). Caution should be taken when prescribing dalbavancin to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) as no data are available.

About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with a strong presence across India, the U.S., Other Developed Markets, and Emerging Markets, with products distributed in over 100 markets. Lupin has a diversified portfolio spanning generics, complex generics, specialty medicines, and biosimilars, and continues to strengthen its market position through a differentiated portfolio. The company maintains strong leadership in the U.S. and India across core therapeutic areas, including cardiovascular, respiratory, diabetes,

Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPCIN

gastrointestinal, and women's health. 15 state-of-the-art manufacturing facilities support sustainable operations, with 6 research centers and a dedicated workforce of over 26,000 professionals. Lupin continues to expand the healthcare ecosystem through diagnostics, digital health, patient-support programs, and disease management initiatives. Sustainability continues to be a core pillar of the company's business strategy.

To know more, visit www.lupin.com or follow us on LinkedIn https://www.linkedin.com/company/lupin

For further information or queries please contact:

Rajalakshmi Azariah
Vice President & Global Head – Corporate Communications, Lupin
rajalakshmiazariah@lupin.com

Elise Titan
Director – U.S. Communications, Lupin
elisetitan@lupin.com

**Safe Harbor Statement*

DALVANCE ® is a registered trademark of Allergan Pharmaceuticals International Limited