Innovating for affordable healthcare

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Date: 11 September 2026

To

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Ltd.
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
Mumbai-400 051

Stock Code: NSE: SHILPAMED/BSE-530549

Dear Sir/Madam,

Sub: Shilpa Medicare's Novel Complex Injectable OERIS™ (Ondansetron Extended-Release Injection, 100 mg/mL) receives final approval from Subject Expert Committee (SEC) for grant of marketing authorization

Ref: Disclosure under Regulation 30 of the SEBI (LODR) Regulations, 2015 ("SEBI Listing Regulations")

Pursuant to Regulation 30 read with other applicable provisions of the SEBI Listing Regulations, we wish to inform you that Shilpa Medicare Limited ("Company") has received **final approval** from the Subject Expert Committee **(SEC)** under the Central Drugs Standard Control Organization (CDSCO) **for grant of marketing authorization for OERIS™** (Ondansetron Extended-Release Injection, 100 mg/mL).

A press release is enclosed for reference.

This is for your information and records.

For SHILPA MEDICARE LIMITED

Ritu Tiwary

Digitally signed by Ritu Tiwary
Date: 2026.09.11 13:20:04 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

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PRESS RELEASE

Shilpa Medicare's Novel Complex Injectable – OERIS™, Receives Final Approval from SEC for grant of marketing authorization for OERIS™ (Ondansetron Extended-Release Injection, 100 mg/mL).

Raichur, India –September 11, 2026

Shilpa Medicare Limited (BSE: 530549 | NSE: SHILPAMED) today announced that the Subject Expert Committee (SEC) under the Central Drugs Standard Control Organization (CDSCO) has issued final approval for grant of marketing authorization for OERIS™ (Ondansetron Extended-Release Injection, 100 mg/mL). OERIS™ is designed to be the **world's first extended-release ondansetron injectable formulation,** providing sustained antiemetic action for up to 120 hours (5 days) following a single administration – a first-of-its-kind approval in both India and globally. **OERIS™ will be launched in India and enjoys patent protection in India until 2039.**

OERIS® is designed to be the world's first extended-release ondansetron injectable formulation providing sustained antiemetic protection for up to 120 hours (5 days) following a single administration.

SEC's approval on granting the marketing authorization is based on the successful completion of a multicenter, randomized, double-blind Phase III trial evaluating the safety and efficacy of Shilpa's OERIS™ for the prophylaxis and control of chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately-to-highly emetogenic chemotherapy. By reducing repeat injections to a single dose administered once every five days, the innovative formulation significantly enhances patient convenience and optimizes healthcare staff efficiency.
Upon receipt of final marketing authorization from the Central Drugs Standard Control Organization (CDSCO), Shilpa plans to initiate commercial launch across India.

Commenting on the development, Mr. Vishnukant Bhutada, Managing Director, Shilpa Medicare Limited, stated:

Final approval from SEC for grant of marketing authorization for OERIS™, marks a pivotal moment in our journey to redefine supportive cancer care. It underscores our dedication to developing complex, patient-first formulations that address real clinical gaps. This milestone further solidifies our differentiated oncology portfolio and propels us closer to our vision of becoming a globally recognized leader in specialty pharmaceuticals and advanced drug delivery systems."

About Shilpa Medicare Limited

Shilpa Medicare Limited is a global pharmaceutical company and integrated CDMO providing end-to-end solutions across small molecules, biologics, and complex therapeutics. The company partners with innovators worldwide to support development through commercialization, with a growing focus on high-value specialty and biologics programs.