



Shilpa Medicare Limited

Corporate & Admin Office:

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CIN: L85110KA1987PLC008739

Date: 10th November 2025

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: PRESS RELEASE- *Shilpa Medicare Announces Positive Phase 3 Results for OERIS™*

Ref: Regulation 30 of the SEBI(LODR) Regulations- Reg.

Shilpa Medicare Announces Positive Phase 3 Results for OERIS™ — A Novel Once-Weekly Ondansetron Extended-Release Injection for Chemotherapy-Induced Nausea and Vomiting (CINV)

Phase 3 study met all primary and secondary endpoints, demonstrating superior convenience, strong efficacy, and excellent safety versus conventional ondansetron injections

Shilpa Medicare Limited today announces the successful completion of its **fourth complex clinical program SMLINJ011**, with positive topline Phase 3 results for **Shilpa's OERIS™ (Ondansetron Extended-Release Injection)**—an innovative formulation designed to improve prophylaxis of chemotherapy-induced nausea and vomiting (CINV).

This milestone underscores Shilpa's growing leadership in **differentiated drug-delivery systems** and **oncology supportive-care therapeutics**, reflecting the company's commitment to advancing patient-centric innovation.

Study Overview and Key Findings

A **Phase III, multicenter, randomized, double-blind, non-inferiority trial** was conducted across multiple oncology centers in India to compare **OERIS™** with conventional ondansetron injections in 240 patients receiving moderately or highly emetogenic chemotherapy.

Design & Endpoints

- **Population:** 240 patients with CINV
- **Primary Endpoint:** Complete response (no emesis episodes through 120 hours post-chemotherapy)
- **Comparator:** Multiple doses of conventional ondansetron injection
- **Secondary Endpoints:** Safety profile, delayed-phase response, patient tolerability

Results

- **Complete response:** 89% in OERIS™ arm vs. 82% in standard ondansetron arm
- **Adverse events:** No serious or severe adverse events reported
- **Safety:** Comparable or better tolerability than conventional therapy

Transformative Innovation

Unlike existing ondansetron formulations requiring multiple daily doses or oral follow-ups, **OERIS™ delivers sustained antiemetic coverage through a single dose** that effectively addresses both **acute and delayed phases of CINV** for up to five days. By reducing injection frequency and simplifying dosing schedules, **OERIS™ significantly enhances patient convenience, reduces treatment burden, and improves compliance**, while optimizing healthcare workflow efficiency.

"We are proud to announce the successful completion of this pivotal Phase 3 study," said Mr. Vishnukant Bhutada, Managing Director, Shilpa Medicare Limited. "OERIS™ exemplifies Shilpa's ability to combine scientific innovation with patient-centric design. This program strengthens our oncology-supportive-care portfolio and reinforces our vision of becoming a global leader in differentiated and specialty products focussing on patient convenience and compliance."



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Next Steps and Regulatory Pathway

Following these positive Phase 3 results, Shilpa Medicare is preparing for **regulatory submission to DCGI** and plans to pursue **global registration and commercial partnerships** through the **505(b)(2)** pathway in the United States and other key markets.

About Chemotherapy-Induced Nausea and Vomiting (CINV)

CINV remains one of the most distressing side effects of cancer therapy, impacting up to 70–80% of patients undergoing moderately or highly emetogenic chemotherapy with market size of ~USD 375 Million. Poor control of CINV can lead to treatment discontinuation, nutritional imbalance, and reduced quality of life. Despite advances, patient compliance with multi-dose regimens remains a significant challenge—highlighting the need for long-acting solutions like OERIS™.

About Shilpa Medicare Limited

Shilpa Medicare Limited (BSE: 530549 | NSE: SHILPAMED) is a leading Indian pharmaceutical company focused on the development, manufacture, and marketing of APIs, formulations, and biologics across oncology, infectious diseases, and specialty segments. With expertise in complex generics, novel drug delivery systems, and CDMO services, Shilpa serves patients in over 80 countries. For more information, visit www.vbshilpa.com

Forward-Looking Statement Disclaimer

This document contains forward-looking statements describing the Company's objectives, plans, and expectations for future performance. Actual results may differ materially due to risks and uncertainties including regulatory approvals, clinical outcomes, market conditions, and competitive developments. Shilpa Medicare undertakes no obligation to update forward-looking statements to reflect subsequent events or circumstances.

For SHILPA MEDICARE LIMITED

Ritu Tiwary
Company Secretary & Compliance Officer