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Shilpa Medicare targets US approval of 5-HT3 receptor antiemetic for chemotherapy-induced nausea and vomiting

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Phase 3 study met all primary and secondary endpoints demonstrating superior convenience and strong efficacy



Shilpa Medicare Limited has announced its intention to pursue a US approval within the next two years and is actively seeking licensing partners for its Ondansetron Extended-Release Injection (OERIS™), following the successful completion of a Phase 3 study in India that met all primary and secondary endpoints.

OERIS™ is a novel extended-release antiemetic [5-HT3 receptor antagonist] used in the treatment of patients with chemotherapy-induced nausea and vomiting (CINV). By blocking 5-HT3 receptors in the gastrointestinal tract and brain, the drug inhibits serotonin-induced vomiting signals.

The phase 3 study evaluated the extended release injection against conventional ondansetron injections – which require multiple daily doses or oral follow-ups – and demonstrated sustained antiemetic coverage through a single dose, effective in both acute and delayed phases of CINV for up to five days.

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 ~$375 million.

OERIS™ formulation is designed to prioritise safety and tolerability by delivering medication steadily over time, minimising peak plasma concentrations that can trigger adverse effects like QTc prolongation or concentration-dependent issues such as constipation. This smooth release profile reduces fluctuations between peak and trough levels, lowering risks associated with conventional immediate-release ondansetron, including cardiac events or gastrointestinal side effects.

“By reducing injection frequency and simplifying dosing schedules, OERIS™ significantly enhances patient convenience, reduces treatment burden, and improves compliance while optimising healthcare workflow efficiency. We are now in the process of filing for regulatory approval in India, and will then seek global registration and commercial partnerships through the 505(b)(2) pathway in the United States and other key markets,” commented Vishnukant Bhutada, Managing Director, Shilpa Medicare Limited.