

Date: 17 November 2025

To,

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

Sub: Shilpa announces the launch of NODUCATM for the first time in India to treat metabolic dysfunction-associated fatty liver disease (MAFLD)**Ref: Regulation 30 of the SEBI(LODR) Regulations**

NODUCA™ (norursodeoxycholic acid), a novel bile acid therapy designed to treat metabolic dysfunction-associated fatty liver disease (MAFLD), offers a first-in-class approach to improving liver health by reducing inflammation, fibrosis, and cholestasis through unique mechanisms distinct from conventional therapies.

Shilpa Medicare Limited is proud to announce the launch of NODUCA™ (Nor Ursodeoxycholic Acid (NorUDCA)), a first-in-class therapy for the first time in India or anywhere in the world, following the historic approval granted in August 2025 by the Central Drugs Standard Control Organisation (CDSCO), India. The drug ushers in a new line of treatment for patients suffering from metabolic dysfunction-associated fatty liver disease (MAFLD), previously referred to as non-alcoholic fatty liver disease (NAFLD).

NorUDCA offers three major therapeutic benefits for MAFLD and associated liver disorders:

- **Anti-inflammatory action:** Actively reduces hepatic and ductular inflammation, limiting progression to cirrhosis and liver failure.
- **Anti-fibrotic effect:** Promotes reversal of liver scarring (fibrosis) and stabilizes liver architecture, as proven in Phase 3 studies, with 83.3% of patients showing fibrosis reversal and 90% achieving normal liver enzyme levels within 3 months.
- **Choleretic protection:** Encourages toxin clearance via enhanced bile secretion and protects cholangiocytes, minimizing risk of advanced disease.

Clinical trial data from India demonstrated excellent efficacy at a dose of 1500 mg daily, with no serious adverse events. NorUDCA is well tolerated and suitable for long-term use, offering new hope to patients with limited treatment options

MAFLD is the world's most prevalent liver disorder, impacting 1 in 4 people and an estimated 188 million patients within India alone. This landmark approval designates Shilpa Medicare as the first company globally to bring Nor Ursodeoxycholic tablets to market for the treatment of MAFLD.

NorUDCA represents a novel, first-in-class therapy demonstrating significant clinical efficacy and safety in reversing liver fibrosis and stabilizing liver function, as evidenced in the Phase 3 trials conducted across India. The launch of NorUDCA tablets underlines Shilpa's commitment to innovation, evidence-based healthcare, and expansion into critical therapeutic areas addressing substantial unmet medical needs.

Mr. Vishnukant Bhutada, Managing Director, commented: "I am delighted to announce the launch of NorUDCA in the Indian market which is a culmination of our dedication to innovation. We are proud to be the first to bring this therapy to patients, and with our multi-pronged commercial strategy, we are confident in making a meaningful impact on the fight against MAFLD"

The company is now commencing commercial launch within India under its own brand NODUCA™ and have also partnered with 3 partners for India market on their own brand. Shilpa will continue to pursue international regulatory approvals to expand access to this vital liver health therapy for patients globally.

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

Kindly take the same on record.

For Shilpa Medicare Limited

Ritu Tiwary

Company Secretary & Compliance Officer