Shilpa Medicare Limited
Corporate & Admin Office:
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Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Date: February 13, 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

Dear Sir/Madam,

Sub: Intimation under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Reg, 2015.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

SEC – CDSCO Approval of Phase 3 Clinical Trial and Recommendation for Grant of Marketing Approval for Shilpa' s IND Nor-Ursodeoxycholic acid Tablets

Shilpa Medicare announces the approval of its IND - Nor Ursodeoxycholic Acid Tablets 500 mg, by the Subject Expert Committee of CDSCO. The Committee has further recommended grant of marketing authorization for this IND for the treatment of non-alcoholic fatty liver disease (NAFLD).

NAFLD is the most common liver disease, and it is estimated to affect about 25% of the population in World (approx. 1.2 billion) and about 188 million people suffer from NAFLD in India. If NAFLD is not treated in a timely manner, it is likely to lead to more severe non-alcoholic steatohepatitis (NASH) which could have fatal implications for the patient.

Shilpa Medicare Ltd. had earlier completed phase-3 clinical studies of this novel product SMLNUD07 – Nor Ursodeoxycholic Acid (Nor UDCA) tablets - and presented the results of the trial titled "A phase - III, Randomized, Double- Blind, placebo controlled, multicenter, Parallel group study" to evaluate the safety and efficacy of Nor-Ursodeoxycholic Acid 500 mg in patients suffering from Non-alcoholic Fatty Liver Disease to the SEC.

This trial was a multicentric, placebo controlled double blinded study conducted on total 165 Non-alcoholic fatty liver disease (NAFLD) patients across India – a significant statistically powered number of patients leading to better reliability of data and results. **No serious adverse events were reported in this phase 3 study** and the treatment was well tolerated at the dose of 1500 mg per day for the duration of 24 weeks.

The Phase 3 trial has met all the primary efficacy endpoints set in the clinical trial protocol, demonstrating a significant improvement in fatty liver stage. In this study 165 participants were randomised to assess and compare the efficacy and safety of nor UDCA 1500 mg against placebo. The data analysis has confirmed that liver fibrosis stage was reversed in significant majority of participants (83.3%) and stabilised in rest, within 24 weeks of nor UDCA treatment. (Primary endpoint) The elevated alanine transaminase (ALT) levels of NAFLD were normalized in significant proportion of participants (~90%) within 12 weeks of study (Primary endpoint).

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These results indicate that Nor UDCA could become a new standard of care with significant improvements in restoring liver function in NAFLD patients. **This IND is expected to revolutionise the treatment of patients suffering from Nonalcoholic Fatty Liver Disease (NAFLD)**.

Nor UDCA will be a first-in-class treatment option for NAFLD in India and has significant advantages over UDCA like enhanced choleretic effect, resistance to amidation, anti-inflammatory properties and reduction in fibrosis.

Commenting on the development, Mr. Vishnukant Bhutada – Managing Director, Shilpa Medicare Limited said, "We are very pleased with this approval from SEC and hope to get the marketing approval soon. We are committed to working closely with regulatory authorities to bring this innovative treatment to patients as quickly as possible and are hopeful of launching it in India in the coming financial year. This NCE molecule approval exemplifies the true spirit of Shilpa, ***'Innovating for affordable healthcare'*** keeping in mind the unmet needs of a large patient pool. Based on the approval in India, we plan to reach out to regulatory authorities in the EU and the USA to seek scientific advice for introduction of this novel product internationally."

About Shilpa:

Shilpa is an integrated pharmaceutical group with business interests in niche Oncology & Non-oncology APIs, Peptides, Polymers, differentiated finished dosage formulations including orally dispersible films & transdermal patches along with carefully crafted biological portfolio. Shilpa also provides end-to-end CDMO services to global pharmaceutical companies across all its business segments based on its strong R&D and manufacturing capabilities backed by four R&D units and seven manufacturing facilities.

Thanking you,

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Digitally signed by Ritu Tiwary
Date: 2025.02.13 13:03:53 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer