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: 26 August 2024

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: BSE – 530549 / NSE – SHILPAMED

Dear Sir/Madam,

Sub: Intimation under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Shilpa Medicare announces successful outcome of Phase 3 studies of SMLNUD07 – NorUDCA

Shilpa Medicare has successfully completed phase-3 clinical studies of its novel product SMLNUD07 - Nor Ursodeoxycholic Acid (NorUDCA) tablets that is **expected to revolutionise the treatment of patients suffering from Nonalcoholic Fatty Liver Disease (NAFLD)**. This trial was a multicentric, placebo controlled double blinded study conducted on total 165 Nonalcoholic 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 trial resulted in significant, at least one stage, decrease in liver fibrosis. Additionally, there was a significant reduction in fat accumulation in liver. The decrease in fibrosis was measured using the "Fibroscan" technique which is the USFDA approved imaging technique for assessment of liver fibrosis. The decrease in fat accumulation was evaluated through the CAP scoring technique. Significant normalization of Alanine Aminotransferase (ALT) was conclusively demonstrated in this study. This approach provides a more holistic view of the treatment's effect by capturing multiple relevant outcomes.

These results indicate that NorUDCA could become a new standard of care with significant improvements in restoring liver function in NAFLD patients. Shilpa Medicare Ltd plans to submit these Phase 3 clinical trial findings at the earliest to the CDSCO, India for seeking marketing authorization in India.

Nor UDCA is likely to 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.

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Commenting on the development, Mr. Vishnukant Bhutada – Managing Director Shilpa Medicare Limited said, "We are very pleased with the successful Phase III trials outcome for this unique product addressing the unmet need of patients suffering from NAFLD with a potential first line of treatment. This development exemplifies Shilpa's constant endeavor to work towards introducing novel first of its kind pharmaceutical products that help improve the healthcare requirements of a large patient pool."

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 turn into nonalcoholic steatohepatitis (NASH) which could have fatal implications for the patient.

This is for your information & records.

Thanking you,
For **Shilpa Medicare Limited**

RITU TIWARY
Digitally signed by RITU TIWARY
Date: 2024.08.26 09:39:53 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer