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: 07 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 Limited, first Indian company to successfully complete Phase 1 Clinical Trial for Recombinant Human Albumin (rHA) 20%**

Shilpa Medicare Limited is pleased to announce the successful completion of its Phase 1 clinical trial for recombinant human albumin 20% (rHA). The positive results from this trial mark a significant milestone in the development of rHA, demonstrating its potential as a viable alternative to plasma derived human serum albumin.

The Phase 1 clinical study is a randomized, dose-escalating, comparative trial against European sourced human derived serum albumin, involving 62 healthy volunteers. The trial aimed to evaluate the safety, efficacy, and pharmacokinetics of rHA at different dose levels. Key findings from the study include:

- **Clinical Benefit**: rHA demonstrated clinical benefits through surrogate endpoints such as colloidal osmotic pressure and hematocrit ratio, comparable to human-derived albumin.
- **Safety**: rHA was generally well-tolerated, with no serious adverse events reported.
- **Immunogenicity**: There was no significant difference in the incidence of anti-drug antibodies compared to human-derived albumin.
- **Bioavailability**: rHA showed comparable bioavailability to human albumin.

Albumin is in high demand for various medical treatments, including restoring blood volume and replacing lost fluids during accidents, serious burn injuries, fetal erythroblastosis, hypoproteinemia, and surgeries. However, the supply of human serum albumin is limited due to the reliance on whole blood or donated human plasma. Shilpa's Recombinant Human Albumin 20% (rHA), derived from yeast, offers a highly purified, structurally and functionally equivalent alternative to human serum albumin.

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

"We are thrilled with the positive outcomes of our Phase 1 clinical trial," said Mr. Vishnukant Bhutada Managing Director - Shilpa Medicare Limited, "this success brings us one step closer to providing a reliable and safe alternative to human serum albumin, addressing the global demand and supply challenges. We have crafted a carefully designed clinical program with comparable trials being carried out against European sourced human albumin to enable quicker registration process in Europe and various emerging markets thus reducing the time to market this unique significant short-supply product"

The success of this Phase 1 clinical study paves the way for further research and development into global markets, advancing rHA to Phase 3 clinical trials. We expect to commence the Phase 3 clinical trials by Q4 of FY25 and the trials are likely to be completed over next 9 to 12 months' post commencement. Filing for product approval in various geographies is expected to commence in FY26.

This is for your information & records.

Thanking you,
For **Shilpa Medicare Limited**

RITU TIWARY

Digitally signed by RITU TIWARY
Date: 2024.08.07 11:47:42 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer