



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@vbsilpa.com, Web: www.vbsilpa.com
CIN: L85110KA1987PLC008739

Date: 26 November 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

Dear Sir/Madam,

**Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549**

.....

Indian Regulatory Authority - SEC approval for conducting Phase III Clinical trials for Recombinant Human Albumin (rHA) 20%

Further to its stock exchange intimation dated 7 August 2024 in relation to successful completion of Phase I clinical trials, Shilpa Medicare Ltd announces that the results of its Phase I clinical trials were accepted by Subject Expert Committee (Haematology) (SEC) which has now provided approval to conduct Phase III clinical trials for Recombinant Human Albumin (rHA) 20%. The studies will be conducted based on the approved protocol by SEC.

Shilpa is the first company in India to receive the approval for conducting Phase III clinical trials. This approval clears regulatory strategy for India and various emerging markets that accept Indian studies and is an important step towards providing a reliable and safe alternative to human serum albumin, addressing the global demand and supply challenges.

About Albumin & Recombinant Human Albumin (rHA) 20%:

Albumin is in high demand for various medical treatments, including restoring blood volume and replacing lost fluids during accidents, serious burn injuries, fatal 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.

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



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

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.

For SHILPA MEDICARE LIMITED

Ritu Tiwary
Company Secretary & Compliance Officer