

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: 19th August, 2022

Corporate Relationship Department
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai – 400001

National Stock Exchange of India Limited
Exchange Plaza, 05th Floor,
Plot No: C/1, G Block,
Bandra Kurla Complex, Bandra (E)
Mumbai – 400051

Sub: Intimation U/R 30 of the SEBI (LODR) Regulations 2015- Reg.

Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Shilpa Medicare Limited Completes Human Clinical Studies of High concentration Biosimilar Adalimumab

Dear Sir / Madam,

This is to inform you that the Company, via its wholly owned subsidiary, Shilpa Biologicals Pvt Ltd (SBPL), has successfully completed the phase 3 Human Clinical studies of its first biosimilar, the 100mg/ml High Concentration (HC) Adalimumab biosimilar and has submitted the dossier to the CDSCO for review and grant of marketing/manufacturing license – a first in India.

The drug is expected to cater to the fast growing Rheumatoid Arthritis, Plaque Psoriasis, JIA, Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis, Crohns disease, HS and Uveitis markets – diseases where India has the largest patient populations.

While the actual dosage to the patients remains at 40mg and 80mg, the high concentration differentiated formulation of adalimumab enjoys the following advantages over the currently available 50mg/ml formulations –

- a. Lower pain/inflammation at the site of injection due to -
 1. Elimination of local inflammation causing components in the HC formulation
 2. Lower volumes delivered for the same dosage, as compared to the older formulations.
 3. Lower viscosity as compared to the older formulations – contributing to ease of delivery.
- b. In diseases like Crohns's Disease, Psoriasis, Ulcerative colitis, where the starting loading doses are high, the high concentration formulation turns out to be significantly more economical for patients and convenient for the doctors (as compared to the older formulations).
- c. Compatibility with autoinjector is higher for this formulation. SBPL intends to also provide patients with the option of self dosing at home via an autoinjector soon.



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

The Drug had global sales of approximately \$19 billion in 2021 and is amongst the most valuable drugs on the market today. The company expects to commercialise the product in the India & RoW markets starting from the end of the current calendar year. SBPL is building a strong biosimilars portfolio around Autoimmune disorders and Ophthalmics – via inhouse development and partnerships with global companies.

This biosimilar was fully developed at its integrated Dharwad facility. The company intends to ensure global accessibility to the product via differentiated pricing and formulations/delivery mechanisms.

SML views Biologics as a strategic growth area and has made significant investments in setting up a High end, Flexible Biologics facility in SBPL, Dharwad to cater to the requirements of the fast-growing biologics field, that include the DNA vaccine, adenoviral, subunit vaccines, Monoclonal antibodies & fusion proteins.

This is for your information and doing the needful.

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary

Company Secretary & Compliance Officer