



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: 27 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

Dear Sir/Madam,

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

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USFDA Approval for Bortezomib Injection NDA 212782

Shilpa Medicare Ltd announces the **approval of its second NDA [505(b)(2)]**, injectable product - Bortezomib Injection, by USFDA.

Bortezomib Injection is approved for subcutaneous or intravenous use. It is available as a single dose vial of 3.5 mg/1.4 mL (2.5 mg/mL).

This is the **first “liquid” injection for Bortezomib, approved for both subcutaneous and intravenous administration by the USFDA**. The Injection is “ready to use” for subcutaneous administration, offering significant advantages to the health care providers. The Injection has to be diluted for intravenous use. The reference product Velcade® is a lyophilized injection which requires reconstitution prior to administration.

Bortezomib Injection, a proteasome inhibitor, contains bortezomib which is an antineoplastic agent. This NDA provides for the use of Bortezomib injection for the treatment of adult patients with multiple myeloma and for the treatment of adult patients with mantle cell lymphoma.

“This second NDA approval in the US market from our novel injectable portfolio is a testament of our capabilities and commitment to introduce patient centric solutions that enhance compliance and ease of administration. I am very pleased to see that our relentless endeavour and self-belief of investing in various value added products across different segments have started paying off with monetization opportunities being created in each of the segments, laying a stronger foundation for the future”, said Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited.



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Shilpa’s Bortezomib Injection shall be marketed by our business partner, Amneal Pharmaceutical LLC USA. The current market for the lyophilised Bortezomib in the US is about USD 95 million (MAT Q4 2023).

For SHILPA MEDICARE LIMITED

Ritu Tiwary
Company Secretary & Compliance Officer