Innovating for affordable healthcare

Shilpa Medicare Limited

Corporate & Admin Office :

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CIN: L85110KA1987PLC008739

Dated: 05 Mar, 2021

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block
Bandra Kurla Complex, Bandra (E)
MUMBAI-400 051

Sub: Intimation U/R 30 of the SEBI (LODR) Regulations 2015- Reg.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Shilpa Medicare Limited receives US FDA tentative approval for Apremilast Tablets, 10 mg, 20 mg, and 30 mg

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Dear Sir/Madam,

This is to inform you that the Company has received U.S Food and Drug Administration tentative approval for its ANDA, Apremilast Tablets, 10 mg, 20 mg, and 30 mg dated 04 Mar 2021. The ANDA was filed as 'First to File' submission on NCE -1 date to seek eligibility for 180 days exclusivity.

Apremilast Tablets, 10 mg, 20 mg, and 30 mg is a generic equivalent of reference listed drug (RLD) OTEZLA of Celgene used in the treatment of 'psoriatic arthritis' as recommended in the label approved by FDA.

According to IQVIA MAT Q2 2020 data, the US market for Apremilast Tablets, 10 mg, 20 mg, and 30 mg is approximately US $2.4 billion.

This is for your information and doing the needful.

With Regards,

For SHILPA MEDICARE LIMITED

V.V. Krishna Chaitanya
Company Secretary

SHILPA MEDICARE LTD. RAICHUR