MEDICAMEN Biotech Limited

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CIN No.: L74899DL1993PLC056594

Ref: STEX/Announcement/2025-26 **Date: 03.06.2025**

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai – 400001

Code No: 531146

National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla complex
Bandra(E) Mumbai- 400051

Symbol: MEDICAMEQ

Sub: Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/ Ma'am,

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015:

We are pleased to share a significant milestone in our journey toward regulatory excellence. Medicamen Biotech Limited has received its first ***Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration (USFDA) today for Bortezomib for injection 3.5 mg.***

The ANDA is for Bortezomib for Injection, 3.5 mg Single-Dose Vial. The FDA has determined that Bortezomib for Injection, 3.5 mg Single-Dose Vial, is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Velcade for Injection, 3.5 mg/vial, of Takeda Pharmaceuticals U.S.A. Inc. (NDA-021602).

This achievement marks a major step forward in our commitment to enter in regulated markets. The Bortezomib API has been developed in its own R&D and API has been manufactured at Shivalik Rasayan having USDMF 036171, It is a testament to our capabilities to successfully develop and commercialize products using in house R&D capabilities and own API facility, built over last few years.it also demonstrate Medicamen's dedication to stringent quality standards, robust regulatory compliance, and adherence to Current Good Manufacturing Practices (cGMP).We remain fully committed to maintaining the integrity of our products and systems as we expand our footprint in the U.S. market.

This approval is a significant milestone for Medicamen's portfolio of vertically integrated drug products manufacturing.

Kindly take the information on record.

Thanking You

Yours truly,
For Medicamen Biotech Limited

PARUL CHOUDHARY
Digitally signed by PARUL CHOUDHARY
Date: 2025.06.03 12:45:34 +05'30'

Parul Choudhary
Company Secretary
ACS: 44157