Panacea Biotec

Innovation in support of life

20th May, 2019

The Manager, Listing Department
The National Stock Exchange of India Ltd.
Exchange Plaza, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol : PANACEABIO

The Manager, Listing Department
BSE Ltd.
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
BSE Scrip Code: 531349

Re.: Panacea Biotec receives Azacitidine USFDA approval for US Market

Dear Sir,

This is to inform that Panacea Biotec's Oncology Parenteral Formulation Facility at Baddi, Himachal Pradesh, India, received United States Food & Drug Administration (USFDA) approval for manufacture and supply of Azacitidine Injection, 100 mg/vial, for the US market. Panacea Biotec's state-of-the-art pharmaceutical formulation facility at Baddi is already approved by National Regulatory Authority (NRA) of India and USFDA for other oral solids and injectable products.

Panacea Biotec had earlier entered into a tripartite agreement with Natco Pharma Ltd. ("Natco") and Breckenridge Pharmaceutical Inc. USA ("Breckenridge") for manufacturing and supply thereof for the US market under Breckenridge's existing approved ANDA for Azacitidine for Injection 100mg/vial, generic equivalent of Vidaza, marketed by Celgene Corp, US. The supplemental abbreviated new drug application (sANDA) submitted by Natco as "Prior Approval Supplement" has recently been approved by the USFDA.

Azacitidine is a chemotherapy drug used to treat myelodysplastic syndromes (MDS) with annual sales of about USD 110 Mn in US markets as per IQVIA data as of December, 2018.

Kindly acknowledge the receipt.

Thanking you,

Sincerely yours,

for **Panacea Biotec Ltd.**

Panacea Biotec Ltd.

Vinod Goel
Group CFO and Head Legal
& Company Secretary

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