Panacea Biotec

Innovation in support of life

9th March, 2018

The Manager, Listing Department
National Stock Exchange of India Ltd.
Exchange Plaza, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
Fax No.:022-26598237 / 38
NSE Symbol: PANACEABIO

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai – 400 001
Fax No.:022–22721919, 3121
BSE Scrip Code: 531349

Re.: Press Release - Panacea Biotec Ltd. announces receipt of Establishment Inspection Report (EIR) from USFDA

Dear Sir,

Panacea Biotec Ltd. (PBL) is pleased to announce the receipt of Establishment Inspection Report (EIR) from the U.S. Food & Drug Administration ('USFDA') indicating the formal closure of the Inspection conducted by USFDA, at its Pharmaceutical Formulation Facility for Oncology Parenteral and Oral Solids Dosage at Malpur, Baddi, District Solan, Himachal Pradesh, India.

The release of EIR notification by USFDA indicating inspection is "closed" means, the USFDA has concluded review of the Company's manufacturing activities and the company is allowed to continue supply of all the approved drug products by USFDA into inter-state commerce. The EIR notification also accelerates approval process for submitted drug product applications.

A copy of the Press Release titled "Panacea Biotec Ltd. Announces Receipt of Establishment Inspection Report (EIR) from USFDA" being issued to the media, etc. in this regard is enclosed for your kind reference and record please.

Kindly acknowledge the receipt.

Thanking you,

Sincerely yours,

for **Panacea Biotec Ltd.**

Vinod Goel
Group CFO and Head Legal
& Company Secretary

Encl. As Above

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Press Release

Panacea Biotec Announces Receipt of Establishment Inspection Report (EIR) from USFDA

New Delhi, March 9, 2018: Panacea Biotec, one of India's leading research based health management company, is pleased to announce the receipt of Establishment Inspection Report (EIR) from the U.S. Food & Drug Administration ('USFDA') indicating the formal closure of the Inspection conducted by USFDA, at its Pharmaceutical Formulation Facility for Oncology Parenteral and Oral Solids Dosage at Malpur, Baddi, District Solan, Himachal Pradesh, India.

Panacea Biotec has state-of-the-art pharmaceutical formulation facility located at Baddi for Oral Solids and Oncology Parenteral Formulations. The Company has been supplying products in US markets for approved ANDAs manufactured in Oral Solids Dosage Facility. A number of abbreviated new drug applications (ANDAs) submitted by the Company, referring these facilities, are also at various stages of approval by USFDA.

The Oral Solids manufacturing facility located at above site has a history of completion of 5 consecutive successful cGMP and Pre-Approval Inspections by USFDA in last 8 years. The manufacturing facility of Oncology Parenteral Formulations has been inspected successfully for the 2nd time by USFDA.

The release of EIR notification by USFDA indicating inspection is "closed" means, the USFDA has concluded review of the Company's manufacturing activities and the company is allowed to continue supply of all the approved drug products by USFDA into inter-state commerce. The EIR notification also accelerates approval process for submitted drug product applications.

Commenting on the development, Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec said "This EIR notification again demonstrates the Company's ability to produce drugs in cGMP compliant environment in a sustainable manner. We remain committed to continue to manufacture and supply quality products to cater to patients' needs across several markets including USA."

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Panacea Biotec Ltd.

About Panacea Biotec

Panacea Biotec Limited is a leading research based biotechnology company with established research, manufacturing and marketing capabilities. It is one of the largest vaccine producers and biotechnology companies in India.

Panacea Biotec is the first company to have developed World's first fully-liquid Quadravalent Vaccine **Easyfour-TT** (DTwP-Hib) Pentavalent Vaccine **Easyfive-TT** (DTwP-HepB-Hib), monovalent Polio vaccine against Type 1 and Type 3 Polio virus and **World's First Fully Liquid whole cell Pertussis (wP) based Hexavalent Combination Vaccine, EasySix**^{TM}.

The Company is also amongst the top 15 pharmaceutical companies (AIOCD AWACS-MAT MAR-2017) in its represented market India and amongst top 60 pharmaceutical Companies in India (AIOCD AWACS-MAT MAR-2017). The Company has been awarded with the prestigious **"India Innovation Award 2016 – Top 50"** by Clarivate Analytics.

The product portfolio of includes highly innovative products in therapeutic areas of oncology, organ transplantation, nephrology, diabetes, osteoporosis, cardiovascular diseases and pediatric vaccines. It is working on a robust pipeline of high barrier to entry generics products, thus leveraging its capabilities in the areas of nanotechnology and platform drug delivery technologies like micro-particles, liposomes, gastroretentive systems. Panacea Biotec has introduced its products in over 20 countries across the world including USA and Germany through a combination of strategic collaborations and direct presence in select geographies.

The Company has research collaborations with leading national and international research organizations and corporations. The company's state-of-the-art manufacturing facilities for vaccines and pharmaceutical formulations comply with several leading regulatory agencies worldwide. The company has around 2,500 employees including around 100 scientists working across 4 R&D centers of the Company.

Caution Statement:

Certain statements made above may be "forward looking statements" within the meaning of applicable laws and regulations.

For more information, please contact –

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