

30th November, 2017

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 announces acceptance of its ANDA for Paclitaxel Protein Bound Particles by US FDA

Dear Sir,


The Company is delighted to announce that its abbreviated new drug application (ANDA) submitted under section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) for Paclitaxel Protein Bound Particles for injectable Suspension, 100mg/vial has been accepted for filing by the U.S. Food and Drug Administration (FDA).

This product is the generic version of Abraxane, marketed for the treatment of Metastatic Breast Cancer, Non-Small Cell Lung Cancer and Adenocarcinoma of the Pancreas in the US market.

A copy of the Press Release 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.**



Devender Gupta
Chief Financial Officer



Encl.: As above.

Corporate Address:-B-1 Extn./G-3, Mohan Co-op. Indl. Estate, Mathura Road, New Delhi - 110 044, India
Ph.: +91-11-4167 9000, 4157 8000, Fax: +91-11-41679070, Email: corporate@panaceabiotec.com

Panacea Biotec Ltd.

CIN: L33117PB1984PLC022350

Registered Office: Ambala-Chandigarh Highway, Lalru - 140 501, Punjab, India. Ph.: +91-1762-505900, Fax: +91-1762-505906.
e-mail: corporate@panaceabiotec.com website: www.panaceabiotec.com

Press Release

Panacea Biotec announces acceptance of its ANDA for Paclitaxel Protein Bound Particles by US FDA

New Delhi – November 30, 2017

Panacea Biotec, India's highly progressive research based pharmaceutical and biotechnology Company, announced that its abbreviated new drug application (ANDA) submitted under section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) for Paclitaxel Protein Bound Particles for injectable Suspension, 100mg/vial has been accepted for filing by the U.S. Food and Drug Administration (FDA).

This product is the generic version of Abraxane, marketed for the treatment of Metastatic Breast Cancer, Non-Small Cell Lung Cancer and Adenocarcinoma of the Pancreas in the US market.

The annual sale of Abraxane worldwide is approximately US\$973.4 million and approximately US\$633.8 million in the US. (Source: Celgene Annual Report 2016, Page 53&54)

Panacea Biotec has already commercialized this product in India and emerging markets like Sri Lanka, Turkey etc. under the trademark - **PacliALL**. The company looks forward to commercializing this product in US and several other markets worldwide in collaboration with Apotex.

Speaking on the occasion Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec Ltd. said "The FDA's acceptance of our ANDA filing is an important milestone for our 'Best-few' products development program and oncology portfolio as a whole. This ANDA filing acceptance gives us confidence in the strong understanding of science of developing such complex products at each level in the company, right from R&D to Operations, to ensure sustainable performance in years to come".

About Panacea Biotec

Panacea Biotec is a leading pharmaceutical and biotechnology company with established Research, Manufacturing and Marketing capabilities. The Company is also amongst the top 15 pharmaceutical companies (AIOCD AWACS-MAT MAR-2017) in its represented market in India and amongst top 60 pharmaceutical Companies in India. The Company has been awarded twice (for 2015 & 2016) with the prestigious "India Innovation Award 2016 – Top 50" by Clarivate Analytics (Thomson Reuters).

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The product portfolio 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, gastro-retentive systems.

It has introduced its products in around 30 countries across the world, including USA, Germany and Russian Federation, 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 standards laid down by 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. For more details, please visit www.panaceabiotec.com

About Apotex

Apotex is a Canadian based, global pharmaceutical company, employing over 11,000 people in research, development, manufacturing and distribution facilities worldwide. Apotex is a vertically integrated business that includes generic medicines, biosimilars, active pharmaceutical ingredients and innovative pharmaceuticals. It produces more than 300 generic molecules in approximately 4,000 different dosages and is the 8th largest generic pharmaceutical company by prescriptions in the U.S. The company's U.S. headquarters is based in Weston, Florida. For more information on the Company, please visit <http://www.apotex.com>

For more information, please contact –



Devender Gupta

Chief Financial Officer

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