



Panacea Biotec

Innovation in support of life

Press Release

Immediate Release

Panacea Biotec Announces Launch of Prasugrel Tablets (its first-to-file ANDA) in US Market

New Delhi – 24th Oct 2017:

Panacea Biotec, India's highly progressive research based biotechnology Company, announced that its first-to-file ANDA of Prasugrel 5mg and 10mg tablets has been approved by the United States Food & Drug Administration (U.S.FDA).

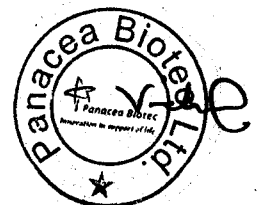
Under the provisions of Hatch-Waxman Act, Panacea Biotec is entitled for 180-days of shared marketing exclusivity for Prasugrel HCL tablets with this final FDA approval. The Company earlier got the tentative approval for this ANDA on 24th May 2017.

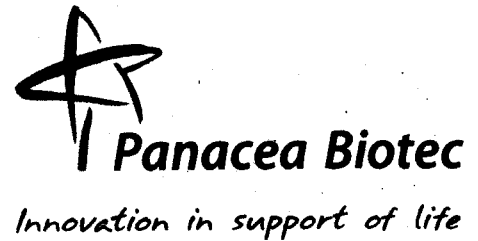
The product has been launched in the market by Apotex Corp., the largest Canadian-owned pharmaceutical company which is the exclusive sales and distribution partner for this product in USA. Prasugrel is indicated for reduction of thrombotic cardiovascular events (including stent thrombosis) in people with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI). The annual sale of Prasugrel prior to the entry of generics in the market was approximately \$ 600 million in USA.

Speaking on the occasion Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec Ltd said "Approval and launch of this first to file ANDA product is an important milestone to achieve growth in our US business!"

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. The Company is also amongst amongst the top 15 pharmaceutical companies (AIOCD AWACS-MAT MAR-2017) in its represented market India and amongst top 60 pharmaceutical Companies in India. 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. 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 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.

About Apotex Inc.

Apotex Corp. is a proudly Canadian, global pharmaceutical company, employing over 11,000 people in research, development, manufacturing and distribution facilities worldwide. Apotex is an 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 Apotex Corp's website at <http://www.apotex.com>

For more information, please contact –

For Panacea Biotec

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