



Panacea Biotec

Innovation in support of life

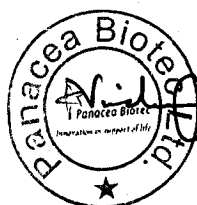
Panacea Biotec announces strategic alliance with Kremers Urban for 11 High Barrier to Entry Generics; and the launch of Tacrolimus Capsules in US

Synopsis:

- The strategic alliance includes 11 high barrier to entry generics, representing a total business potential of USD 4 billion of innovator sales. The first product to reach the market from this portfolio is Tacrolimus Capsules.
- Panacea Biotec's ANDA for Tacrolimus Capsules was approved on 28th Sep 2012.
- Apart from Tacrolimus; ANDA for one out of the 10 remaining products has been filed in Sep 2012 and subsequent ANDAs will be filed over the next 16 months.
- Tacrolimus will be launched in USA in November, 2012 and would be manufactured in Panacea Biotec's USFDA approved facility.
- The total market size of Tacrolimus capsules in US is USD 892 Mn.

New Delhi: 19th November 2012: Panacea Biotec, India's highly progressive research based health management company has entered into a strategic alliance with Kremers Urban Inc. (part of UCB Group) for 11 high barrier to entry generics, whose market size in US at the innovator level is around USD 4 billion.

The first product in this portfolio to reach the market is Tacrolimus Capsules that is being launched in US in Nov 2012. Panacea Biotec was granted approval of the product from the United States Food and Drug Administration (FDA) in September 2012. Tacrolimus is used along with other medications to prevent rejection (attack of a transplanted organ by the immune system of a person receiving the organ) in people who have received organ transplants. Tacrolimus is in a class of medications called immunosuppressants. It works by decreasing the activity of the immune system to prevent it from attacking the transplanted organ.





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The total market size of Tacrolimus is approximately USD 892 million in US. Currently there are 5 generic players in US; namely Sandoz, Dr Reddy's, Mylan, Watson and Accord

Healthcare. The innovator brand Prograf® accounts for approximately 43% of Tacrolimus sales in terms of units sold and generics account for the remaining 57%.

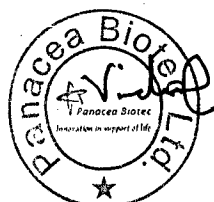
Commenting on the development, Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec Ltd said "Panacea Biotec's proven track record in building strong, collaborative working relationship is a key driver for this strategic alliance with Kremers Urban that will accelerate the company's growth plans in the US. Approval of Tacrolimus from US-FDA is the first milestone achieved in Panacea Biotec's long term plan for USA; the largest pharmaceutical market in the world. This would be followed by a series of high barrier to entry generic product launches that are being developed by the company. The commercialization strength of Kremers Urban for high barrier to entry generics perfectly synergizes with Panacea Biotec's research, development and manufacturing capabilities for such complex products forming a true win-win strategic alliance."

Under the terms of the agreement Panacea Biotec would be responsible for research, development, registration and commercial supplies of the products while Kremers Urban would be responsible for marketing, sales and distribution. The business collaboration is based on long term profit sharing by both companies.

Submission of the first ANDA within this basket of 10 additional products was done in Sep 2012. The remaining 9 ANDAs would be submitted with USFDA over the next 16 months' time period.

About Panacea Biotec

Panacea Biotec is one of India's leading research-based health management companies with established research, manufacturing and marketing capabilities. Panacea Biotec is the 2nd largest vaccine producer in India and is also amongst the top 50 pharmaceutical companies in India based on domestic market sales. The product portfolio of the Company includes highly innovative prescription products in important therapeutic areas such as organ transplantation, pain management, diabetes, renal-disease, cardio-vascular, gastro-intestinal care products and vaccines. The company has collaborations and tie-ups with leading national and international research organizations and corporations. The company's state of the art manufacturing facilities for formulations have been approved by the US-FDA, German Regulatory Agency, TGA Australia, Anvisa Brazil amongst many other global regulatory authorities.





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Panacea Biotec has four dedicated research and development centers with a diverse product pipeline consisting of High Barrier to Entry Generics, Drug Delivery Systems, NCEs, Biosimilars and Vaccines. The company has 3,300 employees with 275 scientists working in R&D.

About Kremers Urban

Kremers Urban Pharmaceuticals Inc., is a specialty generic drug manufacturer and subsidiary of Belgium-based UCB, and is a pioneer in developing generic versions of pharmaceutical products that have a "high barrier to entry". The Company is moving to the forefront of delivering the tough solutions necessary to get complex products into the market.

About Panacea Biotec's Tacrolimus

Panacea Biotec has been in the forefront of immunosuppressive therapy in India and Emerging Markets and Panacea Biotec's Tacrolimus is supported by extensive clinical experience giving it a unique positioning. Panacea Biotec launched Tacrolimus in India in 2004 and since then the product has been registered in 18 countries across the world; including Germany, Brazil and Turkey. The product was launched in Germany under the brand name 'TacPan' in 2011 through a wholly owned subsidiary Panacea Biotec Germany GmbH.

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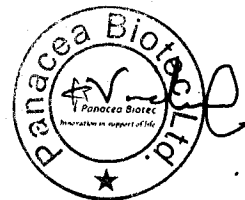
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