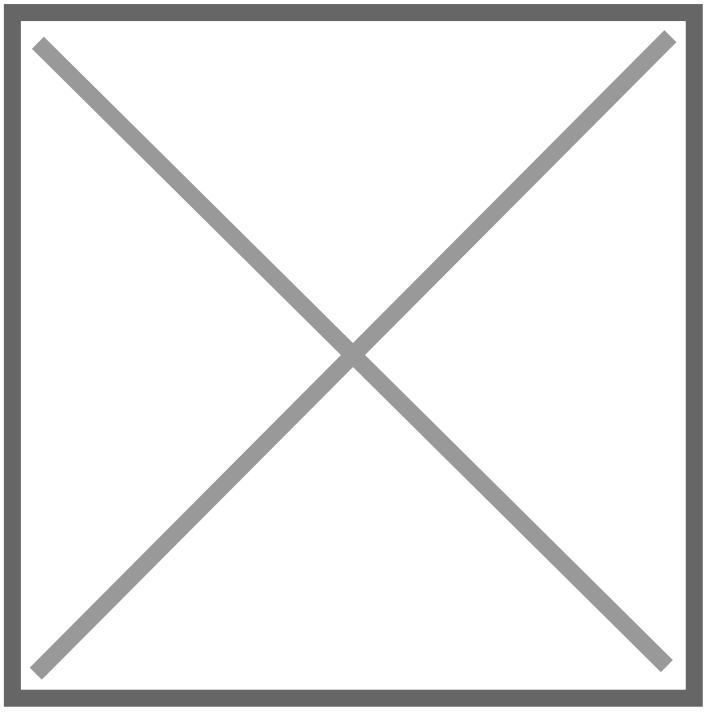
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Indian firms harness streptokinase

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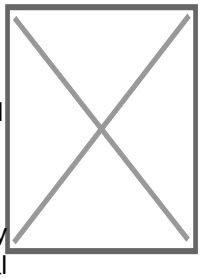


Bharat and Shantha make India proud in biopharma.

India can take pride in another development. In October, two Hyderabad-based companies Bharat Biotech and Shantha Biotechnics have announced the launch of Streptokinase, a drug for dissolving blood clots and used as a life-saving drug in case of acute heart attacks and other conditions like deep vein thrombosis, arterial occlusions and pulmonary embolism.

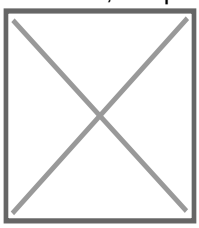
It is believed the duo are the first few biotechnology companies India to launch indigenously developed products. With this the battle for control of the streptokinase battle has begun.

Though there would a silent battle between the two players because they have the same place of origin, the real battle is the desi versus MNC brands. There would also be a debate as to what is so great in developing Streptokinase. It is not a technical marvel. But the counter is if it was not so great why have others not developed it? Three things matter, technology, market opportunity, and the ability to develop and set up the facility. The two have been able to put all this together.



According to market feedback, Streptokinase is currently available at Rs 3,800 a dose. The affordability of the drug is important in the light of the fact that over 60 million Indians are affected with coronary arterial disease and according to WHO by the end of this century India would account for more than half of the total heart patients in the world. "The market for Streptokinase in India is valued at over Rs 65 crore and is poised to grow at 25 percent per annum," said Varaprasad Reddy, MD, Shantha Biotechnics. Bharat too gives a similar market estimate.

Bharat Biotech's recombinant Streptokinase, called Indikinase, is a protein produced from genetically manipulated Escherichia coli. This enzyme is a first line therapy for management of acute myocardial infarction, deep vein thrombosis, arterial occlusion, etc. The total project cost was Rs 30 crore for



producing Indikinase. Technology Development Board, DST funded Rs 11 crore, SBI Rs 7 crore, the rest mobilized by internal generation. The product has been duly approved by national regulatory committees. It estimates the market size for the product to be around Rs 50 crore. Said Dr Krishna M Ella, chairman and managing director, Bharat Biotech, "Manufacturing indigenously, the cost of this drug, which has all along been imported into India, can come down. The recombinant Streptokinase scores over its non-recombinant counterpart in many respects. The most significant one being able to prevent excessive bleeding compared to the existing products."

Shantha Biotechnics, after three years of R&D and an investment of Rs 10 crore, announced the launch of its third recombinant product Streptokinase, branded Shankinase. According to the company, this indigenous clot buster drug recombinant Streptokinase conforms to international standards. "We benchmark our products against the highest quality and

lowest end-user prices," said Varaprasad Reddy, MD, Shantha Biotechnics. Shankinase is likely to be priced in the Rs 1,000 bracket. "The pricing will be in consonance with our commitment to highest quality at affordable prices," said Reddy. According to the company release, the safety and efficacy of Shankinase compared with commercially available natural Streptokinase in patients with acute Myocardial Infarction (heart attack) was proven in a multi-centric double blind randomized phase III trials. The drug's potency was tested by chromogenic assay method and certified by a third party international authority, National Institute of Biological Standards and Controls, UK.

"Shankinase aims to garner a 10 percent market share in the year following the launch," said Reddy. He added, "Doctors are the acid test of the efficacy of any drug," said Reddy confident that Shankinase too will bag all the kudos and the awards just like the earlier two products from the company. The pricing of Indikinase is not yet announced, but it too could be in the same range as Shantha.

It is not that there are no other biotech Streptokinase. Cadilla Pharma has a Streptokinase, which is a thrombolytic agent of bacterial origin, STPase. CPL's streptokinase brand is a purified preparation of Streptokinase produced through bacterial fermentation. The product thus produced, is purified using the most sophisticated protein purification techniques. And CPL claims that its STPase is the only streptokinase indigenously produced in India, which is at par with world standards. Irrespective of who has what products, who claims what, the good news is that Indian are building the capabilities.

Ch. Srinivas Rao, with inputs from Nandita Singh in Hyderabad