

Press Release Details

Title 09 Aug BBIL – The First Indian Company to be Awarded Commercial
 2003 Licence to Manufacture Streptokinase

Details

BBIL – The First Indian Company to be Awarded Commercial Licence to Manufacture Streptokinase :: Currently there is no Recombinant Streptokinase available in India today. Bharat Biotech is the first Company in India to get a commercial license for manufacture and market of Recombinant Streptokinase. :: Bharat Biotech is a second Company in the world to develop a commercially viable recombinant Streptokinase.

Hyderabad, August 9, 2003: Bharat Biotech International Limited (BBIL) in Hyderabad has become the first Biotechnology company in the country and second of its kind in the world to manufacture and market Recombinant Streptokinase – the primary drug for dissolving blood clots, a common occurrence during a heart attack. The Drug Controller General of India, the national regulatory authority for Indian pharmacopoeia, granted the commercial licence to BBIL on Thursday, August 14, 2003.

“The licence will help us realise our dream of making life-saving drugs affordable to the common man,” said Dr.Krishna M. Ella, the Chairman & Managing Director of BBIL. “By manufacturing indigenously, we can bring down the cost of this drug, which has been all along imported into India. 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,” he added.

BBIL’s Recombinant Streptokinase 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 and pulmonary embolism.

Streptokinase is a Plasminogen activator and its major application is in the Thrombolytic therapy for the early management of Myocardial Infraction (MI). Plasminogen activators are life-saving drugs administered in emergency to save patients with acute MI.

The Technology Development Board, Department of Science & Technology, GoI has funded the Rs. 30 crore Recombinant Streptokinase project, which has been completed by BBIL. Funded by Technology Development Board of India (Rs.1,100 lakhs), SBI, Overseas Branch (Rs.700 Lakhs) and rest (Rs.1200 lakhs) by Internal generation.

Consistent with the corporate vision, BBIL has initiated several key research projects in-house and by the way of collaborative research initiatives to address several critical care segments.

BBIL has exclusive production, formulation and packing facilities for manufacturing Streptokinase. The plant has been constructed in accordance with norms set by US FDA and UK MCA. The company has also filed for process patent in the United States in the Year 2000.

BBIL’s Streptokinase has been duly approved by national regulatory committees such as Review Committee of Genetic Manipulation (RCGM), Genetic Engineering Approval Committee, Ministry of Environment & Forests, Recombinant Deoxyribonucleic Acid (RDNA) Committee and by the Drug Controller General of India.

BBIL’s Streptokinase will be much more economically priced compared to the currently imported

products. This has become possible because of BBIL's cutting-edge technology advantage and its innovative R&D; approach.