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Mission: Produce generic version of exenatide

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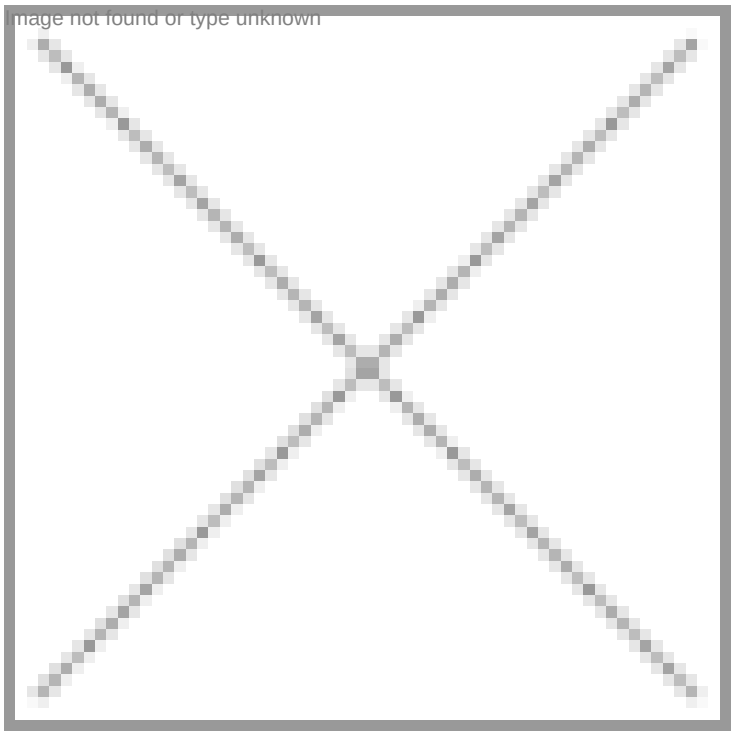
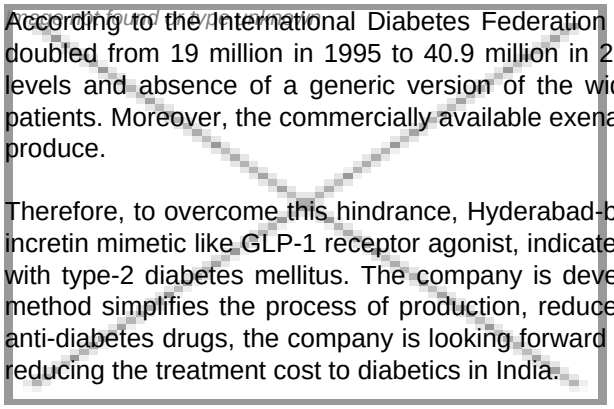


Utilizing the SIBIRI funding, Vivo Bio Tech is working towards developing and launching the generic version of diabetes-controlling molecule exenatide to reduce treatment cost



According to the International Diabetes Federation (IDF) estimate, the number of diabetic patients in India has more than doubled from 19 million in 1995 to 40.9 million in 2007. The projected increase to 69.9 million by 2025, the high incidence levels and absence of a generic version of the widely used drug, exenatide, has increased the suffering of the diabetes patients. Moreover, the commercially available exenatide is synthesized by peptide synthesizer and, hence, is expensive to produce.

Therefore, to overcome this hindrance, Hyderabad-based Vivo Bio Tech has initiated a project on recombinant exenatide, an incretin mimetic like GLP-1 receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus. The company is developing the product through recombinant DNA technology in E.coli. This method simplifies the process of production, reduces cost and also increases yield. Owing to the large market potential for anti-diabetes drugs, the company is looking forward to developing and launching the generic version of the molecule, thereby reducing the treatment cost to diabetics in India.

After approval from the scientific and financial experts designated by the Department of Biotechnology on the technical and economic viability of its project, the company was awarded the small business innovation research initiative (SBIRI) funding through phase II scheme in February 2011. The total project cost of production of recombinant exenatide (incretin mimetic like GLP-1) is ₹580 lakhs and the funding support from the SBIRI allotted is ₹340 lakhs. So far, the company has received the first installment of ₹224.3 lakhs and it has proved to be a major boost for its efforts. The duration of the project is two years.

Talking about the importance of funding, Dr A Sankaranarayanan, CEO, Vivo Bio Tech, says, “The funding was very important as the drug development projects involve long gestational period without any income during the development. The funding pattern and repayment schedule offered by the SBIRI is very industry-friendly, as the repayment starts 10 years after completion of the project in 10 equal installments. During this time, we would be able to successfully complete the project, launch the product in the market, generate post-marketing data, and also record significant revenues from the sales of the product.”

The way forward

According to the company, the project is progressing as per the project implementation plan approved by the SBIRI. Given the positive results, the company is now anticipating submitting preclinical application to the Review Committee on Genetic Manipulation within a couple of months. “We have successfully completed our objectives set forth for the first quarter. These include preparation of cell banks and optimization of lab scale fermentation of recombinant exenatide clones. Now, we look forward to its submission for preclinical submission soon,” says Dr Sankaranarayanan.

While praising the efforts of the DBT, Dr Sankaranarayanan says, “The PPP in biotech industry is the single most enabling means to promote biotech R&D in the country. The initiatives by SBIRI, BIRAP and other agencies under the DBT are a boon to small and mid-size companies striving to make a mark in the industry.”