

Biocon to conduct oral insulin trials on its own

Biopharma major to conduct tests with larger patient pool including in India

Raghu Krishnan | Bengaluru | January 27, 2016

http://www.business-standard.com/article/companies/biocon-to-conduct-oral-insulin-trials-on-its-own-116012700346_1.html

Biopharma major Biocon Ltd will conduct on its own the next phase of clinical trials of its oral insulin Tregopil with a larger patient pool including in India, as the company expects the drug, after regulatory approvals, would offer it licensing opportunity to global drug firms.

India has around 69 million of the 414 million diabetes patients globally, according to the International Diabetes Federation.

Biocon had partnered with British drug maker Bristol Myers Squibb (BMS) for the initial clinical studies in the US on insulin Tregopil under a US investigational new drug application (IND) that yielded positive results. Since then, BMS had hived off its diabetes franchise to AstraZeneca.

"The initial round of studies, which were conducted on about 100 subjects, have demonstrated fast action of Insulin Tregopil with distinct properties compared to other prandial insulins like Aspart," said Kiran Mazumdar Shaw, chairperson and managing director of Biocon. "We cannot discuss specific timelines for the next phase of clinical studies, but suffice to say that we have assembled a world renowned group of endocrinologists and diabetologists to work with us to drive the development of this important molecule."

Biocon plans to spend around 10-12% of its Biopharma revenues on research and development on drugs. In the October to December quarter, it spent Rs 91 crore on R&D.

Typically, a new drug development costs around \$1 billion for Pharma companies globally.

Biocon said that it has rationalised products in its branded formulations and focused on higher margin products in the Indian market.

"Our endeavour is to make sure these key brands grow faster than the current pace so that they make up for the rationalized products. e.g. in our flagship segment, we have held a steady 10% market share in represented insulins market and have

Business Standard

strengthened our offering recently with Basalog One, a ready-to-use disposable device for glargine an insulin analog," Shaw said..

The firm said its products for Hepatitis C and cancer has been received well by doctors.

Biocon said it is on track for regulatory filings for four biosimilar and generic insulin drugs in the US and Europe in 2016, which would help the firm to get an early mover advantage in an addressable \$30 billion market.

"As part of our global biosimilars strategy, Biocon is targeting emerging markets (EMs) in the near term and developed markets subsequently. EMs represent 12-15% of the global opportunity for many of the key biosimilars in our portfolio, she said. We aim to be present in the top 10-15 EMs, which account for over 90% of the overall EMs opportunity. In many of these top 15 Ems, we are either already partnered or in advanced stages of discussion with respect to our biosimilars", " said Shaw.