

Biocon's biosimilars enter global Phase-3 trials

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The partnership has a strong portfolio of generic insulin analogs and biosimilars including Monoclonal Antibodies (MAbs) and recombinant proteins at various stages of development.

Biosimilars

Two molecules Pegfilgrastim (PEG-G-CSF) and Adalimumab have entered global Phase-3 clinical trials. While the PEG-G-CSF trial is well underway the Adalimumab trial has been recently initiated, said the company in a statement.

In addition, the Phase-3 global clinical trial for Trastuzumab is progressing in more than 100 sites around the world. An initial ROW focused Phase-3 trial for Bevacizumab is also underway, said Biocon.

Generic Insulin Analogs

Two global clinical trials for generic Insulin Glargine initiated in 2014, have also made significant progress.

The patient recruitment for Type-1 diabetes study has been completed ahead of schedule, while the recruitment for Type-2 diabetes study is expected to be completed by July 2015, said company.

Dr Arun Chandavarkar, CEO and JMD, Biocon, said, "The advancement of these programs in the clinic represents significant progress towards providing these high quality biologics to patients across the world. I am confident that, together with our partner Mylan, we can build a strong global presence in generic Insulin analogs and biosimilars like monoclonal antibodies and recombinant proteins to address the need for affordable access to these biologics."

As part of a shared commitment to provide access to high-quality and affordable biopharmaceuticals, Biocon and Mylan have

established a strong collaborative RnD partnership for both generic insulin analog products and a high-value portfolio of biosimilars for oncology and autoimmune indications.

Biocon today has one of the largest generic insulin analogs and biosimilars portfolio in advanced stages of development with five molecules in Phase-3 clinical trials, viz. Glargine, Pegfilgrastim, Adalimumab, Bevacizumab and Trastuzumab.

"As we move into FY16, we clearly see our biosimilar strategy playing out with greater clarity, credibility and traction visible across our portfolio of Biologics as they advance in clinical development. We continue to make investments in R&D as a strong future value driver for Biocon," the company said.