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Biocon's Transtuzumab receives marketing authorization in India

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Trastuzumab will be marketed in India under the brand name of *CANMAb* by Biocon, and is expected to be available to Indian patients in Q4 FY14.

Trastuzumab is also the world's first biosimilar version of 'Herceptin' to be brought to the market.

Every year, over 100,000 new breast cancer patients are diagnosed with this disease. The cost of biologics in cancer treatment is extremely high which makes access unaffordable to a large patient pool.

Speaking on the occasion, Ms Kiran Mazumdar Shaw, CMD, Biocon, said, "This is a major milestone for both partners as it is the world's first biosimilar to be accorded regulatory approval. We plan to make CANMAb available to Indian patients in Q4 FY14."

Ms Shaw further added, "The meticulous development of this important cancer drug has involved extensive product characterization and clinical trials to demonstrate comparability and similarity in PK (pharmacokinetic), safety, efficacy, and immunogenicity against the innovator product. We are committed to affordable cancer care and believe that Trastuzumab will expand patient access to this life saving drug. The Indian approval is an encouraging milepost as we plan to leverage this data to support regulatory filings in several countries across the globe."

Trastuzumab is expected to offer an alternative affordable option, thereby enhancing access to treatment for cancer patients in India and the world over said the press release on Tuesday.

The global sales for Trastuzumab stood at US$ 6.4 billion in 2012, while in India it recorded sales of approximately US$ 21 million.

Since 2009, Biocon and Mylan have been involved in co-developing of biosimilar monoclonal antibodies and complex biologics comprising, Trastuzumab, Pegfilgrastim, Bevacizumab, Adalimumab and Etanercept.

The Innovator product sales of these products in 2012 were pegged at US$ 34 billion.

The patent expiry of these products in regulated markets is expected from 2015 onwards.

In 2013, this partnership was extended to co-development of biosimilar Insulin analogs for the global markets.

The overall global opportunity for biosimilars is estimated to be US$ 22 billion by 2020.