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Herceptin (Trastuzumab) Biosimilar Clinical Trial Insight

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Abstracts

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“Herceptin (Trastuzumab) Biosimilar Clinical Trial Insight” report by PNS Pharma gives comprehensive clinical insight on 37 biosimilar version of Herceptin drug in clinical pipeline. Currently there are 4 biosimilars in Phase-III trials and are expected to be commercially available in next 5-8 years. Currently 3 biosimilar version of Herceptin are commercially available in India and Iran for the treatment of Breast cancer. The patent on Herceptin expired in 2014.

Trastuzumab or Herceptin is a recombinant DNA derived humanized monoclonal antibody that interferes with the HER2/Neu receptor. It is the most common biological therapy used particularly for breast cancer, against the Her2+ receptor which stands for Human Epidermal Growth Factor Receptor 2-positive. In some cancers, notably certain types of breast cancer, HER2 is over-expressed, and causes cancer cells to reproduce uncontrollably.

Herceptin as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease. Herceptin in combination with paclitaxel is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have not received chemotherapy for their metastatic disease.

The mechanism of action of this drug is observed clearly in Breast cancer, as HER 2 is overexpressed allowing the cell proliferation in uncontrolled manner. The trastuzumab binds to the domain IV of the extracellular segment of HER2/Neu receptor and the drug

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causes the arrest during G1 phase of cycle, thus reduced proliferation and moreover, it down regulates the activation of AKT pathway too thus ending the uncontrolled cell differentiation.

Herceptin, one of Roche's three HER2+ breast cancer drugs, recorded a 15% sales increase in the US and a 10% rise overall. Sales were driven by longer duration of treatment in combination with Perjeta, another HER2+ breast cancer treatment from Roche, for both early and advanced breast cancer. China and Brazil also contributed to strong growth in Herceptin sales.

It costs around US$ 70,000 for full course treatment, thus allowing the big blockbuster for Roche with the sales of US$ 6.79 Billion in 2015; it is the drug that remained third best seller after about 15 years on the market. Roche has changed the trade name of the drug and has re-introduced an affordable version of the same in the Indian market. The new drug named Herclon would cost approximately INR 75,000 (US$ 1122) in the Indian market.

Biocon Limited, a pharmaceutical in India had received Marketing Authorization from the Drugs Controller General of India (DCGI) for its biosimilar Trastuzumab being developed jointly with Mylan, for the treatment of Her 2+ metastatic breast cancer. The regulatory approval for biosimilar Trastuzumab in India is the world’s first biosimilar version under the brand name of CANMAb.

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