

Herceptin (Trastuzumab) Biosimilar Clinical Trial Insight

https://marketpublishers.com/r/H3ED887154EEN.html

Date: October 2016

Pages: 85

Price: US\$ 1,500.00 (Single User License)

ID: H3ED887154EEN

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



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.



Contents

1. HERCEPTIN (TRASTUZUMAB) CLINICAL INSIGHT

- 1.1 Clinical Introduction
- 1.2 Company Partnerships & Agreements
- 1.3 Patent Analysis by Indication
- 1.4 Brand Names by Country/Region

Herceptin Biosimilars Clinical Insight by Company

2. BOW

- 2.1 Clinical Insight
- 2.2 Development Timeline
- 2.3 Phase of Development

3. TRASTUZUMAB BIOSIMILAR - ISU ABXIS

- 3.1 Clinical Insight
- 3.2 Development Timeline
- 3.3 Phase of Development

4. TRASTUZUMAB BIOSIMILAR - ALLERGAN/AMGEN

- 4.1 Clinical Insight
- 4.2 Development Timeline
- 4.3 Phase of Development

5. TRASTUZUMAB BIOSIMILAR - ALTEOGEN/CRISTALIA

- 5.1 Clinical Insight
- 5.2 Development Timeline
- 5.3 Phase of Development

6. TRASTUZUMAB BIOSIMILAR - ARYOGEN BIOPHARMA

- 6.1 Clinical Insight
- 6.2 Development Timeline
- 6.3 Phase of Development



7. TRASTUZUMAB BIOSIMILAR – AXXO

- 7.1 Clinical Insight
- 7.2 Phase of Development

8. TRASTUZUMAB BIOSIMILAR – BIOCAD

- 8.1 Clinical Insight
- 8.2 Development Timeline
- 8.3 Patent Analysis

9. TRASTUZUMAB BIOSIMILAR - BIOCND/GENOR BIOPHARMA

- 9.1 Clinical Insight
- 9.2 Development Timeline
- 9.3 Phase of Development

10. TRASTUZUMAB BIOSIMILAR - BIOCON/MYLAN

- 10.1 Clinical Insight
- 10.2 Development Timeline
- 10.3 Patent Analysis
- 10.4 Phase of Development

11. TRASTUZUMAB BIOSIMILAR - BIONOVIS/THE INSTITUTO VITAL BRAZIL

- 11.1 Clinical Insight
- 11.2 Development Timeline
- 11.3 Phase of Development

12. TRASTUZUMAB BIOSIMILAR - BIOXPRESS THERAPEUTICS

- 12.1 Clinical Insight
- 12.2 Phase of Development

13. TRASTUZUMAB BIOSIMILAR - CELLTRION

13.1 Clinical Insight



- 13.2 Development Timeline
- 13.3 Phase of Development

14. TRASTUZUMAB BIOSIMILAR – CURAXYS

- 14.1 Clinical Insight
- 14.2 Phase of Development

15. TRASTUZUMAB BIOSIMILAR - DONG-A ST/MEIJI SEIKA PHARMA

- 15.1 Clinical Insight
- 15.2 Development Timeline
- 15.3 Phase of Development

16. TRASTUZUMAB BIOSIMILAR - DR. REDDY'S LABORATORIES

- 16.1 Clinical Insight
- 16.2 Development Timeline
- 16.3 Phase of Development

17. TRASTUZUMAB BIOSIMILAR - GEDEON RICHTER

- 17.1 Clinical Insight
- 17.2 Phase of Development

18. TRASTUZUMAB BIOSIMILAR - HANWHA BIOLOGICS

- 18.1 Clinical Insight
- 18.2 Phase of Development

19. TRASTUZUMAB BIOSIMILAR - HARVEST MOON PHARMACEUTICALS

- 19.1 Clinical Insight
- 19.2 Development Timeline
- 19.3 Phase of Development

20. TRASTUZUMAB BIOSIMILAR - HETERO DRUGS

20.1 Clinical Insight



- 20.2 Development Timeline
- 20.3 Phase of Development

21. TRASTUZUMAB BIOSIMILAR - INTERNATIONAL BIOTECH CENTER GENERIUM

- 21.1 Clinical Insight
- 21.2 Phase of Development

22. TRASTUZUMAB BIOSIMILAR - MABION

- 22.1 Clinical Insight
- 22.2 Development Timeline
- 22.3 Phase of Development

23. TRASTUZUMAB BIOSIMILAR – MABXIENCE

- 23.1 Clinical Insight
- 23.2 Development Timeline
- 23.3 Phase of Development

24. TRASTUZUMAB BIOSIMILAR - NANOGEN BIOPHARMACEUTICAL

- 24.1 Clinical Insight
- 24.2 Phase of Development

25. TRASTUZUMAB BIOSIMILAR - NICHI-IKO PHARMACEUTICAL/APROGEN

- 25.1 Clinical Insight
- 25.2 Development Timeline
- 25.3 Phase of Development

26. TRASTUZUMAB BIOSIMILAR – ONCOBIOLOGICS

- 26.1 Clinical Insight
- 26.2 Development Timeline
- 26.3 Phase of Development

27. TRASTUZUMAB BIOSIMILAR - PARAS BIOPHARMACEUTICALS



- 27.1 Clinical Insight
- 27.2 Phase of Development

28. TRASTUZUMAB BIOSIMILAR - PFIZER

- 28.1 Clinical Insight
- 28.2 Development Timeline
- 28.3 Phase of Development

29. TRASTUZUMAB BIOSIMILAR - PLANTFORM CORPORATION

- 29.1 Clinical Insight
- 29.2 Development Timeline
- 29.3 Patent Analysis
- 29.4 Phase of Development

30. TRASTUZUMAB BIOSIMILAR – POLPHARMA

- 30.1 Clinical Insight
- 30.2 Phase of Development

31. TRASTUZUMAB BIOSIMILAR - PROBIOGEN AG/BIO FARMA INDONESIA

- 31.1 Clinical Insight
- 31.2 Phase of Development

32. TRASTUZUMAB BIOSIMILAR - RELIANCE LIFE SCIENCES

- 32.1 Clinical Insight
- 32.2 Development Timeline
- 32.3 Phase of Development

33. TRASTUZUMAB BIOSIMILAR - SAMSUNG BIOEPIS

- 33.1 Clinical Insight
- 33.2 Development Timeline
- 33.3 Phase of Development



34. TRASTUZUMAB BIOSIMILAR - SHANGHAI CP GUOJIAN PHARMACEUTICAL

- 34.1 Clinical Insight
- 34.2 Development Timeline
- 34.3 Phase of Development

35. TRASTUZUMAB BIOSIMILAR - SHANGHAI HENLIUS BIOTECH

- 35.1 Clinical Insight
- 35.2 Development Timeline
- 35.3 Phase of Development

36. TRASTUZUMAB BIOSIMILAR - STC BIOLOGICS

- 36.1 Clinical Insight
- 36.2 Development Timeline
- 36.3 Phase of Development

37. TRASTUZUMAB BIOSIMILAR - THERAPEUTIC PROTEINS INTERNATIONAL

- 37.1 Clinical Insight
- 37.2 Phase of Development

38. TRASTUZUMAB BIOSIMILAR - ZYDUS

- 38.1 Clinical Insight
- 38.2 Development Timeline
- 38.3 Phase of Development

39. TRASTUZUMAB GLYCO-OPTIMISED - GLYCOTOPE

- 39.1 Development Timeline
- 39.2 Phase of Development

40. TRASTUZUMAB SUBCUTANEOUS

- 40.1 Clinical Insight
- 40.2 Development Timeline
- 40.3 Patent Analysis



40.4 Phase of Development



List Of Tables

LIST OF TABLES

- Table 2-1: EPIRUS Biopharmaceuticals BOW 040 Biosimilar by Indication & phase
- Table 3-1: ISU Abxis Trastuzumab Biosimilar by Indication & Phase
- Table 4-1: Allergan/Amgen Trastuzumab Biosimilar by Indication & Phase
- Table 5-1: Alteogen/Cristalia Trastuzumab Biosimilar by Indication & Phase
- Table 6-1: AryoGen Biopharma Trastuzumab Biosimilar by Indication & Phase
- Table 7-1: Axxo Trastuzumab Biosimilar by Indication & Phase
- Table 9-1: BIOCND/Genor Biopharma Trastuzumab Biosimilar by Indication & Phase
- Table 10-1: Biocon/Mylan Trastuzumab Biosimilar by Indication & Phase
- Table 11-1: Bionovis/The Instituto Vital Brazil Trastuzumab Biosimilar by Indication & Phase
- Table 12-1: BioXpress Therapeutics Trastuzumab Biosimilar by Indication & Phase
- Table 13-1: Celltrion Trastuzumab Biosimilar by Indication & Phase
- Table 14-1: Curaxys Trastuzumab Biosimilar by Indication & Phase
- Table 15-1: Dong-A ST/Meiji Seika Pharma Trastuzumab Biosimilar by Indication & Phase
- Table 16-1: Dr. Reddy's Laboratories Trastuzumab Biosimilar by Indication & Phase
- Table 17-1: Gedeon Richter Trastuzumab Biosimilar by Indication & Phase
- Table 18-1: Hanwha Biologics Trastuzumab Biosimilar by Indication & Phase
- Table 19-1: Harvest Moon Pharmaceuticals Trastuzumab Biosimilar by Indication & Phase
- Table 20-1: Hetero Drugs Trastuzumab Biosimilar by Indication & Phase
- Table 21-1: International Biotech Center Generium Trastuzumab Biosimilar by
- Indication & Phase
- Table 22-1: Mabion Trastuzumab Biosimilar by Indication & Phase
- Table 23-1: mAbxience Trastuzumab Biosimilar by Indication & Phase
- Table 24-1: Nanogen Biopharmaceutical Trastuzumab Biosimilar by Indication & Phase
- Table 25-1: Nichi-Iko Pharmaceutical/Aprogen Trastuzumab Biosimilar by Indication & Phase
- Table 26-1: Oncobiologics Trastuzumab Biosimilar by Indication & Phase
- Table 27-1: Paras Biopharmaceuticals Trastuzumab Biosimilar by Indication & Phase
- Table 28-1: Pfizer Trastuzumab Biosimilar by Indication & Phase
- Table 29-1: PlantForm Corporation Trastuzumab Biosimilar by Indication & Phase
- Table 30-1: Polpharma Trastuzumab Biosimilar by Indication & Phase
- Table 31-1: ProBioGen AG/Bio Farma Indonesia Trastuzumab Biosimilar by Indication & Phase



- Table 32-1: Reliance Life Sciences Trastuzumab Biosimilar by Indication & Phase
- Table 33-1: Samsung Bioepis Trastuzumab Biosimilar by Indication & Phase
- Table 34-1: Shanghai CP Guojian Pharmaceutical Trastuzumab Biosimilar by Indication & Phase
- Table 35-1: Shanghai Henlius Biotech Trastuzumab Biosimilar by Indication & Phase
- Table 36-1: STC Biologics Trastuzumab Biosimilar by Indication & Phase
- Table 37–1: Therapeutic Proteins International Trastuzumab Biosimilar by Indication & Phase
- Table 38-1: Zydus Trastuzumab Biosimilar by Indication & Phase
- Table 39-1: Glycotope Trastuzumab Glyco-optimised by Indication & Phase
- Table 40-1: Trastuzumab Subcutaneous by Indication & Phase



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