Humira Biosimilars Clinical Trial Insight

Description:
The "Humira Biosimilars Clinical Trial Insight" report gives comprehensive clinical insight on 33 biosimilars version of Humira drug in clinical pipeline. More than 10 of these biosimilars are in Phase-III trials and are expected to be commercially available in next 5-8 years. The patent protection assigned to Humira will expire in 2016 for US and 2018 for European market.

The Humira stands for Human Monoclonal Antibody in Rheumatoid Arthritis. It is also termed as Adalimumab or D2E7 and is a recombinant Immunoglobulin G1 monoclonal antibody which is specific for tumor necrosis factor alpha (TNF-a). It is a drug designed by the mode of recombinant DNA technology for the treatment of rheumatoid arthritis, psoriatic arthritis, Crohn's disease and ulcerative colitis. In the rheumatoid arthritis adalimumab has the equivalent efficacy as that of methotrexate.

The chemical and biological components of Humira define it as a TNF inhibiting anti-inflammatory biologic medication. It binds to the TNF-a which leads to the inflammatory response of autoimmune diseases but after the conjugation of Humira it reduces the inflammatory response.

The mechanism of action includes the binding of HUMIRA specifically to TNF-a and renders it, incapable of binding to its receptors on cell surfaces. TNF-a exerts its pro-inflammatory role by binding to its cell surface receptor. When HUMIRA binds to the membrane bound version of TNF-a on TNF-a-producing cells, it can lead to lysis of these TNF-a producing cell in the presence of complement.

TNF- a level is found elevated in the synovial fluids of rheumatoid arthritis. TNF-a is one of the important factors that contribute to the pathology and perpetuation of the inflamed and destroyed joints in rheumatoid arthritis. Given that rheumatoid arthritis is a complex disease with multiple factors involved, the ability for a monoclonal antibody to neutralize the function of one single cytokine TNF-a and greatly improve the symptoms and progression of rheumatoid arthritis.

It is produced by Abbot Laboratories but originally Humira was emerged from collaboration between Bioresearch Center in Massachusetts (BASF) and the Cambridge Antibody Technologies in the UK. Mid stage clinical trials were so promising that, at the end of 2000, Abbott agreed to buy the BASF Bioresearch Center for US$ 6.9 Billion. When Humira was launched in 2003, it was the third TNF-alpha antibody to the market. Its US, FDA approval for marketing was achieved on December 31, 2002. In 2012 to 2015 Humira topped the top selling pharmaceutical product lists and in 2015, Humira had topped US$ 14 Billion of sales globally.

However, its superior dosing schedule and improved toleration over existing therapy enabled it to become the best in class agent. Furthermore, Abbott had a robust development program for Humira and expanded its use to other inflammatory disease such as psoriasis, Crohn's disease, and juvenile idiopathic arthritis. While prescribed to far fewer patients than Lipitor, the high cost of this biological medicine is such that Humira's sales were projected to exceed US$ 9 Billion.

In December 2014, Indian drug maker Cadila Healthcare declared the launch of the first adalimumab biosimilar at a fifth of its U.S. price. The generic has been launched under the brand name Exemptia. In January 2016, another Indian drug maker Torrent Pharmaceuticals launched its biosimilar for adalimumab. Torrent's Adfrar would be the second generic biosimilar of adalimumab in the world. In September 2016 the US FDA approved Amgens biosimilar adalimumab-atto sold under the brand name Amjevita.

Contents:
1. Humira (Adalimumab) Clinical Insight
   1.1 Clinical Introduction
   1.2 Company Partnerships & Agreements
   1.3 Patent Analysis by Indication
   1.4 Designated Orphan Status by Indication & Country
   1.5 Brand Names by Country/Region

Humira Biosimilars Clinical Insight by Company
   2.1 Clinical Insight
   2.2 Development Timeline
   2.3 Phase of Development

3. Adalimumab Biosimilar - Alphamab
   3.1 Clinical Insight
   3.2 Development Timeline
   3.3 Phase of Development

4. Adalimumab Biosimilar - Alteogen/Cristalia
   4.1 Clinical Insight
   4.2 Phase of Development

5. Adalimumab Biosimilar - Amgen
   5.1 Clinical Insight
   5.2 Development Timeline
   5.3 Phase of Development

6. Adalimumab Biosimilar - Axxo
   6.1 Clinical Insight
   6.2 Phase of Development

7. Adalimumab Biosimilar - Biocad
   7.1 Clinical Insight
   7.2 Development Timeline
   7.3 Phase of Development

8. Adalimumab Biosimilar - BIOCND/Genor Biopharma
   8.1 Clinical Insight
   8.2 Development Timeline
   8.3 Phase of Development

9. Adalimumab Biosimilar - Biocon/Mylan
   9.1 Clinical Insight
   9.2 Development Timeline
   9.3 Phase of Development

10. Adalimumab Biosimilar - Bionovis/The Instituto Vital Brazil
    10.1 Clinical Insight
    10.2 Development Timeline
    10.3 Phase of Development

11. Adalimumab Biosimilar - Boehringer Ingelheim
    11.1 Clinical Insight
    11.2 Development Timeline
    11.3 Phase of Development

12. Adalimumab Biosimilar - Celltrion
    12.1 Clinical Insight
    12.2 Phase of Development

13. Adalimumab Biosimilar - CinnaGen
    13.1 Clinical Insight
    13.2 Phase of Development

14. Adalimumab Biosimilar - Coherus BioSciences
    14.1 Clinical Insight
    14.2 Development Timeline
    14.3 Phase of Development

15. Adalimumab Biosimilar - Dong A ST/Meiji Seika Pharma
    15.1 Clinical Insight
15. Development Timeline
15. Phase of Development

16. Adalimumab Biosimilar - EMD Serono/Merck
   16.1 Clinical Insight
   16.2 Development Timeline
   16.3 Phase of Development

17. Adalimumab Biosimilar - Fujifilm Kyowa Kirin Biologics
   17.1 Clinical Insight
   17.2 Development Timeline
   17.3 Phase of Development

18. Adalimumab Biosimilar - Gene Techno Science
   18.1 Clinical Insight
   18.2 Phase of Development

19. Adalimumab Biosimilar - Harvest Moon Pharmaceuticals
   19.1 Clinical Insight
   19.2 Development Timeline
   19.3 Phase of Development

20. Adalimumab Biosimilar - Hetero Drugs
   20.1 Clinical Insight
   20.2 Development Timeline
   20.3 Phase of Development

21. Adalimumab Biosimilar - Innoven Biologics
   21.1 Clinical Insight
   21.2 Development Timeline
   21.3 Phase of Development

22. Adalimumab Biosimilar - LG Life Sciences
   22.1 Clinical Insight
   22.2 Development Timeline
   22.3 Phase of Development

23. Adalimumab Biosimilar - mAbxience
   23.1 Clinical Insight
   23.2 Development Timeline
   23.3 Phase of Development

24. Adalimumab Biosimilar - Meridian Biopharmaceuticals
   24.1 Clinical Insight
   24.2 Phase of Development

25. Adalimumab Biosimilar - Momenta Pharmaceuticals
   25.1 Clinical Insight
   25.2 Development Timeline
   25.3 Phase of Development

26. Adalimumab Biosimilar - Oncobiologics
   26.1 Clinical Insight
   26.2 Development Timeline
   26.3 Phase of Development

27. Adalimumab Biosimilar - Pfizer
   27.1 Clinical Insight
   27.2 Development Timeline
   27.3 Phase of Development

28. Adalimumab Biosimilar - PlantPraxis
   28.1 Clinical Insight
28.2 Development Timeline
28.3 Phase of Development

29. Adalimumab Biosimilar - Reliance Life Sciences
29.1 Clinical Insight
29.2 Development Timeline
29.3 Phase of Development

30. Adalimumab Biosimilar - Samsung Bioepis
30.1 Clinical Insight
30.2 Development Timeline
30.3 Phase of Development

31. Adalimumab Biosimilar - Sandoz
31.1 Clinical Insight
31.2 Development Timeline
31.3 Phase of Development

32. Adalimumab Biosimilar - Shanghai Henlius Biotech
32.1 Clinical Insight
32.2 Development Timeline
32.3 Phase of Development

33. Adalimumab Biosimilar - Therapeutic Proteins International
33.1 Clinical Insight
33.2 Phase of Development

34. Adalimumab Biosimilar - Zydus Cadila
34.1 Clinical Insight
34.2 Development Timeline
34.3 Phase of Development

35. Patent Litigation Issues Involving Development of Humira (Adalimumab) Biosimilar
35.1 Amgen v/s AbbVie
35.2 Coherus v/s AbbVie

List of Tables:
Table 1-1: Humira Clinical Trial by Phase of Development
Table 1-2: Humira - Designated Orphan Status by Indication & Country
Table 1-3: Humira - Brand Names by Country/Region
Table 2-1: AET BioTech/BioXpress Therapeutics Adalimumab Biosimilar by Indication & Phase
Table 3-1: Alphamab Adalimumab Biosimilar by Indication & Phase
Table 4-1: Alteogen/Cristalia Adalimumab Biosimilar by Indication & Phase
Table 5-1: Amgen Adalimumab Biosimilar by Indication & Phase
Table 6-1: Axxo Adalimumab Biosimilar by Indication & Phase
Table 7-1: Biocad Adalimumab Biosimilar by Indication & Phase
Table 8-1: BIOCN/DGenor Biopharma Adalimumab Biosimilar by Indication & Phase
Table 9-1: Bioclon/Mylan Adalimumab Biosimilar by Indication & Phase
Table 10-1: Bionovis/The Instituto Vital Brazil Adalimumab Biosimilar by Indication & Phase
Table 11-1: Boehringer Ingelheim Adalimumab Biosimilar by Indication & Phase
Table 12-1: Celltrion Adalimumab Biosimilar by Indication & Phase
Table 13-1: CinnaGen Adalimumab Biosimilar by Indication & Phase
Table 14-1: Coherus BioSciences Adalimumab Biosimilar by Indication & Phase
Table 15-1: Dong A ST/Meiji Seika Pharma Adalimumab Biosimilar by Indication & Phase
Table 16-1: EMD Serono/Merck Adalimumab Biosimilar by Indication & Phase
Table 17-1: Fujifilm Kyowa Kirin Biologics Adalimumab Biosimilar by Indication & Phase
Table 18-1: Gene Techno Science Adalimumab Biosimilar by Indication & Phase
Table 19-1: Harvest Moon Pharmaceuticals Adalimumab Biosimilar by Indication & Phase
Table 20-1: Hetero Drugs Adalimumab Biosimilar by Indication & Phase
Table 21-1: Innovent Biologics Adalimumab Biosimilar by Indication & Phase
Table 22-1: LG Life Sciences Adalimumab Biosimilar by Indication & Phase
Table 23-1: mAbxience Adalimumab Biosimilar by Indication & Phase
Table 24-1: Meridian Biopharmaceuticals Adalimumab Biosimilar by Indication & Phase
Table 25-1: Momenta Pharmaceuticals Adalimumab Biosimilar by Indication & Phase
Table 26-1: Oncobiologics Adalimumab Biosimilar by Indication & Phase
Table 27-1: Pfizer Adalimumab Biosimilar by Indication & Phase
Table 28-1: PlantPraxis Adalimumab Biosimilar by Indication & Phase
Table 29-1: Reliance Life Sciences Adalimumab Biosimilar by Indication & Phase
Table 30-1: Samsung Bioepis Adalimumab Biosimilar by Indication & Phase
Table 31-1: Sandoz Adalimumab Biosimilar by Indication & Phase
Table 32-1: Shanghai Henlius Biotech Adalimumab Biosimilar by Indication & Phase
Table 33-1: Therapeutic Proteins International Adalimumab Biosimilar by Indication & Phase
Table 34-1: Zydus Cadila Adalimumab Biosimilar by Indication & Phase

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