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Humira Biosimilars Clinical Trial Insight

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Abstracts

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“Humira Biosimilars Clinical Trial Insight” report by PNS Pharma 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-?). 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-? 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-? and renders it, incapable of binding to its receptors on cell surfaces. TNF-? exerts its pro-inflammatory role by binding to its cell surface receptor. When HUMIRA binds to the membrane bound version of TNF-? on TNF-?-producing cells, it can lead to lysis of these TNF-? producing cell in the presence of complement.

TNF- ? level is found elevated in the synovial fluids of rheumatoid arthritis. TNF-? is one of the important factors that contribute to the pathology and perpetuation of the inflamed

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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-? 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.

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