

Remicade (Infliximab) Biosimilar Clinical Trial Insight

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Abstracts

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“Remicade (Infliximab) Biosimilar Clinical Trial Insight” report by PNS Pharma gives comprehensive clinical insight on 17 biosimilar version of Remicade drug in clinical pipeline. Currently there are 2 biosimilars in Phase-III trials and are expected to be commercially available in next 5-8 years. Currently 3 biosimilar version of Remicade are commercially available in India, Brazil and European countries for the treatment of Ankylosing spondylitis, Crohn's disease and Rheumatoid Arthritis. The patent on Remicade is set to expire in 2018 for US and 2017 for rest of world.

Remicade is the trade name for infliximab which is a chimeric monoclonal antibody biologic drug, marketed by Janssen Biotech. Infliximab is used to fight against tumor necrosis factor alpha (TNF-?) to treat auto immune diseases such as rheumatoid arthritis. The drug is a purified form of recombinant DNA-derived human-mouse monoclonal antibodies consisting of mouse and human's heavy and light chain variable regions. It is a prescribed drug, approved by Food and Drug Association for the treatment of Crohn's disease, Pediatric Crohn's disease, Ulcerative colitis, Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing spondylitis and Plaque psoriatic.

FDA approved infliximab in September 2006, for chronic Plaque Psoriasis. Infliximab comes under the form of naturally occurring antibodies (anti-TNF bodies) with the ability to neutralize all forms of TNF. It is capable of breaking down of cell causing inflammatory process. Biological activities such as pro inflammatory cytokines, enhancement of leukocyte movement and increasing the release of adhesion molecules are attributed to TNF-?.

Infliximab is made up of human and mouse antibodies. It is an artificial antibody originally developed from mice. Due to human immune reaction to mouse proteins, the

mouse common domains are replaced with human antibody domains. Infliximab is has main key components as human mouse antibody amino acids because of which is referred as chimeric monoclonal antibody.

Infliximab works by binding action of remicade with TNF-?. Playing a crucial role in auto immune systems, TNF-? is a chemical messenger. In the case of rheumatoid arthritis, infliximab works to prevent TNF-? by attaching to its receptor in the cell. Infliximab works by neutralizing the biological activity of TNF-?. It inhibits the functional activity of wide variety utilizing human fibroblasts, endothelial cells, neutrophils, B and T-lymphocytes and epithelial cells. Though, the biological responses through which remicade exert clinical effects in the body are still considered to be unknown.

Remicade is necessarily induced intravenously because of the fact that the drug can be destroyed by the digestive system of a patient in case given by mouth. The dosages are typically administered by infusion within the interval of 6 to 8 weeks. The initial process involves the 3 starter infusions over first 6 weeks, followed by 2 more after next 2 and 4 weeks. Along with remicade, patients are prescribed with a particular amount of medication, depending upon the patient's weight to reduce its side effects

Similar to other TNF inhibitors, infliximab is an expensive drug costing range from US\$ 1300 – US\$ 2500 for every dosage. It is manufactured as a sterile lyophilized white freeze dried powder which necessarily requires administration and reconstitution by a health care professional. Due to this need of extra care during treatment and infusion of remicade, it is a part of major health insurances.

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