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Enbrel Biosimilars Clinical Trial & Opportunity Insight

https://marketpublishers.com/r/E6C3A30A8CFEN.html
Date: October 2016
Pages: 70
Price: US$ 1,500.00 (Single User License)
ID: E6C3A30A8CFEN

Abstracts

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“Enbrel Biosimilars Clinical Trial Insight” report by PNS Pharma gives comprehensive clinical insight on 36 biosimilar version of Enbrel drug in clinical pipeline. More than 5 of these biosimilars are in Phase-III trials and are expected to be commercially available in next 5-8 years. Currently 5 biosimilar version of Enbrel are commercially available in Iran, Mexico, India, UK and Australia. The patent on Enbrel was originally set to expire on October 23, 2012, but, in the United States, a second patent, granting exclusivity for another 16 years (2028), has been granted.

Etanercept or Enbrel is a biopharmaceutical that has been designed to treat autoimmune diseases by interfering with Tumor necrosis factor. It is a TNF inhibitor which is made in living cell cultures rather than in a chemistry lab. It was one of the first successful products to emerge from the flourishing of innovations in cell biology since the 1990s.

Structurally, Enbrel (etanercept) is a dimeric fusion protein consisting of the extracellular ligand binding portion of the human 75 Kilo Dalton (p75) tumor necrosis factor receptor (TNFR) linked to the Fc portion of human immunoglobulin (IgG1). Etanercept is produced by recombinant DNA technology in a Chinese hamster ovary (CHO) mammalian cell expression system. It consists of 934 amino acids and has an apparent molecular weight of approximately 150 Kilo Daltons.

Enbrel is usually indicated for treatment of moderately to severely active rheumatoid arthritis (RA) in adults. It is effective in reducing the signs and symptoms of RA, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function. It is also used for the improvement of physical function in adult patients with psoriatic arthritis (PsA). Another role of Enbrel is for the management

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of adult patients with chronic moderate to severe plaque psoriasis.

The mechanism of Enbrel includes the induction of immune response by attracting additional white blood cells to sites of inflammation and through additional molecular mechanisms which initiate and amplify inflammation. Inhibition of its action by etanercept reduces the inflammatory response which is especially useful for treating autoimmune diseases.

TNF receptors are found on the surface of almost all nucleated cells, it imitates the inhibitory effects of naturally occurring soluble TNF receptors, the difference being that etanercept, because it is a fusion protein rather than a simple TNF receptor, has a greatly extended half-life in the bloodstream, and therefore a more profound and long lasting biologic effect than a naturally occurring soluble TNF receptor.

Etanercept was developed by researchers at Immunex, and was released for commercial use in late 1998 after its FDA approval, which was the first chimeric monoclonal antibody against TNF-? to be marketed for clinical use. In North America, etanercept is co-marketed by Amgen and Pfizer under the trade name Enbrel in two separate formulations, one in powder form, and the other as a pre-mixed liquid. Wyeth was the sole marketer of Enbrel outside North America excluding Japan where Takeda Pharmaceuticals markets the drug.

The Indian pharmaceutical major Cipla made an announcement about launching the first biosimilar of Etanercept in India under the brand name 'Etacept' for the treatment of rheumatic disorders in 2013. The company's claimed that the biosimilar will cost 30% less as compared to the innovator. However, Enbrel is costly in U.S. as in 2008; the cost of Enbrel was reported to be US$ 1,500 per month or US$ 18,000 per year. By 2016, the cost had reportedly exceeded US$ 24,000 per year (US$ 2183 Per Month).

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