Zydus launches world's first biosimilar of Adalimumab

Access to this therapy will impact 12 million people suffering from auto immune disorders like rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and Ankylosing Spondylitis in India

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After more than a decade long wait, the revolutionary therapy that provided a new lease of life to millions of patients suffering from rheumatoid arthritis and other auto immune disorders globally will now be accessible to patients in India. Zydus Cadila becomes the first company anywhere in the world to launch the biosimilar of Adalimumab – the world's largest selling therapy. Developed by the researchers at the Zydus Research Centre, the biosimilar has been approved by the Drug Controller General of India and will be marketed under the brand name, Exemptia to treat auto immune disorders such as rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and Ankylosing Spondylitis.

This novel non-infringing process for Adalimumab and a novel non-infringing formulation has been researched, developed and produced by scientists at the Zydus Research Centre. The biosimilar is the first to be launched by any company in the world and is a 'fingerprint match' with the originator in terms of safety, purity and potency of the product. The biosimilar of Adalimumab is a part of Zydus' robust biologics programme which has the largest number of monoclonal antibodies under development in India. The group's R&D pipeline which comprises 24 biologics includes biosimilars and three novel biologics. These biologics are being developed to treat auto immune disorders like arthritis, cancer, infertility and stroke.

Adalimumab, the fully human anti-TNF alpha monoclonal antibody, was first approved globally in 2002 and has since then been the most preferred therapy to treat patients suffering from auto immune disorders. However, the therapy was not available to patients in India. It is estimated that more than 12 million patients in India suffer from these chronic conditions which progressively deteriorate and lead to lifelong pain and in some cases, even disability.

Speaking on the breakthrough, Deputy Managing Director of Zydus Cadila, Dr. Sharvil P. Patel said, "At Zydus, we believe that innovations must bridge unmet healthcare needs and provide solutions to patients who are suffering from disease and disability especially in such chronic conditions. This therapy will offer a new lease of life to millions in India who did not have access to this therapy so far. We are happy to offer them hope, freedom from pain and better quality of life through Exemptia."

Biosimilars are biological products that are ‘similar’ or ‘highly similar’ to the reference medicinal products (originator products) following the EMA (European Medicines Agency), FDA (Food and Drug Administration, USA) and the CDSCO regulatory guidelines. Biosimilars have similar level of efficacy and safety compared to that of the originator products and provide additional advantage to patients in terms of affordability and accessibility.

Exemptia is given as a 40 mg subcutaneous injection once every alternate week. Patients normally would have to take the treatment for six months. It has been clinically observed that the therapy is able to arrest the degeneration and the patient goes into remission – which means the auto immune disorder is under control and the patient is able to live a life without pain and can actually lead a fully active life.

Zydus will offer a dedicated Exemptia Care support programme to patients and caregivers. The programme shall provide important support and information regarding access, adherence, awareness and thereby help patients to appropriately manage their disease.

The therapy will be marketed by Zydus Biovation - a new division launched to exclusively market this ground breaking therapy. The launch of Exemptia begins with a series of CMEs and scientific symposia to highlight the gaps in the current management of auto immune disorders.

About Zydus’ Innovation Programme

Zydus’ Innovation programme is spearheaded by 1200 researchers across 19 sites, working on differentiated medicines for the future. From NCEs to vaccines, biosimilars and niche technologies, the group is exploring different ideas and concepts to bring in a relentless flow of innovation. In 2013, the group was the first to identify and develop Lipaglyn™ (Saroglitazar) and launch India's first NCE in the market.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 16,000 people worldwide and is dedicated to creating healthier communities globally. It aims to be a leading global healthcare provider with a robust product pipeline, achieve sales of over Rs. 10000 crore by 2015 and be a research-based pharmaceutical company by 2020.

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