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ASIA EDITION

Lupin, YL Biologics receive PMDA approval for Etanercept biosimilar in Japan

March 26, 2019 | News

The approval to treat moderate to severe Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis was received today



Lupin has announced that YL Biologics Limited (YLB), a joint venture between Lupin's subsidiary Lupin Atlantis Holdings SA (LAHSA) and Yoshindo Inc. in Japan, and Lupin (through its Japanese subsidiary, Kyowa Pharmaceutical Industry Co. Ltd) have received an approval to manufacture and sell their biosimilar Etanercept in Japan. The approval to treat moderate to severe Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis was received today.

Commenting on this development, Nilesh Gupta, Managing Director, Lupin Limited stated, "We are delighted to bring our first biosimilar to market in Japan. Etanercept is a very complex product and this was a truly world-class development. The timely approval of our filing which involved successfully addressing the PMDA queries as well as going through a PMDA inspection for our Biosimilar drug substance facility in Pune, India speaks volumes of the quality that we have been able to build into the product, our process and our facilities. We now look forward to bringing this important product to Japanese patients. We have a carefully selected, high-value pipeline of biosimilars going forward and are committed to advancing research and development in this space. This is part of our overall move to evolve our complex generic portfolio and offer better access to affordable and high-quality products for patients across the world."

Dr. Toshihiko Hibino, President, YL Biologics Limited emphasized that "We are delighted to receive the approval from the authorities and this makes it a significant milestone for the JV. YLB will continue to offer high quality yet cost-effective medical solutions to the Japanese patients. YLB113 is one such product that reduces the healthcare burden of patients suffering from Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis".

Dr. Cyrus Karkaria, President, Lupin Biotech said, "Etanercept is used globally in the fight against a range of severe autoimmune disorders. The successful filing and eventual approval of YLB113 is a major step in the fight against these diseases, and will allow access to an effective, affordable equivalent. After significant investment in our biotechnology R&D division over the years, this is the first biosimilar for regulated markets developed in-house at Lupin and the first etanercept

biosimilar developed by an Indian pharmaceutical player. It is an important achievement for us that sets the tone for future biosimilar development."

In February 2018, YL Biologics announced the successful completion of the global Phase III study of their biosimilar Etanercept (YLB113). The study was a multi-country randomized double-blind controlled trial of 52 weeks duration which included more than 500 patients with rheumatoid arthritis (RA) across 11 countries. It compared YLB113's efficacy and safety directly against Enbrel®. The study was conducted at 110 rheumatology clinics across Japan, Europe and India.

This study included over 260 Japanese patients from 62 rheumatology clinics, a scale that is distinctive for a global RA trial. Based on the results of this Phase III study, YLB and Lupin (through its Japanese subsidiary, Kyowa Pharmaceutical Industry Co. Ltd) submitted an NDA to the Pharmaceutical and Medical Devices Agency (PMDA) in Japan in March 2018. In addition to addressing queries on its applications, Lupin Biotech facilities at Pune, India were inspected by the PMDA, with successful outcome.