

Lupin and YL Biologics receives PMDA approval for Etanercept biosimilar in Japan

Mumbai, March 26, 2019: Pharma major Lupin Limited (Lupin) 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.

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.

Commenting on this development, **Mr. 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".

"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," said **Dr. Cyrus Karkaria, President, Lupin Biotech**. "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."

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player

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in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 8th largest generics pharmaceutical company in terms of market capitalization (28th December 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th September 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT December 2018); 3rd largest Indian pharmaceutical company by global revenues (30th September 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT December 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT December 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

About Yoshindo

Over the course of Yoshindo's long history started from 1929, it has made contributions to human health and social wellbeing through the manufacturing and sales of generic pharmaceutical products. At present, Yoshindo is advancing research and development into biopharmaceuticals and essential drugs for transfusion and dialysis. Yoshindo is building new technologies and know-how, with the aim of remaining an irreplaceable pharmaceutical company for Japan moving into the future.

About YL Biologics

YL Biologics is a joint venture company incorporated by Yoshindo and LAHSA in 2014, which focuses on conducting clinical trials in respect of biosimilar drugs in Japan. Through providing their drugs to medical field, YL Biologics is committed to contribute to the society and people by cutting medical spending and reducing financial burden of patients.

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