Press Release

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Lupin submits New Drug Application for Etanercept biosimilar in Japan

Mumbai, May 8th, 2018: Pharma major Lupin announced that YL Biologics (YLB) – its JV with Yoshindo and Kyowa (Lupin's Subsidiary) in Japan has submitted a New Drug Application (NDA) for Marketing Authorization to the Pharmaceuticals and Medical Devices Agency (PMDA) for a biosimilar of Etanercept (YLB113) to treat indications for moderate to severe Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis. YL Biologics and Kyowa filed the NDA in Japan in March, 2018.

"The application for Etanercept biosimilar is a significant milestone for Lupin as we build our biosimilars pipeline. With the application now filed, we are preparing to launch an affordable and high-quality biosimilar for consumers in Japan. This is an encouraging outcome as we make a strategic shift across Lupin to higher complexity products.", said **Mr. Nilesh Gupta, Managing Director** of Lupin Limited.

In February this year, YL Biologics announced the successful conclusion of its global Phase III study of biosimilar of Etanercept (YLB113). The study was a multinational randomized double-blind controlled trial of 52 weeks duration which included more than 500 patients with rheumatoid arthritis (RA) in 11 countries. It compared YLB113's efficacy and safety directly against Enbrel® (of Pfizer). 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 distinct for a global RA trial in Japan.

According to **Dr. Toshihiko Hibino, President of YLB,** "This application marks the first biosimilar developed as part of the JV between Lupin and Yoshindo. We are excited by the development which is a complex fusion protein for a regulated market like Japan, and will help make the product accessible to the patients. The Biologics market in Japan is expected to reach $13.5 Billion (1480 Bn JPY) next year and the current healthcare spends on biologics is around 14% by the government in Japan and this is expected to rise in the coming years."

"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 ever complex fusion protein like etanercept in regulated markets by an Indian pharmaceutical player. It is an important achievement for us that sets the tone for future developments."

This filing also opens up other key markets like Europe, Canada, Australia, the Middle East, South East Asia and Latin America for this product. The approvals for these markets are expected within the next 12 to 18 months timeframe. The ex-US market for Etanercept is estimated at USD 4 billion in Japan and Europe along with other regulated and emerging markets. Lupin is also on course with its plans for filing in the US and is targeting a filing in FY 2019-20.

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

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 11th and 7th largest generics pharmaceutical company by market capitalization (December 31st, 2017, Bloomberg) and revenues (September 30th, 2017, Bloomberg LTM) respectively. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT December 2017); 2nd largest Indian pharmaceutical company by global revenues (September 30th, 2017, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in Indian Pharmaceutical Market (IQVIA MAT December2017).

For the financial year ended 31st March, 2017, Lupin's consolidated sales and Net profit stood at Rs. 171,198 million (USD 2.55 billion) and Rs. 25,575 million (USD 381 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 founded by Yoshindo and Lupin in 2014, which focuses on clinical development, NDA filing and PMDA approval, and sales and marketing of biosimilar drugs in Japan. Through providing our 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.

About Etanercept

Enbrel® (Etanercept) was the first TNF biologic treatment to be FDA approved for moderate to severe RA in 1998, and is used in the treatment of five long-term inflammatory conditions. These are moderate to severe rheumatoid arthritis, moderate to severe plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and moderate to severe polyarticular juvenile idiopathic arthritis (JIA).

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Safe Harbor Statement

Enbrel® is a registered trademark of Amgen in US & Canada and Pfizer in rest of the world.