Press Release

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Lupin and Yoshindo's JV – YL Biologics announces successful outcome of global Phase III study for Etanercept biosimilar in Rheumatoid Arthritis

Pune, February 7, 2018: In their board meeting held at Pune last week, YL Biologics (YLB) announced that a global Phase III clinical trial of its investigational Etanercept biosimilar (YLB113) has met with successful outcome. YLB is the joint venture of Pharma major Lupin and Yoshindo in Japan. The Phase III study of YLB113 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 Amgen/Pfizer) which has a global market of USD 11 billion (IQVIA MAT Q3 2017), and is a widely successful biologic agent globally used for the treatment of multiple autoimmune disorders including RA. 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.

The primary endpoint was an equivalent improvement in the rheumatoid arthritis, as measured by American College of Rheumatology 20 (ACR20) response rate. The ACR20 response rate of YLB113 has been found to be within a pre-defined equivalence margin that is expected by most advanced regulatory agencies for marketing authorization. In addition, safety and immunogenicity (antibody formation) of YLB113 was also found to be similar to Enbrel® indicating therapeutic equivalence.

"We are excited by the positive results from the Phase III trial. This helps us put together a robust regulatory dossier intended for global regulatory filings for YLB113. We currently have multiple high value biosimilar candidates in our late-stage global development pipeline. We remain committed to advancing our biotech R&D capabilities so that more patients across the world can access affordable, high-quality biosimilars" said Mr. Nilesh Gupta, MD of Lupin Limited.

Dr. Toshihiko Hibino, President of YLB expressed his satisfaction in achieving this important milestone that will recognize YLBs efforts in commercializing its first biosimilar for a crippling disease like Rheumatoid Arthritis in Japan. "We believe that it is our joint responsibility with our parent companies to subsidize the cost of RA treatment by offering a clinically equivalent biosimilar Etanercept to the Japanese patients", he said. YLB is in the process of compiling a regulatory dossier for submission to PMDA for its marketing authorization.

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, Paediatric, 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

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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.

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Safe Harbor Statement

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