

May 10, 2018

Press Release

YL Biologics Ltd.
Yoshindo Inc.

Pharmaceuticals and Medical Devices Agency accepts the filing for YLB113, a biosimilar product of anti-rheumatoid arthritis biopharmaceutical Enbrel®

YL Biologics Ltd. (Head Office: Chuo-ku, Tokyo, President: Toshihiko Hibino) (YLB) and Yoshindo Inc. (Head Office: Toyama, Japan, President: Hiroki Kitamura) announced today that Pharmaceuticals and Medical Devices Agency (PMDA) has accepted YLB's filing for YLB113, a biosimilar product of anti-rheumatoid arthritis (RA) biopharmaceutical Enbrel®.

Yoshindo and Lupin Limited (Head Office: Mumbai, India) established YLB in April 2014 as a joint venture company specializing in development of biosimilar products, and YLB has conducted a clinical phase III study of YLB113 in Japan, Europe and India since July, 2015, that was a randomized double-blind controlled trial.

The study was planned and performed by mainly YLB in 9 countries, which was enrolled over 500 RA patients and a half of them were recruited in Japan. YLB filed YLB113 to PMDA by using the data with the study.

Although YLB obtains active pharmaceutical ingredients of YLB113 from Lupin, YLB subcontracts manufacturing of it to AY Pharma Co. Ltd. (Head Office: Chuo-ku, Tokyo), a wholly owned subsidiary of Yoshindo, that complies with "Japan Quality". YLB expects that it is able to provide high quality biosimilar products that would be "Japan Made" and supplied for medical needs.

YL B and Yoshindo will cooperate with Lupin which has a global focus on biosimilar products which show high medical needs. They will efficiently develop biosimilar products using their large stock of know-how in biotechnology products, and expect to provide biosimilar products to not only

the domestic but also the global market with high quality and reliability as well as contribute to medical economy.

For further information, please contact to
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About YL Biologics Ltd.

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 Yoshindo Inc.

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 Lupin Limited

Lupin Limited, established in 1968, is an innovation led transnational pharmaceutical company producing a wide range of quality, affordable generic and branded formulations and APIs for the world. Lupin is the 11th and 7th largest generic pharmaceutical company by market capitalization (December 31st, 2017, Bloomberg) and revenues (March 31st, 2017, Bloomberg) respectively.