

Lupin's JV yields positive results for Etanercept clinical trials

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YL Biologics (YLB), a joint venture by drugmaker Lupin and Yoshindo, has successfully completed the late phase clinical studies on a biosimilar version of Etanercept (YLB113).

YLB 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.

The global Phase III study of YLB113 was a multinational randomised double-blind controlled trial of 52 weeks on more than 500 patients with rheumatoid arthritis in 11 countries.

The study compared YLB113's efficacy and safety directly against Enbrel, the branded version of the biological drug from innovator Amgen which has an estimated \$11-billion market.

The study was conducted at 110 rheumatology clinics across Japan, Europe and India and included 260 Japanese patients from 62 rheumatology clinics, a scale distinct for a global RA trial in Japan.

YLB is in the process of compiling a regulatory dossier for submission to Japanese regulator PMDA for its marketing authorisation.