

February 2, 2021

News Release

YL Biologics Ltd.

Regarding the NDA filing for YLB217, a biosimilar product of long-acting erythropoiesis stimulating agent Nesp®

YL Biologics Ltd. (Head Office: Chuo-ku, Tokyo, President: Toshihiko Hibino) (YLB) announced that the NDA filing for YLB217, a biosimilar product of long-acting erythropoiesis stimulating agent Nesp®, which YLB solely developed, was executed through Yoshindo Inc. (Head Office: Toyama, Japan, President: Hiroki Kitamura).

YLB contracted a technology transfer agreement with CJ Healthcare (currently HK Inno.N, South Korea, Seoul) on September 28, 2017, including exclusive development and marketing rights for Nesp® biosimilar and started domestic development with the sponsorship of Yoshindo. Since January 2019, YLB has conducted a clinical phase III study, that was randomized, double-blind, controlled trial in Japan.

The study enrolled 136 patients with renal anemia at 25 centers in Japan. Based on the data from this study, Yoshindo submitted a manufacturing and marketing approval application in Japan.

Although manufacturing of active pharmaceutical ingredients for YLB217 is subcontracted to PanGen Biotech Inc. (Gyeonggi-do, South Korea), manufacturing of syringe formulation is outsourced to AY Pharma Co. Ltd. (Head Office: Chuo-ku, Tokyo), an affiliate company 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.

YLB will continuously cope with Yoshindo and has a global focus on biosimilar products which show high medical needs. YLB 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

YL Biologics Ltd.

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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.