

March 26, 2019

Press Release

YL Biologics Ltd.
Yoshindo Inc.
Teijin Ltd.

Obtainment of Manufacturing and Sales Approval for Etanercept Biosimilar, Anti-rheumatoid Arthritis Agent

YL Biologics Ltd. (Head office: Chuo-ku, Tokyo, President and Representative Director: Toshihiko Hibino), Yoshindo Inc. (Head Office: Toyama City, Toyama, President and Representative Director: Hiroki Kitamura) and Teijin Ltd. (Head office: Kita-ku, Osaka, President and CEO: Jun Suzuki) have announced that on March 26, 2019, YL Biologics obtained manufacturing and sales approval for Etanercept biosimilar, an agent for anti-rheumatoid arthritis and polyarticular-course juvenile idiopathic arthritis (Development code: YLB113) which YL Biologics has developed globally.

YL Biologics has led the global phase III study enrolled over 500 Rheumatoid Arthritis patients and a half of them were recruited in Japan. Based on the results of phase III study, YL Biologics submitted NDA to MHLW in March, 2018. Although YL Biologics obtains active pharmaceutical ingredients of YLB113 from Lupin Ltd., an India based global pharmaceutical company, YL Biologics subcontracts manufacturing of it to AY Pharma Co. Ltd., a wholly owned subsidiary of Yoshindo.

Yoshindo entered into the sales collaboration agreement with Teijin Pharma Ltd. (Head Office: Chiyoda-ku, Tokyo, President and Representative Director: Akihisa Nabeshima) in July, 2018, which is playing central role of health care business in Teijin group. Based on the agreement, Yoshindo and Teijin Pharma will jointly distribute and market YLB113 in Japan.

YL Biologics is committed to take the biosimilar products with high medical

needs as the targets for the pipeline and effectively develop them by making good use of the company's rich know-how. YL biologics will contribute to the society and people by cutting medical spending and reducing financial burden of patients through stably providing its products to the medical field around the world.

Yoshindo manufactures generic drugs with high quality and reasonable prices through its systems with research and development, manufacturing and sales and marketing. Furthermore, Yoshindo is accelerating manufacturing and sales activities for essential drugs such as infusion and dialysis fluid, and advancing research and development into biopharmaceuticals. Yoshindo is building new technologies and know-how, with the aim of remaining an irreplaceable pharmaceutical company for Japan moving into the future.

Teijin Pharma intends to contribute the healthier lives of rheumatoid arthritis patients and improve their quality of life through putting YLB113 on their product line-up and accordingly further strengthening "Bone and Joint Field" as Teijin Pharma's expertise area.

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