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Pharma Major, Lupin Limited announced today that it has entered into a strategic joint venture agreement with Toyama based Japanese pharmaceuticals company, Yoshindo Inc. (Yoshindo) to create a new entity, YL Biologics (YLB).

YLB will be jointly managed by both partners and will be responsible for conducting clinical development of certain Biosimilars including regulatory filings and obtaining marketing authorizations in Japan.

The new entity YLB will in-license Monoclonal Antibodies (mAbs) from Lupin and also partner with other companies across the globe for the Japanese market which already has a clear cut regulatory regime in place for the development and commercialization of Biologicals. Lupin's Etanercept biosimilar, developed by its Biotechnology Research Group in Pune will be the first product to be licensed for clinical development to YLB. Etanercept (Originator Trade name: Enbrel®) is a biopharmaceutical product approved globally for treating autoimmune diseases such as Rheumatoid arthritis, Psoriasis and Ankylosing spondylitis. Enbrel is marketed in Japan by Takeda Pharmaceutical and had sales of \$496 million (IMS MAT March, 2013).

The Japanese Biological market is currently valued at close to \$12 billion and growing at 2-3 percent annually. mAbs make up \$3.5 billion of the overall Japanese biological sales and growing at 5 percent (IMS Health).

Lupin will be entitled to milestone based licensing income in addition to commercial supplies of the drug substance. Both Lupin and Yoshindo will then market the product under their own brand names by leveraging their respective sales networks.

Commenting on the joint venture Dr Kamal K Sharma, vice chairman, Lupin Limited said, "We are very excited about the joint venture with Yoshindo, a partner who shares our commitment to bringing biosimilars to market in Japan. YLB is a reflection of Lupin's long-term commitment to the Japanese market and is an important first step forward to establishing Lupin's global Biosimilar portfolio".

Commenting on the JV, Mr Kenzo Shimomura, president, Yoshindo said, "YL Biologics is our bridgehead to expand Yoshindo's activities to the Biosimilar market in Japan and highlight on the strategic representation of company. We are very pleased to enter into a strong partnership with Lupin which will make it possible to jointly develop a meaningful biosimilar product pipeline for the Japanese market".