Press Release

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Lupin and Nichi-Iko announce strategic partnership for commercialization of biosimilar Etanercept in Japan

Mumbai, June 18, 2018: Pharma major Lupin and Nichi-Iko announced that the two companies have entered into an agreement for the distribution, promotion and sale of Lupin's recently-filed biosimilar Etanercept (YLB113) in Japan. Developed by YL Biologics, a joint venture between Lupin's subsidiary Lupin Atlantis Holdings SA (LAHSA) and Yoshindo, the product will be launched by Nichi-Iko after receiving approval from the Pharmaceuticals and Medical Devices Agency (PMDA).

Kyowa (Lupin's subsidiary in Japan) had submitted a New Drug Application (NDA) for Marketing Authorization to the Pharmaceuticals and Medical Devices Agency (PMDA) in March this year following the successful conclusion of its global Phase III study. The study was a multinational randomized double-blind controlled trial of 52 weeks duration which included more than 500 patients with rheumatoid arthritis (RA) in 11 countries. It compared YLB113's efficacy and safety directly against Enbrel® of Amgen/Pfizer. The study was conducted at 110 rheumatology clinics across Japan, Europe and India. This study included over 260 Japanese patients from 62 rheumatology clinics, a scale that is unique for a global RA trial for Japan.

Speaking about the partnership, **Nilesh Gupta, Managing Director of Lupin Limited stated** "Etanercept is a key product as we build our biosimilars and complex generics pipeline. Our partnership with Nichi-Iko, takes us a step closer to the launch of our first in-house developed biosimilar that is used to combat a range of severe autoimmune disorders. The market for biologics in Japan is expected to reach US$13.5 Bn next year. The successful commercialization of our first biosimilar will help our foray into the fast-growing biologics space and also provide patients in Japan access to a high-quality affordable alternative."

"We at Nichi-Iko are very pleased that this agreement will allow us to provide patients with our second biosimilar product, following Infliximab biosimilar. This will enable us to offer different treatment options that add value to the quality of life for our patients and their families." said **Yuichi Tamura, CEO of Nichi-Iko.**

In addition to Japan, Lupin has also submitted the Marketing Authorization Application (MAA) for its Etanercept biosimilar to the European Medicines Agency (EMA). The indications targeted for approval are Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Axial spondyloarthritis, Non-radiographic Axial Spondyloarthritis and Plaque Psoriasis. The ex-US market for Etanercept is estimated at USD 4 billion in Japan and Europe, along with other regulated and emerging markets.

About Etanercept

Enbrel® (Etanercept) was the first TNF biologic treatment to be FDA approved for moderate to severe RA in 1998, and is used in the treatment of five long-term inflammatory conditions. These are rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis (JIA).

About Nichi-Iko

Since the establishment of Nichi-Iko Group in 1965, Nichi-Iko has steadily developed its business to contribute to people's health and quality of life by manufacturing premium-quality, cost-effective pharmaceuticals, resulting in a

leading company in Japan generic pharmaceuticals. Our mission is to provide value-added, premium-quality generic products which meet the needs of patients and their families, doctors, pharmacists, wholesalers and pharmaceutical companies in the global market as one of the most respected, well established generic companies in the world. In working to fulfil this mission, we seek to earn the trust and respect of all our stakeholders and to be the first choice for our customers.

More patient-friendly, more patient-choice, more high-quality. That is what we mean by Premium Quality. And Premium Quality underpins our commitment to becoming a global Top 10 leader in generic pharmaceuticals.

For more information about Nichi-Iko Pharmaceuticals Co., Ltd., please visit https://www.nichiiko.co.jp/english/

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 12th and 8th largest generics pharmaceutical company by market capitalization (31st March 2018, Bloomberg) and revenues (31st December 2017, Bloomberg LTM) respectively. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT March 2018); 3rd largest Indian pharmaceutical company by global revenues (31st December 2017, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT March 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits were at Rs. 155,598 million (USD 2.41 billion) and Rs. 2,513 million (USD 39 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

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*Safe Harbor Statement