Lupin and Mylan Partner to Commercialize Enbrel® (Etanercept) Biosimilar

June 28, 2018

MUMBAI, India and HERTFORDSHIRE, England and PITTSBURGH, June 28, 2018 /PRNewswire/ -- Pharma major Lupin Limited (Lupin) and global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced that the two companies will partner to commercialize a biosimilar to Enbrel® (etanercept). Through the partnership agreement, Mylan will commercialize Lupin's proposed etanercept biosimilar in Europe, Australia, New Zealand, Latin America, Africa and most markets throughout Asia.

Enbrel is a TNF-inhibitor[1] indicated to treat certain autoimmune diseases, including rheumatoid arthritis, psoriatic arthritis, plaque psoriasis and ankylosing spondylitis. Enbrel had global brand sales of approximately $11.6 billion for the 12 months ending Dec. 31, 2017, according to IQVIA.

Commenting on the development, Vinita Gupta, CEO, Lupin Limited said, "We are extremely pleased to announce this partnership as both Lupin and Mylan share a commitment to bring affordable and high quality medicines to market, especially in areas of unmet need. Mylan is well-positioned to commercialize our Etanercept biosimilar given their significant expertise and global infrastructure. This partnership enables us to accelerate our Etanercept market plans across multiple regions globally, as we continue to advance our pipeline of biosimilar candidates."

Mylan President Rajiv Malik commented, "The collaboration with Lupin is yet another positive step in our ongoing efforts to bring key biosimilars, like etanercept, to patients around the world as quickly as possible. The introduction of biosimilars is an important mechanism to help increase access to more affordable biologics treatments, and our industry-leading portfolio of 20 biosimilar products positions Mylan to be at the forefront of delivering those savings. We look forward to working closely with Lupin to commercialize their etanercept biosimilar and reach patients in Europe, Australia, New Zealand, Latin America, Africa and most Asian markets."

Lupin successfully completed its Etanercept biosimilar Phase 3 clinical trial in February 2018. Lupin has filed the product with the European Medicines Agency and plans to file the product in other jurisdictions.

Under the terms of the agreement, Lupin will receive an up-front payment of $15 million and potential commercial milestones together with an equal share in net profits of the product.

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 (March 31st, 2018, Bloomberg) and revenues (December 30th 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 (December 30th 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.

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

1 TNF-α (tumor necrosis factor alpha) is a cytokine that is involved in inhibition of tumorigenesis and defense against infection. Overexpression of TNF-α is implicated in a range of inflammatory diseases, including rheumatoid arthritis and psoriasis.

This press release includes statements that constitute "forward-looking statements", including with regard to: Mylan and Lupin's commercialization of a biosimilar to Enbrel® (etanercept); that the introduction of biosimilars is an important mechanism to help increase access to more affordable biologics treatments, and our industry-leading portfolio of 20 biosimilar products positions Mylan to be at the forefront of delivering those savings; that Mylan looks forward to working closely with Lupin to bring their etanercept biosimilar to market and reach patients in Europe, Australia, Latin America and Asia. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-

looking statements. Factors that could cause or contribute to such differences include, but are not limited to: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

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