



August 26, 2020

BSE Limited,

Department of Corporate Services,
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

✓ **National Stock Exchange of India Ltd.,**

Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Dear Sir/Madam,

**Sub: Disclosure pursuant to Regulation 30 of the SEBI
(Listing Obligations and Disclosure Requirements) Regulations, 2015.**

Enclosed is a Press Release as regards launch of Nepexto[®], biosimilar etanercept, in the German market by the Company and Mylan N.V. (NASDAQ: MYL). Nepexto[®] is approved for all therapeutic indications of the reference product Enbrel[®].

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

For LUPIN LIMITED

**R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)**

Encl- : a/a.

Lupin and Mylan Launch Nepexto[®], Biosimilar Etanercept in Germany

- *Nepexto[®] is Lupin's biosimilar etanercept approved for all indications of the reference product Enbrel[®]*
- *Nepexto[®] is available as an injectable in an easy-to-use pre-filled pen and a pre-filled syringe*
- *The approval of Nepexto[®] by the European Medicines Agency (EMA) underlines the scientific success of Lupin's biosimilar programs*

Mumbai, India | BAD HOMBURG, Germany, August 26, 2020: Lupin Limited (Lupin) and Mylan N.V. (NASDAQ: MYL) announced today the launch of Nepexto[®], biosimilar etanercept, in the German market. Nepexto[®] is indicated for the treatment of moderate to severe active rheumatoid arthritis, juvenile idiopathic arthritis from the age of 2 years, active and progressive psoriatic arthritis, severe axial spondyloarthritis, moderate to severe plaque psoriasis and chronic severe plaque psoriasis in children and adolescents from the age of 6 years. Nepexto[®] is approved for all therapeutic indications of the reference product Enbrel[®].

Etanercept as an established therapy option

The Tumor Necrosis Factor (TNF) inhibitor etanercept was first approved for the treatment of rheumatoid arthritis in Germany in 2000 and since then has offered an effective treatment option for several chronic inflammatory diseases.

"TNF inhibitors such as etanercept make it possible to intervene precisely in the inflammatory process," commented Prof. Dr. med. Rieke Alten, chief physician in the Department of Internal Medicine (Rheumatology, Clinical Immunology, Osteology) at the Schlosspark-Klinik Charlottenburg, Berlin. "In patients with moderately severe to severe rheumatoid arthritis who do not respond adequately to basic therapeutics, remission of the disease through therapy with etanercept in combination with methotrexate is a quite realistic therapeutic goal. Rheumatologists have many years of clinical experience with this substance in terms of its efficacy and safety profile. Rheumatologists particularly like to opt for etanercept when 'safety first' is the top priority. Besides rheumatoid arthritis, this TNF inhibitor is also firmly established in other rheumatological indications."

Simple application by means of pre-filled pen

Nepexto[®] is available as a solution for injection in a pre-filled pen and pre-filled syringeⁱ. Data show a high patient acceptance of the easy-to-handle pre-filled pen. Patients favored this latex-free device for self-injection, which can lead to improvement in complianceⁱⁱ.

Cost-effective treatment with Nepexto[®]

Nepexto[®], with an equivalent efficacy and safety to reference product Enbrel[®], is an attractive cost-effective treatment alternative that can contribute to sustainable healthcare and treatment options. The European Commission approved the marketing authorization of Nepexto[®] on June 4, 2020 after the biosimilar received a favorable opinion from the Committee for Medicinal Products for Human Use (CHMP). The CHMP concluded

that the development program including analytical, functional, clinical and immunogenicity data^{iii,iv} demonstrated biosimilarity with its reference product, Enbrel®.

Thierry Volle, President, EMEA, Lupin said, “We are excited to bring Nepexto® in Germany. Nepexto® is our first biosimilar to receive regulatory approval in Europe. This launch is a remarkable milestone for our biosimilar group and we are glad that we are able to bring an affordable biosimilar to the European market through our partner Mylan. Biosimilars like Nepexto® will play a vital role in expanding access to effective treatment for multiple therapies including rheumatoid arthritis.”

Dr. Maximilian von Wülfing, Managing Director of Mylan Germany said, "Germany is the first country in Europe to introduce Nepexto®, the etanercept from Mylan. The approval of Nepexto® (etanercept) by the European Medicines Agency (EMA) once again underlines the scientific success of Mylan’s biologics program. To date Mylan has launched and commercialized four biosimilar products in Germany, two in immunology and two in oncology. Mylan offers a comprehensive and diverse biologics pipeline, and we want to make as many of these complex drugs as possible available to patients in Germany.”

Nepexto is the second immunology product to be introduced into the German market. In addition to Hulio®, an adalimumab biosimilar, Nepexto® expands Mylan’s therapeutic portfolio for the effective treatment of various immune-mediated diseases including rheumatoid arthritis.

About Etanercept

Etanercept is an injectable biologic medicine that inhibits the biological activity of Tumor Necrosis Factor (TNF). TNF is a key cytokine involved in the pro-inflammatory cascade in many chronic, immune-mediated inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis. Etanercept as a soluble TNF receptor fusion protein specifically binds to TNF and blocks its activity, thereby reducing inflammation and disease symptoms.

About Lupin

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women’s health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions and in India by global revenues. The Company invests 9.6 % of its revenues on research and development.

Lupin has fifteen manufacturing sites, seven research centres, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

Please visit www.lupin.com for more information.

Follow us on Twitter: www.twitter.com/LupinGlobal | LinkedIn: www.linkedin.com/company/lupin/

Facebook: www.facebook.com/LupinWorld/

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 portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 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.

For further information or queries please contact –

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***Safe Harbor Statement**

- ⁱ Mylan. Nepexto[®]-Fachinformation (prescribing information), as at May 2020
- ⁱⁱ Yoshida T et al. YLB113 Pre-filled Pen for Convenient Self-Injection by Patients with Rheumatoid Arthritis: Results of a Usability Study and Compliance Survey. Abstract presented at 10th International Conference on Applied Human Factors and Ergonomics 2019, Washington, DC, USA
- ⁱⁱⁱ Shennak M, Al-Jaouni R, Kshirasagar S, et al. An Open-Label, Randomized, Single-Dose, Crossover, Comparative Pharmacokinetics Study of YLB113 and the Etanercept Reference Product in Healthy Adult Male Subjects. Eur J Drug Metab Pharmacokinet. 2020;14:1–9.
- ^{iv} Yamanaka H et al. A Comparative Study to Assess the Efficacy, Safety and Immunogenicity of YLB113 and the Etanercept Reference Product for the Treatment of Patients with Rheumatoid Arthritis. Rheumatol Ther. 2020;7(1):149–163. doi:10.1007/s40744-019-00186-3.