



## Mylan and Lupin Receive European Marketing Authorization for Nepexto®, Biosimilar Etanercept

June 4, 2020

HERTFORDSHIRE, England, PITTSBURGH and MUMBAI, India, June 4, 2020 /PRNewswire/ -- [Mylan N.V.](#) (NASDAQ: MYL) and Lupin Limited (Lupin) today announced that the European Commission (EC) has granted marketing authorization for Nepexto®, a biosimilar to Enbrel® (etanercept), for all indications of the reference product including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.

The regulatory approval follows the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP), which was based on a biosimilarity assessment including preclinical and clinical studies demonstrating bioequivalence to Enbrel. In addition, a phase 3 clinical study in patients with moderate-to-severe active rheumatoid arthritis confirmed equivalence of Nepexto to Enbrel in terms of efficacy, safety and immunogenicity.

The centralized marketing authorization applies to all member countries of the European Union.

Mylan President [Rajiv Malik](#) commented, "The approval of Nepexto, our biosimilar etanercept, is a positive step forward as we work to broaden our biosimilars franchise offerings and do our part to increase access to biologic treatments for patients in many European countries. This milestone reflects a strong scientific program behind Nepexto and commitment by our teams and our partner, Lupin, to bring the product to market as soon as possible. We look forward to launching Nepexto in the second half of this year."

Vinita Gupta, CEO, Lupin Limited said, "We are truly delighted with this approval. Nepexto is our first biosimilar to receive regulatory approval in Europe. With this important milestone, we bring an affordable biosimilar to the European market through our partner Mylan. Biosimilars like Nepexto will play a critical role in expanding access to patients in Europe, providing an effective treatment for multiple therapies including rheumatoid arthritis."

Enbrel had sales of approximately \$9.6 billion globally for the 12 months ending December 2019, according to IQVIA.

In June 2018, Lupin and Mylan announced a collaboration to commercialize a biosimilar to etanercept in several global markets.

### About Etanercept

Etanercept is an injectable, biologic medicine which inhibits Tumour 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 or plaque psoriasis. By specifically binding to TNF, etanercept blocks its activity, thereby reducing inflammation and other disease symptoms.

### 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](#).

### About Lupin Limited

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 centers, 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.

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### Forward-Looking Statements: Mylan

*This press release includes statements that constitute "forward-looking statements," including with regard to the approval of Nepexto, a biosimilar etanercept, being a positive step forward as we work to broaden our biosimilars franchise offerings and do our part to increase access to biologic treatments for patients in many European countries; this milestone reflecting a strong scientific program behind Nepexto and commitment by our teams and our partner, Lupin, to bring the product to market as soon as possible; and looking forward to launching Nepexto in the second half of this*

year. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to[1] the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other 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.

#### **Forward-Looking Statements: Lupin**

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 Mylan's 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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