Mylan and Lupin Announce Positive CHMP Opinion for Nepexto®, Biosimilar Etanercept

March 27, 2020

HERTFORDSHIRE, England, PITTSBURGH and MUMBAI, India, March 27, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Lupin Limited (Lupin) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of 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 positive CHMP opinion is based on a biosimilarity assessment which included preclinical and clinical studies demonstrating bioequivalence to the reference product. In addition, a phase 3 clinical study[i] in patients with moderate-to-severe active rheumatoid arthritis confirmed equivalence of Nepexto to the reference product in terms of efficacy, safety and immunogenicity.

The CHMP positive opinion will now be considered by the European Commission (EC). Once approved the EC will grant a centralized marketing authorization for member countries of the EU. The decision on the EC's approval is expected in May 2020.

Mylan President Rajiv Malik commented, "We are pleased with the positive CHMP opinion for Nepexto, biosimilar etanercept. This recommendation validates the strong scientific program supporting this important treatment, which is one of 20 products in our broad and diverse biosimilars portfolio, and our shared commitment with Lupin to help increase access to more affordable biologic treatments, such as etanercept, in Europe and many other regions around the world."

Vinita Gupta, CEO, Lupin Limited said, "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. We are extremely pleased with the positive CHMP opinion on our application. This milestone brings us one step closer to bringing an affordable biosimilar to etanercept to the European market through our partner Mylan. Once approved by the European Commission, Nepexto will be our first biosimilar to receive regulatory approval in Europe. Building on this progress, we continue to focus on advancing our biosimilar pipeline."

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 growing 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 more than 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.

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Forward-Looking Statements: Mylan
This press release includes statements that constitute "forward-looking statements," including with regard to the timing of regulatory approvals; that

the CHMP positive opinion will now be considered by the EC; once approved the EC will grant a centralized marketing authorization for member countries of the EU; and the decision on the EC's approval is expected in May 2020. 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 the impact of public health outbreaks 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 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.

[i] 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

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