



Mylan Partners with Fujifilm Kyowa Kirin Biologics to Commercialize Biosimilar to Humira® (adalimumab)

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Mylan acquires exclusive license to commercialize in Europe

HERTFORDSHIRE, England and PITTSBURGH, April 11, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced it is partnering with Fujifilm Kyowa Kirin Biologics Co., Ltd. to commercialize a biosimilar to Humira® (adalimumab) developed by Fujifilm Kyowa Kirin Biologics. Through the partnership agreement, Mylan will leverage its regulatory platform to seek approval and commercialize the product in Europe.

Humira is a TNF-inhibitor¹ aimed at treating multiple chronic inflammatory conditions. The product is indicated in Europe for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis. Humira is the world's best-selling biologic medication and had brand sales of approximately \$4.1 billion in Europe for the 12 months ending Dec. 31, 2017, according to IQVIA.

Mylan CEO [Heather Bresch](#), "Expanding access to biologics through the introduction of biosimilars around the world is a key area of focus for Mylan. Our partnership with Fujifilm Kyowa Kirin Biologics for an adalimumab biosimilar in Europe is an exciting advancement for Mylan and for patients who are living with chronic autoimmune conditions and need access to a high-quality, more affordable treatment option."

President [Rajiv Malik](#) added, "We believe Mylan's strong regulatory commercial platform in Europe and scientific leadership in the biosimilars space make us an ideal partner of choice. These attributes combined with Fujifilm Kyowa Kirin Biologics' expertise in biologics, position the two companies to bring an adalimumab biosimilar to the European market in the near term."

The European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application for its proposed biosimilar to Humira on May 18, 2017. The companies expect to receive a decision from EMA in the second half of 2018.

Under the terms of the agreement between two companies, Fujifilm Kyowa Kirin Biologics grants Mylan an exclusive license to commercialize the adalimumab biosimilar in Europe and will receive an up-front fee. In addition, Fujifilm Kyowa Kirin Biologics is eligible to receive a subsequent commercialization milestone payment and sales royalties. Mylan will be responsible for the sales activity of the product in European countries. The two companies continue to negotiate for commercializing the product in additional territories. In addition, Mylan's partner Biocon will receive economic benefit through this collaboration.

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.

Forward-Looking Statement

This press release includes statements that constitute "forward-looking statements", including with regard to: the commercialization of a biosimilar to Humira® (adalimumab) developed by Fujifilm Kyowa Kirin Biologics; that through the partnership agreement, Mylan will leverage its regulatory platform to seek approval and commercialize the product in Europe; that we believe Mylan's strong regulatory commercial platform in Europe and scientific leadership in the biosimilars space make us an ideal partner of choice; that these attributes combined with Fujifilm Kyowa Kirin Biologics' scientific expertise in biologics, position the two companies to bring an adalimumab biosimilar to the European market in the near term; that the companies expect to receive a decision from EMA in the second half of 2018; and that the two companies continue to negotiate for commercializing the product in additional territories. 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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