



Mylan and Fujifilm Kyowa Kirin Biologics Announce Positive CHMP Opinion for Hulio™, Biosimilar Adalimumab

July 27, 2018

HERTFORDSHIRE, England and PITTSBURGH, and TOKYO, July 27, 2018 /PRNewswire/ -- [Mylan N.V.](#) (NASDAQ: MYL) and Fujifilm Kyowa Kirin Biologics Co., Ltd. today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the Marketing Authorization Application of Hulio™ (Product Code: FKB327), the companies' biosimilar to Humira® (adalimumab), for all indications.



The decision of the European Commission (EC) on the approval is expected in October 2018, which would grant marketing authorization in the 28 European Union (EU) member countries and European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.

Mylan CEO [Heather Bresch](#) commented, "We see an urgent need to bring greater access to a more affordable treatment option for patients living with chronic inflammatory conditions such as rheumatoid arthritis, plaque psoriasis and Crohn's disease. CHMP's decision to recommend the approval of Hulio, a biosimilar to adalimumab, represents a positive step to bring this treatment to patients and demonstrates the strength of our collaboration with Fujifilm Kyowa Kirin Biologics."

Fujifilm Kyowa Kirin Biologics President and CEO Dr. Yoshifumi Torii said, "I am delighted that CHMP decided to recommend approval of our proposed biosimilar adalimumab. We continue to commit all efforts to provide high quality biosimilars and strongly hope that Hulio, the first biosimilar product from Fujifilm Kyowa Kirin Biologics, will provide tremendous value for patients throughout European countries."

Mylan President [Rajiv Malik](#) added, "Mylan is extremely proud to be among the first wave of biosimilars of adalimumab in Europe. We continue to identify opportunities in markets around the world to increase treatment options for patients and minimize the healthcare cost burden often associated with complex products like biosimilars. Today's milestone demonstrates our commitment to the development and commercialization of biosimilars and complex products globally."

CHMP has recommended approval of Hulio for multiple chronic inflammatory diseases in adults, including:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Axial spondyloarthritis without radiographic evidence of ankylosing spondylitis
- Psoriatic arthritis
- Psoriasis
- Hidradenitis suppurativa
- Crohn's disease
- Ulcerative colitis
- Uveitis

CHMP also recommended approval of Hulio for the treatment of pediatric inflammatory diseases, including polyarticular juvenile idiopathic arthritis (age 2 and older), enthesitis-related arthritis (age 6 and older), plaque psoriasis (age 4 and older), Crohn's disease (age 6 and older), hidradenitis suppurativa (age 12 and older) and uveitis (age 2 and older).

Data submitted as part of the Marketing Authorization Application included similarity assessment in analytical testing, preclinical and clinical studies that demonstrated biosimilarity to the adalimumab reference product, Humira. The Phase III clinical study, ARABESC, conducted by Fujifilm Kyowa

Kirin Biologics, demonstrated no clinically meaningful differences in terms of safety, efficacy and immunogenicity compared with the reference product, Humira, in rheumatoid arthritis patients.

Fujifilm Kyowa Kirin Biologics granted an exclusive license to Mylan for commercializing biosimilar adalimumab in Europe.

About Adalimumab

Adalimumab is an injectable, biologic medication which inhibits Tumour Necrosis Factor (TNF). This can cause inflammation in autoimmune diseases such as rheumatoid arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis. By specifically binding to TNF, adalimumab 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 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](#).

About Fujifilm Kyowa Kirin Biologics

Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President: Kenji Sukeo; hereinafter "Fujifilm") and Kyowa Hakko Kirin Co., Ltd. (President and COO: Masashi Miyamoto, hereinafter "Kyowa Hakko Kirin") on March 27, 2012 as a company for developing, manufacturing, and marketing biosimilars. Its pipeline includes an adalimumab biosimilar (Product Code: FKB327) and a biosimilar of the anti-VEGF humanized monoclonal antibody bevacizumab (Product Code: FKB238), a drug used to treat a range of cancers including colorectal and non-small cell lung cancer. Fujifilm Kyowa Kirin Biologics established Centus Biotherapeutics Ltd., a joint venture for the development and commercialization of FKB238 with AstraZeneca plc.

By merging the technologies in advanced production, quality control and analysis which Fujifilm has developed over many years through its photographic film business, with the proprietary technologies and know-how which Kyowa Hakko Kirin has accumulated through its biopharmaceutical R&D and manufacturing, Fujifilm Kyowa Kirin Biologics creates revolutionary production processes and reduces costs for the production of biosimilars. Through this partnership, the company will develop and manufacture reliable, high quality, cost-competitive biosimilar products and commercialize these products in a timely manner. With this strategy, Fujifilm Kyowa Kirin Biologics aims to hold a leading position in the expanding biosimilar market.

You can learn more about the business at: [fujifilmkyowakirin-biologics.com](#)

Forward-looking statements: Mylan

This press release includes statements that constitute "forward-looking statements", including with regard to: CHMP adopting a positive opinion for the Marketing Authorization Application of Hulio; and that the decision of the EC on the approval is expected in October 2018, which would grant marketing authorization in the 28 EU member countries and EEA member states of Norway, Iceland and Liechtenstein. 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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SOURCE Mylan N.V.

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