Mylan Launches Hulio™ (Biosimilar Adalimumab) in Markets Across Europe

October 19, 2018

HERTFORDSHIRE, England and PITTSBURGH, Oct. 19, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced that it has initiated the commercial launch of Hulio™, a biosimilar to AbbVie's Humira® (adalimumab), across major markets in Europe. The product, which is approved for all adalimumab indications, will be available to patients as soon as possible.

Mylan President Rajiv Malik commented: "We're proud of our strategic partnership with Fujifilm Kyowa Kirin Biologics and the strong collaboration of our science and technology teams to bring Hulio to market for patients. As the cost of healthcare continues to rise around the world, we know the important role that biosimilars play to ensure patients can access the medicines they need. The availability of Hulio, the fourth product in the area of complex generics and biosimilars that Mylan is bringing to market in Europe, will positively impact the lives of patients in Europe suffering from chronic diseases such as autoimmune disorders. We look forward to continuing our leadership in bringing high quality, more affordable biosimilar products to market around the world."

"The availability of Hulio in Europe represents an important milestone, signifying our commitment to building and executing on robust scientific programs around our portfolio of biosimilar products in development," said Dr. Yoshifumi Torii, Fujifilm Kyowa Kirin Biologics President and CEO. "We are delighted by our partnership with Mylan to bring this important product to market in Europe."

Mylan and Fujifilm Kyowa Kirin Biologics partnered earlier this year. Fujifilm Kyowa Kirin Biologics has a nonexclusive royalty bearing license with AbbVie (Mylan has a sublicense) for the use and sale of Hulio in European countries.

The European Commission (EC) approved Hulio in September 2018, following the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP), which concluded that the development program including analytical, functional, clinical and immunogenicity data demonstrated biosimilarity with Humira.

The EC approval of Hulio applies to all 28 European Union (EU) member countries and European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.

Hulio is indicated for the same indications of Humira, including:

Adults

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

Children

- 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)
- Uveitis (age 2 and older)

Humira is the world's best-selling biologic medication. It had brand sales of approximately $4.3 billion in Europe for the 12 months ending July 31, 2018, according to IQVIA.

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 Sukeno; 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 Hulio® 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 advanced technologies in production, quality control and analysis which Fujifilm has developed in its relentless pursuit of innovation, 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 Hulio being available to patients as soon as possible. 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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