Mylan and Fujifilm Kyowa Kirin Biologics Announce U.S. FDA Approval of Hulio® (adalimumab-fkjp)

July 9, 2020

HERTFORDSHIRE, England and PITTSBURGH and TOKYO, July 9, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) and Fujifilm Kyowa Kirin Biologics Co., Ltd. today announced that the U.S. Food and Drug Administration (FDA) has approved Hulio® (adalimumab-fkjp), a biosimilar to AbbVie's Humira® (adalimumab), for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis (4 years and older), psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis, in both prefilled syringe and auto-injector presentations.

Mylan President Rajiv Malik commented: "We are very pleased with FDA's approval of Hulio, a biosimilar to the world's top selling drug Humira, which will help bring another treatment option to U.S. patients living with chronic inflammatory conditions. This approval represents yet another date-certain launch opportunity and demonstration of our commitment to expand patients' access to medicine thanks to the power of our global platform, including our global reach and scale, our continued demonstration of scientific excellence, and the benefits of strategic partnerships, such as the one we are proud to have with Fujifilm Kyowa Kirin Biologics. With one of the industry's largest and most diverse global biosimilars franchises, Mylan is committed to improving patient access to this and other critically important biologic medicines as well as providing more affordable treatment options for patients worldwide."

"The FDA approval of Hulio marks a significant milestone for both Fujifilm Kyowa Kirin Biologics and Mylan, increasing access to affordable treatment for U.S. patients with inflammatory conditions." said Atsushi Matsumoto, Fujifilm Kyowa Kirin Biologics President and CEO. "In cooperation with Mylan, we continue to make all efforts to deliver this high quality and affordable biosimilar throughout the world."

In accordance with its patent license agreement with AbbVie, Mylan will be able to launch Hulio in the U.S. during July 2023.

The approval of Hulio was based on a comprehensive analytical, preclinical and clinical program. The Phase 3 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.

Mylan and Fujifilm Kyowa Kirin Biologics entered into a partnership in 2018 for the commercialization of Hulio in Europe and Mylan has commercialized the product in several countries across the region. In 2019, Mylan and Fujifilm Kyowa Kirin Biologics expanded the partnership globally. Recently, Hulio (Brand name in Japan: Adalimumab BS "FKB") received regulatory approval in Japan. These approvals and launches form part of Mylan's commitment to patients by offering one of the industry's largest and most diverse global biosimilars franchises focused on the areas of oncology, immunology, endocrinology, ophthalmology and dermatology.

Humira had brand sales of approximately $14.9 billion in the U.S. for the 12 months ending December 2019, according to AbbVie's 2019 annual report.

Hulio carries a Boxed Warning for an increased risk of serious infections leading to hospitalization or death, such as tuberculosis (TB), bacterial sepsis, invasive fungal infections and infections due to opportunistic pathogens. Hulio should be discontinued if a patient develops a serious infection or sepsis during treatment. Test for latent TB and if positive, begin TB treatment before initiating Hulio. Monitor all patients for active TB during treatment, even if the initial TB test is negative. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including Hulio. Post-marketing cases of hepatosplenic T-cell lymphoma have occurred in young adults with inflammatory bowel disease treated with TNF blockers including Hulio.

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 Fujifilm Kyowa Kirin Biologics
Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President: Kenji Sukeno; hereinafter "Fujifilm") and Kyowa Kirin Co., Ltd. (President and CEO: Masashi Miyamoto, hereinafter "Kyowa 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 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 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 bringing another treatment option to U.S. patients living with chronic inflammatory conditions; launching Hulio in the U.S. beginning July 2023; product approvals; and the Company's global platform, product franchises and strategic partners. 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 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.

Humira is a registered trademark of AbbVie.

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