

Fujifilm Kyowa Kirin Biologics Announces Approval of “Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]” in Japan

TOKYO, June 29, 2020 –Fujifilm Kyowa Kirin Biologics Co., Ltd. today announced that Fujifilm Kyowa Kirin Biologics received manufacturing and marketing approval (MMA) in Japan on June 29 for “Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]” (Product Code: FKB327).

The product is the first biosimilar in Japan to AbbVie Inc's Humira® (adalimumab) marketed most widely around the world. In Japan, Fujifilm Kyowa Kirin Biologics is the marketing authorization holder and Mylan EPD G.K. will be in charge of the commercialization of the product.

Fujifilm Kyowa Kirin Biologics entered into a partnership with Mylan in 2018 for the commercialization of the biosimilar adalimumab in Europe and expand it globally in 2019. To date, Mylan has commercialized the product as Hulio® in over 20 countries across Europe. Fujifilm Kyowa Kirin Biologics will continue to work obtaining marketing approvals in other countries around the world.

"We are proud to be a leader by providing the first Adalimumab biosimilar in Japan." said Atsushi Matsumoto, Fujifilm Kyowa Kirin Biologics President and CEO. "It is our commitment to contribute to increasing the treatment options for the patients with inflammatory conditions as well as saving healthcare costs. We continue to make all efforts to deliver the high quality and affordable biosimilar throughout the world"

“Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]” is indicated as follows:

Brand name	Adalimumab BS Subcutaneous Injection 40mg Syringe 0.8mL [FKB] Adalimumab BS Subcutaneous Injection 40mg Pen 0.8mL [FKB]	Adalimumab BS Subcutaneous Injection 20mg Syringe 0.4mL [FKB]
Generic name	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]	
Indications	Rheumatoid Arthritis, Psoriasis Vulgaris, Arthritic Psoriasis, Pustular Psoriasis, Ankylosing Spondylitis, Entero-Behcet's Disease, Crohn's Disease, Polyarticular-course Juvenile Idiopathic Arthritis	Polyarticular-course Juvenile Idiopathic Arthritis

Humira is the world's best-selling medication. It had brand sales of approximately \$26.9 billion globally for the 12 months ending Dec. 31, 2019, according to IQVIA.

About Adalimumab

Adalimumab is an injectable, biologic medication which inhibits Tumour Necrosis Factor (TNF). TNF 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 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