

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

TOKYO, Japan– April 11, 2018 – Fujifilm Kyowa Kirin Biologics Co., Ltd. today announced the company will partner with Mylan N.V. (NASDAQ: MYL) to commercialize FKB327, a biosimilar to Humira® (adalimumab) developed by Fujifilm Kyowa Kirin Biologics. It has entered into an agreement with Mylan to grant an exclusive commercialization right of FKB327 in Europe.

Humira is a TNF- $\alpha$ <sup>1</sup> inhibitor 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.

"I am delighted that we entered into partnership with Mylan for an adalimumab biosimilar, FKB327 in Europe," said Dr. Yoshifumi Torii, President and CEO of Fujifilm Kyowa Kirin Biologics. "I believe that the establishment of this agreement with Mylan attests to the value of Fujifilm Kyowa Kirin Biologics' proprietary technology in biosimilars space and Mylan's significant experience and expertise in regulatory commercialization with Fujifilm Kyowa Kirin Biologics' scientific expertise will ensure patients across Europe benefit from the treatment option."

Under the terms of the agreement between two companies, Fujifilm Kyowa Kirin Biologics grants Mylan an exclusive license to commercialize FKB327 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.

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.

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 and a biosimilar of the anti-VEGF humanized monoclonal antibody bevacizumab (Development No. 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.

<sup>1</sup> TNF- $\alpha$  (tumor necrosis factor alpha) is a cytokine that is involved in inhibition of tumorigenesis and defense against infection. Overexpression of TNF- $\alpha$  is implicated in a range of inflammatory diseases, including rheumatoid arthritis and psoriasis.