

**FUJIFILM KYOWA KIRIN BIOLOGICS Announces Marketing Authorisation Application for  
FKB327 Accepted for Review by European Medicines Agency**

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FUJIFILM Corporation  
Kyowa Hakko Kirin Co., Ltd.

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. (President & CEO: Hideaki Nomura; “Fujifilm Kyowa Kirin Biologics”) announces that on May 18, 2017, the European Medicines Agency (EMA) has accepted for review the Marketing Authorisation Application (MAA) for FKB327, an adalimumab biosimilar candidate to the fully human anti-TNF- $\alpha$ \*1 monoclonal antibody, Humira®.

In December 2014, Fujifilm Kyowa Kirin Biologics began a Phase 3 global clinical study of FKB327 at sites in the US, Europe and other countries to compare the efficacy and safety profile of FKB327 with Humira®(reference product) in patients with moderate to severe rheumatoid arthritis\*2. In this study, FKB327 met the primary endpoint and prespecified criteria for equivalence, and there were no significant differences in the rate of adverse events between FKB327 and Humira®. Based on the top-line results, announced on October 19, 2016, Fujifilm Kyowa Kirin Biologics decided to file the MAA for FKB327 to EMA in April 2017.

“We are delighted that EMA has accepted the application,” said Hideaki Nomura, President & CEO of Fujifilm Kyowa Kirin Biologics. “The acceptance of this filing brings us one step closer to meeting the demand for high quality and affordable biopharmaceuticals.”

Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President & COO: Kenji Sukeno; “Fujifilm”) and Kyowa Hakko Kirin Co., Ltd. (President and CEO: Nobuo Hanai; “Kyowa Hakko Kirin”) on March 27, 2012 as a company for the development, manufacture, and marketing of biosimilars.

Fujifilm Kyowa Kirin Biologics creates revolutionary production processes and reduces the production cost of biosimilars 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 accumulated by Kyowa Hakko Kirin through its biopharmaceutical R&D and manufacture. As the results of this partnership, the goal of Fujifilm Kyowa Kirin Biologics is to develop and manufacture reliable, high quality, cost-competitive biosimilar products that it will commercialise in a timely manner. Through this strategy, Fujifilm Kyowa Kirin Biologics aims to attain a leading position in the expanding biosimilar market. For more information about Fujifilm Kyowa Kirin Biologics, please visit <http://fujifilmkyowakirin-biologics.com/en/>.

- \*1 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.
- \*2 Rheumatoid arthritis is an inflammatory autoimmune disorder that affects the joints, in particular arms and legs. It typically results in painful joints and joint degeneration, leading to deterioration of the daily functional activities. The disease may also cause malaise as one of the general symptoms.