

**Fujifilm Kyowa Kirin Biologics Announces Positive Result in Primary Endpoint from  
Phase 3 Study of Adalimumab Biosimilar, anti-TNF- $\alpha$  Monoclonal Antibody**

October 19, 2016  
FUJIFILM Corporation  
Kyowa Hakko Kirin Co., Ltd.

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. (President and CEO: Hideaki Nomura; hereinafter “Fujifilm Kyowa Kirin Biologics”) today announced that it has achieved major objectives in the Phase 3 global clinical study of FKB327, an adalimumab biosimilar candidate of the fully human anti-TNF- $\alpha$ <sup>\*1</sup> monoclonal antibody referencing Humira<sup>®</sup>.

This Phase 3 global clinical study of FKB327 was initiated in December 2014 at sites in the US, Europe, and other countries by Fujifilm Kyowa Kirin Biologics, and compared the efficacy and safety profile of FKB327 with Humira<sup>®</sup> (reference product) in moderate to severe rheumatoid arthritis<sup>\*2</sup> patients.

The primary endpoint (ACR20 response<sup>\*3</sup>), evaluating the disease activity of rheumatoid arthritis after 24 weeks of treatment, met the prespecified criteria of equivalence. No major difference was observed in adverse events between FKB327 and Humira<sup>®</sup>.

Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President & COO: Kenji Sueno; hereinafter “Fujifilm”) and Kyowa Hakko Kirin Co., Ltd. (President and CEO: Nobuo Hanai, hereinafter “Kyowa Hakko Kirin”) on March 27, 2012 as a company for developing, manufacturing, and marketing biosimilars. The company has been developing FKB327 and a biosimilar candidate of the anti-VEGF humanized monoclonal antibody “Bevacizumab” (Code No.: FKB238), a drug used to treat a range of cancers including colorectal and non-small cell lung cancer. A Phase 3 global clinical study of FKB238 is being conducted by Centus Biotherapeutics Ltd, a joint venture established by Fujifilm Kyowa Kirin Biologics and AstraZeneca plc (London, UK, CEO: Pascal Soriot) for the development and commercialization of FKB238.

Fujifilm Kyowa Kirin Biologics creates revolutionary production processes and reduces costs for the production 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 which Kyowa Hakko Kirin has accumulated through its biopharmaceutical R&D and manufacturing. 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.

\*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.

- \*3 ACR20 response is at least 20% improvement according to American College of Rheumatology criteria. Subjects will be considered an ACR20 responder if : they achieve : at least 20% improvement in swollen and tender joint counts, and 20% improvement at least 3 of the following 5 measures: 1) Subject's pain assessment 2) Subject's Global Assessment 3) Physician's Global Assessment 4) Health Assessment Questionnaire – Disability Index 5) Acute-phase reactant (CRP).