The UK High Court of Justice (Patents) Rules in Fujifilm Kyowa Kirin Biologics' Favor on Rheumatoid Arthritis, Psoriasis and Psoriatic Arthritis Dosing Regimens for Adalimumab are Obvious and Unpatentable

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FUJIFILM Corporation
Kyowa Hakko Kirin Co., Ltd.

FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. (President and CEO: Hideaki Nomura; "Fujifilm Kyowa Kirin Biologics") today announced that on March 3, 2017, the UK High Court of Justice ruled in Fujifilm Kyowa Kirin Biologics' favor in patent litigation proceedings brought against AbbVie Biotechnology Limited ("AbbVie") in respect of the validity of certain adalimumab dosing regimens for rheumatoid arthritis, psoriasis and psoriatic arthritis. Fujifilm Kyowa Kirin Biologics brought the action in relation to FKB327, its adalimumab biosimilar candidate of the fully human anti-TNF-α[*1] monoclonal antibody referencing Humira®, which Fujifilm Kyowa Kirin Biologics has been developing.

On October 29, 2015, Fujifilm Kyowa Kirin Biologics commenced patent revocation proceedings against AbbVie seeking a declaration that AbbVie's dosing regimen patents for rheumatoid arthritis, psoriasis and psoriatic arthritis were invalid in the light of certain prior art[*2]. Although, following the commencement of the proceedings, AbbVie abandoned and/or withdrew the patents in the UK, the Court permitted Fujifilm Kyowa Kirin Biologics to continue the proceedings so as to obtain the UK High Court declaration that the dosing regimens were known and/or obvious, and are therefore not eligible for patent protection.

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 developing, manufacturing, and marketing biosimilars. The company has achieved major objectives in the Phase 3 global clinical study of FKB327 in October 2016 and is preparing to file its application for marketing authorization for FKB327.

The company also has been developing 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 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-α (tumor necrosis factor alpha) is a cytokine that is involved in inhibition of tumorigenesis and defense against infection. Overexpression of TNF-α is implicated in a range of inflammatory diseases, including rheumatoid arthritis and psoriasis.

*2 About 5 months after commencement of Fujifilm Kyowa Kirin Biologics' revocation action, third parties filed a similar action against the Patents on March 24, 2016, which further to a court order was consolidated with Fujifilm Kyowa Kirin Biologics' action.