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Fujifilm Kyowa Kirin Biologics Co., Ltd.

Fujifilm Kyowa Kirin Biologics Presents Results from Randomized Phase 3 Study in Patients with Rheumatoid Arthritis, Demonstrating Clinical Equivalence of FKB327 with Adalimumab

**- EFFICACY AND SAFETY RESULTS OF A PHASE III STUDY COMPARING FKB327, AN
ADALIMUMAB BIOSIMILAR, WITH THE ADALIMUMAB REFERENCE PRODUCT IN PATIENTS WITH
ACTIVE RHEUMATOID ARTHRITIS – EULAR 2017**

Fujifilm Kyowa Kirin Biologics Co., Ltd. announced results from the randomized Phase 3 trial of FKB327 in patients with Rheumatoid arthritis (ARABESC study) *1 were presented at the Annual Meeting of the European Congress of Rheumatology (EULAR) on June 14, 2017 in Madrid by Rieke Alten, MD, PhD from the Medical University of Berlin in Germany. The study demonstrated that treatment with FKB327 (an adalimumab Biosimilar Candidate) is equally effective and safe compared with the reference product (RP) adalimumab. ACR20 response rate (20 percent or greater improvement in ACR assessment) at week 24 was 74.4% of patients in the FKB327 group and 75.7% in the adalimumab group, at 95% CIs for treatment difference (FKB327 – adalimumab: -7.6 to 5.0) and fell well within equivalence margin, meeting the primary endpoint. The safety profile, anti-drug antibody formation and pharmacokinetics of FKB327 were also similar compared with those of the reference product, supporting comparability of FKB327 and adalimumab RP in patients with rheumatoid arthritis.

EULAR 2017 abstract

<http://scientific.sparx-ip.net/archiveular/index.cfm?searchfor=FKB327&c=a&view=1&item=2017OP0021>

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 that can reduce 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 result of this partnership, Fujifilm Kyowa Kirin Biologics' aim is to develop and manufacture reliable, high quality, cost competitive biosimilar products that will be marketed 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 Phase III Study design (NCT02260791)**

This randomized, double-blind, active-controlled Phase 3 study (ARABESC) evaluated efficacy and safety of FKB327 (proposed adalimumab biosimilar) compared to adalimumab RP in adult patients with moderate-to-severe rheumatoid arthritis who had an inadequate response to methotrexate. A total of 728 patients were randomized to receive either 40 mg FKB327 or adalimumab RP by subcutaneous injection every two weeks for 22 weeks. The primary endpoint of the study was the ACR20 response rate at week 24, followed by a safety follow-up period through to week 26 or continuation into the Open Label Extension Study.

<https://clinicaltrials.gov/ct2/show/NCT02260791?term=FKB327&rank=1>