

November 08, 2017

Fujifilm Kyowa Kirin Biologics Co., Ltd.

Fujifilm Kyowa Kirin Biologics co. Ltd., presented results from Phase 3 studies consisted of Randomized Double-Blind and Open-Label Extension Studies in Patients with Rheumatoid Arthritis, Demonstrating clinical similarity of FKB327 with Adalimumab including switching treatment

- Efficacy, Safety and Immunogenicity in a Randomised Double-Blind (DB) and Open-Label Extension (OLE) Studies Comparing FKB327, an Adalimumab Biosimilar, with the Adalimumab Reference Product (Humira®; RP) in Patients with Active Rheumatoid Arthritis (RA) – ACR 2017

Fujifilm Kyowa Kirin Biologics Co., Ltd. announced results from the Phase 3 studies, which consist of the randomized double-blind (DB) study and the first interim analysis of the open-label extension (OLE) study of FKB327 in patients with rheumatoid arthritis (ARABESC^{*1} and ARABESC-OLE^{*2} study) were presented at the Annual Meeting of the American College of Rheumatology (ACR) on November 07, 2017 in San Diego, USA by Mark C, Genovese MD from Medicine – Immunology and Rheumatology at Stanford University School of Medicine, Palo Alto, California, USA. The DB 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 comparable (FKB327 72.5%; RP 74.3%), 90% CI (-7.3, 3.6) fell within prespecified equivalence margin. Safety profiles and prevalence/ titer of anti-drug antibodies (ADAs) were all well-matched. At interim analysis of the OLE study, which was re-randomized FKB327 or RP, 1 year safety and immunogenicity comparison and treatment switched data were provided. The results showed safety profiles were comparable on all treatment sequences, and no consistent differences in ADA profiles were seen between continuous and switched treatments.

ACR abstract

<http://acrabstracts.org/abstract/efficacy-safety-and-immunogenicity-in-randomized-double-blind-db-and-open-label-extension-ole-studies-comparing-fkb327-an-adalimumab-biosimilar-with-the-adalimumab-reference-product-humira/>

Fujifilm Kyowa Kirin Biologics (President & CEO: Yoshifumi Torii) 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 ARABESC 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>

***2 ARABESC-OLE Study design (NCT02405780)**

The open-label extension study of FKB327 study (ARABESC-OLE) evaluated to compare long-term safety, efficacy and Immunogenicity of FKB327 with RP in rheumatoid arthritis patients. A total of 645 patients who had completed ARABESC study randomized to receive either 40 mg FKB327 or adalimumab RP by subcutaneous injection every two weeks for 28 weeks and patients continued to receive single arm FKB327 for up to 76 weeks. The primary endpoint of the study was to compare the safety of long-term treatment with FKB327 and RP and evaluated safety, changes in efficacy, and changes in PK and immunogenicity in patients who were switched from treatment from the preceding ARABESC study.

<https://clinicaltrials.gov/ct2/show/NCT02405780?cond=FKB327&rank=2>