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Translation

Japanese Study for ACTEMRA® Showed New Data on the Improvement of Symptoms and Safety in Rheumatoid Arthritis at EULAR 2015

June 15, 2015 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] (hereafter “Chugai”) announced today that it presented new data of the humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody, ACTEMRA® based on the study for Japanese patients with rheumatoid arthritis at the European League Against Rheumatism Annual Congress (EULAR 2015) in Rome, Italy, 10 – 13 June, 2015.

The FIRST BIO STUDY, one of the Japanese studies presented at EULAR 2015 was conducted with the aim to evaluate the effectiveness and safety of ACTEMRA for biologic-naïve patients with moderate RA in real-world clinical setting.

"The results of the FIRST BIO STUDY reinforced that ACTEMRA is an effective treatment for Biologics-naïve RA patients which has already been proven through the result of the post-marketing surveillance conducted in Japan,” said Dr. Tsuneyo Mimori, professor at Kyoto University, a presenter and investigator of this study. “This evidence encourages us the proper use of ACTEMRA in our daily clinical practice."

"We are pleased to be in a position to share these new findings of ACTEMRA, the first antibody drug originating from Japan, with the medical community at EULAR 2015,” said Dr. Naoki Ishiguro, professor at Nagoya University, a lead investigator of this study. “This is a significant news for patients who will start receiving their first biologic treatment."

< Main abstracts of ACTEMRA >

Abstract title	Effectiveness and safety of tocilizumab in biologics naïve RA patients —PMS for investigating success in achieving clinical and functional remission and sustaining efficacy with tocilizumab in biologics-naïve RA patients (FIRST BIO) STUDY
Abstract number	SAT0211
Summary	Clinical benefit of tocilizumab in biologics-naïve RA patients has already been shown through the result of all-patient registry PMS (PMS7901) conducted in Japan. The aim of the FIRST BIO study is to evaluate overall effectiveness and safety of tocilizumab (TCZ) only in biologics-naïve RA patients. As the result of 52 weeks treatment with 8mg/kg of TCZ administered every 4 weeks in 839 RA patients, CDAI remission rate and HAQ-DI remission rate at week 52 were 36.8% and 65%, respectively. No new safety issues were observed.
Abstract title	Long term safety for tocilizumab in real-world setting; 3 year follow-up postmarketing surveillance of 5573 patients with rheumatoid arthritis in Japan
Abstract number	SAT0194
Summary	The objective of this study was to evaluate the safety of Actemra treatment in RA patients with a 3-year follow-up period in a real-world clinical setting in Japan. Incidence of fatal events, malignancies, cardiac dysfunction, gastrointestinal perforation, and serious infections did not increase over time. Long-term use of Actemra was not associated with any new safety issues.
Abstract title	The effect of anti-IL-6 receptor antibody on cartilage destruction in a mouse model of collagen-induced arthritis
Abstract number	THU0061
Summary	Bone and cartilage destruction are one of the serious symptoms in rheumatoid arthritis. The purpose of this study was to investigate the effect of anti-IL-6 receptor antibody on cartilage destruction in a murine arthritis model. Although arthritis induced joint space narrowing and the increased expression of cartilage matrix–degrading enzymes and oxidative stress were observed, these events were inhibited by administering anti-IL-6 receptor antibody.

ACTEMRA is approved in over 100 countries and launched in over 90 countries across the globe. Chugai positions the Bone and Joint diseases as one of our core therapeutic areas, and committed to contribute to the treatments through delivering new data of ACTEMRA to patients and health care providers.