



Efficacy of "Actemra[®] Subcutaneous Injection" Confirmed in Dose Interval Reduction Study in Patients with Rheumatoid Arthritis Who Inadequately Respond to Bi-weekly Dose

TOKYO, May 16, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that "Actemra[®] Subcutaneous Injection" (Actemra), the humanized antihuman IL-6 receptor monoclonal antibody, successfully met the primary endpoint in a dose interval reduction study (MRA231JP study) conducted in patients with rheumatoid arthritis who inadequately respond to the currently approved bi-weekly dosage regimen.

"The efficacy and safety of the weekly dose, easy-to-use subcutaneous injection that was demonstrated in the study will further expand treatment options for patients with rheumatoid arthritis," said Chugai's Director and Executive Vice President, Dr. Yutaka Tanaka. "Chugai will continue its efforts on early submission of the product to broaden treatment options for patients with rheumatoid arthritis."

MRA231JP study is a double-blind controlled study intended to verify the efficacy and safety of the weekly dose of Actemra in patients randomized to either receive the weekly or bi-weekly dose among patients with rheumatoid arthritis who inadequately respond to the bi-weekly dose of Actemra 162 mg/dose. Variation of DAS28-ESR at Week 12 of treatment was selected as the primary endpoint.

In terms of the primary endpoint, superiority of weekly dose to bi-weekly dose was confirmed in the MRA231JP study. In addition, safety profile of the weekly dose was demonstrated to be comparable to those reported to date on Actemra. The details of the study results will be released in scientific journals and presented at academic conferences in due course.