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Application for Approval of Additional Dosage for "Actemra® Subcutaneous Injection" in Patients with Rheumatoid Arthritis Who Inadequately Respond to Every Other Week Dosage

TOKYO, August 25, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has filed an application with the Ministry of Health, Labour and Welfare (MHLW) for the approval of an additional dosage of "Actemra® Subcutaneous Injection," the humanized antihuman IL-6 receptor monoclonal antibody, in patients with rheumatoid arthritis who inadequately respond to the currently approved every other week dosing regimen.

This filing was based on the data of Japanese MRA231JP study which is a randomized, parallel group, double-blind controlled study conducted to verify the efficacy and safety of the weekly dose of Actemra 162mg subcutaneous injection, comparing to the every other week dosing regimen in patients with rheumatoid arthritis who inadequately respond to the every other week dose of Actemra 162mg subcutaneous injection.

The result of MRA231JP study confirmed the superiority of weekly dose to every other week dose in its primary endpoint of the change from baseline in the DAS28-ESR at weeks 12. 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 published in scientific journals and presented at academic conferences in due course.

Chugai will continue its efforts on approval of an additional dosage to broaden treatment options for patients with rheumatoid arthritis.

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