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Approval of Additional Dosage for "Actemra® Subcutaneous Injection" Reducing Dose Interval to One Week in Patients with Rheumatoid Arthritis Who Inadequately Respond to Bi-weekly Dose

TOKYO, June 26, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained approval by the Ministry of Health, Labour and Welfare (MHLW) for the additional dosage and administration of "Actemra® Subcutaneous Injection" (Actemra), the humanized antihuman IL-6 receptor monoclonal antibody, reducing the dose interval to one week in patients with rheumatoid arthritis who inadequately respond to the bi-weekly dosage.

This approval is based on the results of the Japanese SHINOBI study (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 the SHINOBI 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.

"We are delighted that this additional dosage was approved as a new treatment option for patients with rheumatoid arthritis who had responded inadequately to treatment until now. The subcutaneous injection is easy to use, and we are confident that it will enhance the QOL of patients," said Dr. Yasushi Ito, Senior Vice President, Head of Project & Lifecycle Management Unit. "Since it was launched in 2005 as the first antibody drug developed in Japan, Actemra has repeatedly expanded its indications and has contributed to the treatment of many patients fighting against disease. Going forward, we will continue to promote the appropriate use of the drug to enable patients to feel confident and secure when receiving treatment."

With the conventional dosage, patients who responded inadequately to treatment were required to switch to intravenous injection, resulting in inconvenience in terms of the time required for patients to go to the hospital or clinic and receive the treatment and burden on health care providers. Due to the approval, by shortening the dose interval to one week, it is expected to continue the treatment for patients without lowering the convenience.

[Indications]
Rheumatoid arthritis that does not respond sufficiently to existing therapies (including inhibition of structural joint damage)
[Dosage and Administration] * The underlined description is newly added.
The recommended dose of tocilizumab (genetical recombination) for adults is 162mg as a single subcutaneous injection administered at 2-week intervals. The dosing interval can be shortened to a minimum of 1 week when sufficient response is not seen.

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