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# Approval of Actemra® for Additional Indications of Takayasu Arteritis and Giant Cell Arteritis, Both are Designated Intractable Diseases

TOKYO, August 25, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained an approval for the humanized anti-human IL-6 receptor monoclonal antibody, “Actemra® 162mg Syringe for subcutaneous (SC) Injection” and “Actemra® 162mg Auto-Injector for SC Injection”(Actemra) by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the additional indications of Takayasu arteritis (TAK) and giant cell arteritis (GCA) that have not responded sufficiently to existing therapies.

This approval is based on the results of the following two phase III studies: MRA632JP study in patients with TAK conducted in Japan and WA28119 study (GiACTA Study) in patients with GCA which is initiated by Roche.

Large vessel vasculitis (LVV) is composed of TAK and GCA, and leads to development of artery stenosis and aneurysms through the inflammation of the blood vessels, and is known to cause severe organ damages such as strokes, valvular incompetence, and impaired renal function depending on location of the lesion. Both TAK and GCA are designated as an intractable disease by Japanese authorities. There are estimated to be approximately 7,000 patients in Japan with LVV, and Actemra was designated as an orphan drug for the treatment of LVV by MHLW in June 2014.

“We are pleased that Actemra has obtained new indications for TAK and GCA which have not responded sufficiently to existing therapies, while the development of the drugs for orphan diseases are not so active in Japan even though there remains high unmet medical needs,” said Dr. Yasushi Ito, Senior Vice President, Head of Project & Lifecycle Management Unit. “Actemra, created by Chugai, was first launched in 2005 as the treatment of the rare disease, Castleman’s disease. We expect that the drug will contribute to the patients with TAK or GCA as well.”

The result of GiACTA study was published in the online version of The New England Journal of Medicine (NEJM) on July 27, 2017.
http://www.nejm.org/doi/full/10.1056/NEJMoa1613849

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[Indications] * The underlined description is newly added.

- The following diseases that have not responded sufficiently to existing therapies
  Rheumatoid arthritis (including inhibition of structural joint damage)
  Takayasu arteritis, giant cell arteritis

[Dosage and Administration]

- Rheumatoid arthritis
  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.
- Takayasu arteritis, giant cell arteritis
  The recommended dose of tocilizumab (genetical recombination) is 162mg as a single subcutaneous injection administered at 1-week intervals.