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Filing for Approval of "Actemra®" for Additional Indication of "Large Vessel Vasculitis," the Designated Intractable Disease

TOKYO, November 30, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the approval of an additional indication of large vessel vasculitis (LVV) for the humanized anti-human IL-6 receptor monoclonal antibody, Actemra®.

LVV is composed of Takayasu arteritis (TAK) and giant cell arteritis (GCA), both are designated as an intractable disease by Japanese authorities. As reports of TAK are made mainly in Asia and the Middle and Near East, and there are a particularly large number of cases reported in Japan, a phase III clinical study (MRA632JP study) in patients with TAK was conducted in Japan. Based on the results of this study along with the results of a Phase III global study (WA28119: GiACTA Study) in patients with GCA, mainly found in the US and Europe, conducted and led by Roche, the application was submitted for approval.

LVV 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. Steroids are used for the treatment of the disease as a first choice, however, severe adverse reactions with long-term administration and recurrence of the disease are seen when tapering the dosage of steroids. Due to this situation, new treatment options have been sought from all sides including patients and healthcare professionals. 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.

Chugai is dedicated to acquiring this additional indication in an effort to expand and enhance the treatment options available to patients with LVV, and will continue to strive to create innovative new medicines for patients who suffer from rare diseases.

The results of the GiACTA study were presented at the American College of Rheumatology (ACR) conference on November 13 of this year and at the Association for Rheumatology Health Professionals (ARHP) annual meeting.
http://www.roche.com/media/store/releases/med-cor-2016-11-12.htm

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