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Chugai's ACTEMRA®/RoACTEMRA® Receives Breakthrough Therapy Designation from US FDA for Giant Cell Arteritis

—The Fifth Breakthrough Therapy Designation Granted for a Chugai Originated Drug—

TOKYO, October 5, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to ACTEMRA®/RoACTEMRA® (tocilizumab), a Chugai originated drug, which is currently under development by Roche and Genentech for the indication of Giant Cell Arteritis (GCA).

"We are very pleased that the FDA has once again granted Breakthrough Therapy Designation to ACTEMRA/RoACTEMRA, following last year's designation for systemic sclerosis," said Chugai's Senior Vice President, Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "This designation indicates that ACTEMRA/RoACTEMRA is highly regarded, and has great potential to fulfill unmet medical needs in auto-immune diseases."

This designation was based on the GiACTA study, which is a global Phase III study assessing the efficacy and safety in patients with GCA. This is the fifth Breakthrough Therapy Designation for a Chugai originated drug, following these three products: alectinib (ALK-positive non-small cell lung cancer with disease progression on crizotinib, first line treatment for ALK-positive non-small cell lung cancer), tocilizumab (systemic sclerosis), and emicizumab (prophylactic treatment for patients 12 years or older with hemophilia A with factor VIII inhibitors).

Based on Chugai's business philosophy "innovation all for the patients," Chugai will collaborate with Roche and Genentech to submit marketing applications for ACTEMRA/RoACTEMRA in a number of countries around the world, with the intent to increase access to this new treatment option for patients and healthcare professionals as soon as possible.

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About Breakthrough Therapy

The Breakthrough Therapy Designation was adopted as part of the FDA Safety and Innovation Act (FDASIA) enacted in July 2012 aiming at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms. In order to grant Breakthrough Therapy Designation, preliminary clinical evidence is required demonstrating that the drug may have substantial improvement on at least one clinically significant endpoint over existing therapies. Breakthrough Therapy Designation includes the features of a Fast Track designation, with the addition of intensive guidance on efficient drug development as well organizational commitment from FDA.

About Giant Cell Arteritis

Giant Cell Arteritis (GCA) belongs to an autoimmune disease called large-vessel vasculitis. GCA is a granulomatous vasculitis occurring primarily in the aorta and aortic branches, mainly the temporal arteries. Common initial symptoms include headache, systemic conditions such as fever, and loss of vision. GCA is prevalent in Western countries and affects women more than men with the typical age of onset 50 years or older[1)]. Vasculitis can be classified into three different groups depending on the size of the inflammatory vessels, such as large vessel vasculitis, medium vessel vasculitis and small vessel vasculitis[2)]. Besides GCA, Takayasu's arteritis which appears more commonly in Asian young ladies is also included in large-vessel vasculitis.

About the GiACTA Study

GiACTA (NCT01791153) is a Phase III, global, randomised, double-blind, placebo-controlled trial investigating the efficacy and safety of ACTEMRA®/RoACTEMRA® as a novel treatment for GCA. It is the largest clinical trial ever conducted in GCA and the first to use blinded, variable-dose, variable-duration steroid regimens. The multicenter study was conducted in 251 patients across 76 sites in 14 countries. The study's primary endpoint was the proportion of patients achieving sustained disease remission at week 52. The secondary endpoints were the time to first GCA flare after clinical remission, cumulative corticosteroid dose at week 52, and also safety outcome measures.

The GiACTA data will be submitted for presentation at an upcoming medical conference and to regulatory authorities around the world for approval consideration.

Reference

1. Lawrence C, et al. Arthritis & Rheum 1998; 41: 778-99
2. Jennet JC, et al. Arthritis & Rheum 2013; 65: 1-11

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop

new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.
The consolidated revenue in 2015 of Chugai totaled 498.8 billion yen and the operating income was 90.7 billion yen (IFRS Core basis).
Additional information is available on the internet at http://www.chugai-pharm.co.jp/english.

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