



Chugai's Satralizumab Receives FDA Breakthrough Therapy Designation for Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders — Designation is Seventh for Chugai Originated Drug —

TOKYO, December, 19, 2018 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for Chugai's anti-interleukin-6 (IL-6) receptor humanized recycling antibody satralizumab, an investigational medicine for neuromyelitis optica and neuromyelitis optica spectrum disorders (NMO/NMOSD).

“Satralizumab is a recycling antibody created utilizing Chugai's proprietary antibody engineering technologies. We are delighted by the FDA's designation for this innovative antibody based on the results of a Chugai-initiated global Phase III study” said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. “Satralizumab is designed to inhibit signaling of the inflammatory cytokine IL-6, which is known to play a role in the pathogenesis of NMO/NMOSD. We continue our efforts to hopefully bring satralizumab as a new treatment option as soon as possible to people living with this devastating disease with no approved drugs.”

The designation for satralizumab is based on data from the Phase III study (SAkuraSky study, NCT02028884) evaluating satralizumab added to baseline therapy. This is the seventh Breakthrough Therapy Designation received for four drugs created by Chugai.

[Reference]

Press release issued on October 15, 2018

Chugai Presents Results from Phase III Study of Satralizumab in NMOSD at ECTRIMS 2018

https://www.chugai-pharm.co.jp/english/news/detail/20181015120001_561.html

About Breakthrough Therapy

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 as organizational commitment from FDA.

About Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorder (NMOSD)

Neuromyelitis optica spectrum disorder (NMOSD) is a rare, lifelong, and debilitating autoimmune disease of the central nervous system (CNS) characterized by inflammatory lesions in the optic nerves and spinal cord. Patients with NMOSD frequently experience a relapsing disease course with repeated attacks leading to accumulating neurological damage and disability. Symptoms may include visual impairment, motor disability, and loss of quality of life. In some cases, attacks of NMOSD result in death.

NMOSD pathogenesis is thought to involve AQP4-IgG autoantibody entry into the CNS, however approximately one-third of patients with NMOSD are AQP4-IgG seronegative¹⁾⁻⁴⁾. The inflammatory cytokine IL-6 is now emerging as an important factor in NMOSD pathogenesis.

Diagnostic criteria introduced in 2006 for neuromyelitis optica were characterized by inflammation of the optic nerve (optic neuritis) and the spinal cord (myelitis). These were revised in 2007 with the definition of NMOSD, proposed for diseases with either optic neuritis or myelitis. In 2015, the definition of NMOSD was further revised to include a broader spectrum of disease. The diagnostic term NMOSD is now widely used⁵⁾.

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 2017 of Chugai totalled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis).

Additional information is available on the internet at <https://www.chugai-pharm.co.jp/english>.

References

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Contact:

For Media

Chugai Pharmaceutical Co., Ltd.

Media Relations Group, Corporate Communications Dept.,

Tomoko Shimizu

Tel: +81-3-3273-0881

E-mail: pr@chugai-pharm.co.jp

For US media

Chugai Pharma USA Inc.

Casey Astringer

Tel: +1-908-516-1350

E-mail: pr@chugai-pharm.com

For European media

Chugai Pharma France SAS

Nathalie Leroy

Tel: +33-1-56-37-05-21

E-mail: pr@chugai.eu

For Taiwanese media

Chugai Pharma Taiwan Ltd.

Susan Chou

Tel: +886-2-2715-2000

E-mail: pr@chugai.com.tw

For Investors

Chugai Pharmaceutical Co., Ltd.

Investor Relations Group, Corporate Communications Dept.,

Toshiya Sasai

Tel: +81-3-3273-0554

E-mail: ir@chugai-pharm.co.jp