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Chugai Announces Phase II Global Study Results of Nemolizumab (CIM331) in Late-breaking Research Forums at AAD

- Efficacy and Tolerability in Atopic Dermatitis were Observed -

TOKYO, March 6, 2016 - Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the results of global phase II study of anti-IL-31 receptor A, humanized monoclonal antibody, nemolizumab (CIM331), which is currently developed for atopic dermatitis, were released at the annual meeting of the American Academy of Dermatology currently held in Washington, D.C. The results were released at the Late-breaking Research Forums at 10:00 on Saturday, March 5 (local time).

The global phase II study was conducted to evaluate the efficacy and safety of CIM331 in 264 patients with moderate to severe atopic dermatitis. Efficacy and tolerability for 12 weeks treatment were observed in this study.

"Itch in atopic dermatitis disturbs sleep and quality of life of those who suffer from the disease. Moreover, the itch-scratch cycle may aggravate symptoms of dermatitis. CIM331 is a drug candidate with a novel mechanism of action, which improves dermatitis by blocking the itch-scratch cycle," said Chugai's Director and Executive Vice President, Dr. Yutaka Tanaka. "We are delighted that the efficacy and safety results in this study have demonstrated the possibility of CIM331 to provide a new treatment concept for patients around the world."

[Study overview]
Patients were randomized to one of the following four CIM331 dose groups or placebo group in the ratio of 1:1:1:1:1.

- CIM331 (0.1 mg/kg) subcutaneous dosing every 4 weeks (Day 1, Week 4, and Week 8)
- CIM331 (0.5 mg/kg) subcutaneous dosing every 4 weeks (Day 1, Week 4, and Week 8)
- CIM331 (2.0 mg/kg) subcutaneous dosing every 4 weeks (Day 1, Week 4, and Week 8)
- CIM331 (2.0 mg/kg) subcutaneous dosing every 8 weeks (reference group)
- Placebo subcutaneous dosing every 4 weeks (Day 1, Week 4, and Week 8)

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[Study results]

Efficacy

- The percent change in pruritus VAS at Week 12, which was the primary endpoint, was significantly higher in the CIM331 treatment groups than in the placebo group ($p<0.01$ in all).

	Placebo every 4 weeks	0.1 mg/kg every 4 weeks	0.5 mg/kg every 4 weeks	2.0 mg/kg every 4 weeks
Percent change in pruritus VAS (At Week 12; %)	-20.1	-41.5	-61.2	-60.5

- In addition, dermatitis endpoints (i.e. EASI and sIGA) and sleep quality endpoints (i.e. sleep onset latency and total sleep time) were presented.

Safety

- Tolerability was observed in CIM331 treatment groups. Adverse events reported relatively frequently were atopic dermatitis and nasopharyngitis.

About Late-breaking Research Forums

This session will highlight the latest ground-breaking clinical and basic research performed. New therapies will be given top priority, particularly data from pivotal trials of unapproved drugs or unapproved indications. In addition, novel observations that could be practice changing will also be given top consideration.

About nemolizumab (CIM331)

It is a humanized anti-human-IL-31-receptor-A (IL-31RA) monoclonal antibody. IL-31 is identified as a cytokine that can induce the pruritus, and reported to be associated with pruritus in atopic dermatitis and dialysis patients. Nemolizumab works by inhibiting biological activity of IL-31 through competitively blocking the binding of IL-31 to its receptor.

About pruritus VAS

Pruritus VAS stands for pruritus visual analogue scale, by which the severity of pruritus is measured with a 10 cm scale on which patients draw a line to express their assessment of severity (0: no itch, 10: worst imaginable itch).

About EASI

EASI (Eczema Area and Severity Index) is a tool to demonstrate severity of dermatitis with score from 0 to 72.

About sIGA

sIGA (static Investigator's Global Assessment) is a tool to evaluate overall severity of dermatitis

with a six-level scale from 0 to 5 (0: clear, 5: very severe).

About Itch-scratch cycle

Skin itchiness causes scratch, which enhances inflammation and further aggregation of itchiness. This vicious cycle called the itch-scratch cycle is known as an exacerbating factor for dermatitis.

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 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 totalled 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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