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Chugai's Anti-IL-31 Receptor A Humanized Monoclonal Antibody "nemolizumab (CIM331)" Global Phase II Study Data Published in The New England Journal of Medicine Online

TOKYO, March 2, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the data from the global phase II study (the XCIMA study) for the planned indication of atopic dermatitis (AD) was published in The New England Journal of Medicine Online on March 2, 2017 (EST). The study was conducted to evaluate the safety and efficacy of nemolizumab in 264 patients with moderate-to-severe AD, and the safety and efficacy of nemolizumab at 12 weeks were confirmed.
"Anti-Interleukin-31 Receptor A Antibody for Atopic Dermatitis.," Thomas Ruzicka, M.D., et al
http://www.nejm.org/doi/full/10.1056/NEJMoa1606490

The efficacy and safety data obtained from a one-year extension of the study will be presented on March 4th at the Late-Breaking Research Forums of the 2017 Annual American Academy of Dermatology (AAD) Meeting which will be held on March 3 to 7 in Orlando, Florida, USA.

"Control of pruritus is crucial for AD patients. It is directly related to their quality of life," said Dr. Yasushi Ito, Senior Vice President, Head of Project & Lifecycle Management Unit. "This data emphasizes the importance of controlling IL-31 in AD. It also indicates that nemolizumab, an anti-IL-31 antibody, may offer a promising treatment option for the disease. Chugai will closely work together with its partners - Galderma and Maruho, toward helping AD patients by offering this new treatment option as early as possible."

"Nemolizumab is the first drug specifically targeting pruritus. Its use is very convenient to patients with one subcutaneous injection per month," said, Professor Thomas Ruzicka, Ludwig-Maximilian University Munich, the first author of the article. "Since IL-31 is involved in a variety of other pruritic skin diseases, the innovative drug has a large potential in dermatology."

Chugai granted the exclusive development and marketing rights of nemolizumab worldwide, excluding Japan and Taiwan to Galderma and licensed out the development and marketing rights in the skin disease area to Maruho for the Japanese market respectively.
Please refer to the press release for the details of the license agreement with
Galderma: https://www.chugai-pharm.co.jp/english/news/detail/20160721083000.html
Maruho: https://www.chugai-pharm.co.jp/english/news/detail/20160928150000.html

[Overview of the study]
264 patients were randomized to one of the four nemolizumab dose groups (0.1, 0.5, 2.0 mg/kg every 4 week (Q4W) or 2.0 mg/kg every 8 week) or placebo group (Q4W) in the ratio of 1:1:1:1:1. The primary endpoint of the study showed significant improvement of the change in pruritus VAS

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at 12 weeks compared with placebo with the score of -43.7% for nemolizumab 0.1 mg/kg Q4W, -59.8% for nemolizumab 0.5 mg/kg Q4W, -63.1% for nemolizumab 2.0 mg/kg Q4W and -20.9% for placebo Q4W ($p<0.01$ for all comparisons). The secondary endpoint was the change in EASI at week 12 of −23.0%, −42.3%, and −40.9% for the nemolizumab 0.1, 0.5 and 2.0 mg/kg Q4W groups, respectively, versus −26.6% for placebo. Another secondary endpoint, the proportion (%) of patients with ≥2-point improvement in sIGA was 13.8%, 37.5%, 25.1% for the nemolizumab 0.1, 0.5 and 2.0 mg/kg Q4W groups, respectively, compared with 10.5% for placebo.
The most common adverse events (AEs) were the exacerbation of AD, nasopharyngitis, upper respiratory tract infections, peripheral edema, and increased creatine phosphokinase. 15 patients experienced AEs related discontinuations and 10 out of 15 were due to AEs related to AD (such as exacerbation of AD and dermatitis exfoliativa).

About nemolizumab (CIM331)
A humanized anti-human IL-31 receptor A (IL-31RA) monoclonal antibody. IL-31 is identified as a cytokine that can induce 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).

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