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Chugai's Anti-IL-31 Receptor A Humanized Monoclonal Antibody "nemolizumab," Long Term Data from Global Phase II Study Published in Journal of Allergy and Clinical Immunology Online

-- Confirmed Safety and Efficacy of nemolizumab for One Year Treatment --

TOKYO, May 10, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the long-term data from a global phase II study (the XCIMA study) for nemolizumab (CIM331) was published in Journal of Allergy and Clinical Immunology Online on May 9, 2018.
"Nemolizumab in moderate-to-severe atopic dermatitis: Randomized, phase II, long-term extension study" Kenji Kabashima, M.D., Ph.D., et al
https://www.jacionline.org/article/S0091-6749(18)30698-5/abstract

"Control of chronic pruritus and inflammation of the skin is crucial for patients with atopic dermatitis (AD). This long-term extension data which demonstrated efficacy and safety of nemolizumab reinforced anticipation that nemolizumab may offer a novel treatment option for the disease," said Dr. Yasushi Ito, Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "Chugai's mission is to contribute to patients through innovative medicines. We will closely work together with our partners - Galderma and Maruho, towards helping AD patients by developing this new treatment option as quickly as possible."

"I am delighted to see a steady development of the novel treatment which addresses pathogenesis of pruritus in atopic dermatitis," said, Professor Kenji Kabashima, Kyoto University, the first author of the article. "I would like to carefully examine safety and efficacy of nemolizumab further, in the expectation of future clinical use."

The study was conducted to evaluate safety and efficacy of nemolizumab in 264 patients with moderate-to-severe AD. The safety and efficacy of nemolizumab at 12 weeks, the study's primary endpoint, were confirmed and published in The New England Journal of Medicine Online in March 2017. The data published this time was obtained to assess safety and efficacy of long-term administration. It confirmed that nemolizumab maintained its safety and efficacy after one year of continuous treatment.

About the results of the global phase II study
Press release issued in March 2, 2017.
https://www.chugai-pharm.co.jp/english/news/detail/20170302150000.html

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. Currently, Galderma is conducting a phase 2b study and Maruho is conducting a phase 3 study.

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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

About nemolizumab (CIM331)

Nemolizumab (CIM331) is a humanized anti-human IL-31 receptor A (IL-31RA) monoclonal antibody intending to be a first-in-class treatment. IL-31 is identified as a pro-inflammatory cytokine that can induce pruritus, inflammation, and skin barrier dysfunction in atopic dermatitis, as well as pruritus in dialysis patients[1, 2, 3, 4]. Nemolizumab is thought to work by inhibiting biological activity of IL-31 through competitively blocking the binding of IL-31 to its receptor.

[References]

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