



Maruho Obtained Regulatory Approval for Mitchga, the First Antibody Targeting IL-31 for Itching Associated with Atopic Dermatitis

- Maruho obtains regulatory approval for Mitchga, a novel antibody pharmaceutical which was created by Chugai
- Mitchga is the first antibody drug targeting interleukin-31 (IL-31), for the treatment of itching associated with atopic dermatitis (AD)
- Improvement of pruritus, the burdensome symptom of AD, by Mitchga is expected to provide a better quality of life (QoL) for patients

TOKYO, March 28, 2022 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that [Maruho Co., Ltd.](#) (hereafter, Maruho) obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for the anti-IL-31 receptor A humanized monoclonal antibody Mitchga[®] Subcutaneous Injection 60 mg Syringes [generic name: nemolizumab (genetical recombination)] for the treatment of itching associated with atopic dermatitis (only when existing treatment is insufficiently effective).

“We are very pleased that regulatory approval has been obtained for Mitchga, the first antibody drug targeting IL-31 created by Chugai. IL-31 is a cytokine that is known to play a role in skin inflammation and pruritus associate with multiple skin diseases including AD,” said Chugai’s President and CEO Dr. Osamu Okuda. “Itchiness is one of the most burdensome symptoms of AD, and scratching may worsen skin inflammation. We hope that Mitchga will contribute to increase QoL by reducing barriers in patients’ lives, such as poor sleep quality and concentration, through the improvement of itch and skin inflammation, which has important therapeutic significance ^{1,2)}.”

The approval is based on the results from a Japanese phase III clinical study in patients with moderate to severe AD who are older than 13 years old and are tolerant to existing treatments.

[Reference information]

Maruho Acquires Manufacturing and Marketing Approval in Japan for “Mitchga[®] Subcutaneous Injection 60mg Syringes,” a New Treatment Targeting Itch Associated with Atopic Dermatitis (Press release issued by Maruho on March 28, 2022)

<https://www.maruho.co.jp/english/information/20220328.html>

Results of Maruho’s Phase III Study with Chugai’s Nemolizumab for Atopic Dermatitis Published in The New England Journal of Medicine Online (Press release issued by Chugai on July 9, 2020)

https://www.chugai-pharm.co.jp/english/news/detail/20200709120000_726.html

About nemolizumab

Nemolizumab is an anti-IL-31 receptor A humanized monoclonal antibody originating from Chugai. The drug is expected to improve itching and skin inflammation in AD by blocking IL-31, a proinflammatory cytokine, from binding to its receptor ³⁾.

In July 2016, Chugai entered into a global license agreement granting Galderma S.A. of Switzerland exclusive rights for the development and marketing of nemolizumab worldwide, with the exception of Japan and Taiwan. In September 2016, Chugai entered into a license agreement granting Maruho Co., Ltd., the rights for the development and marketing of nemolizumab in the skin disease area for the Japanese market. In development for AD, Galderma initiated global Phase III studies in 2019. In addition, nemolizumab was granted breakthrough therapy designation by the U.S. FDA for pruritus associated with prurigo nodularis (PN). Galderma launched a Phase III clinical study for the treatment of PN in October 2020, while Maruho, started Phase II/III clinical studies in Japan in December 2020.

About atopic dermatitis (AD)

A type of allergic disorder, AD is a chronic skin disease characterized by an itchy rash that alternately improves and worsens. Scratching the affected area exacerbates the skin symptoms and makes the itching worse, leading to an itch-scratch cycle. The basic treatment is drug therapy using topical steroid preparations and/or immunosuppressants to control the inflammation and a skin care regimen to prevent the inflammation from recurring ⁴⁾. The prevalence of the disease in Japanese adults is estimated to be about 5.5 million ⁵⁾.

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Sources

- 1 Kabashima K., et al. Trial of Nemolizumab and Topical Agents for Atopic Dermatitis with Pruritus. *N Engl J Med* 2020; 383:141-150
- 2 Ruzicka T., et al. Anti-Interleukin-31 Receptor A Antibody for Atopic Dermatitis. *N Engl J Med* 2017; 376:826-835
- 3 Oyama S., et al. Cynomolgus monkey model of interleukin-31-induced scratching depicts blockade of human interleukin-31 receptor A by a humanized monoclonal antibody. *Exp. Dermatol.* 2018; 27(1): 14-21
- 4 Annual Reports 2020. Chugai Pharmaceutical Co., Ltd.
- 5 T Muto, et al. Prevalence of atopic dermatitis in Japanese adults. *British Journal of Dermatology.* 2003; Volume148, Issue1

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