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## Maruho Launched in Japan the Anti-IL-31 Receptor A Humanized Monoclonal Antibody Mitchga for the Treatment of Itching Associated with Atopic Dermatitis

- Maruho launched Mitchga, a novel antibody pharmaceutical originated by Chugai
- Mitchga is the first antibody drug targeting IL-31 receptor A, for the treatment of itching associated with atopic dermatitis (only when existing treatment is insufficiently effective)

TOKYO, August 8, 2022 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that [Maruho Co., Ltd.](#) (hereafter, Maruho) launched the anti-IL-31 receptor A humanized monoclonal antibody Mitchga<sup>®</sup> 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). Mitchga was approved by the Ministry of Health, Labour and Welfare (MHLW) on March 28, 2022 and listed on the national health insurance (NHI) reimbursement price list on May 25, 2022.

“We are very pleased that Mitchga, created by Chugai as the first antibody drug that inhibits IL-31 signaling, has been launched by Maruho in Japan,” said Chugai’s President and CEO Dr. Osamu Okuda. “Maruho and Chugai has been collaborating in the development of Mitchga under the license agreement for the Japanese market in September 2016. Maruho will provide information on Mitchga based on their extensive expertise in dermatology. We hope that Mitchga will contribute to improve the QOL of patients with atopic dermatitis by reducing itchiness.”

[Reference information]

Maruho Launches the First Antibody Treatment Targeting Itch Associated with Atopic Dermatitis "Mitchga<sup>®</sup> Subcutaneous Injection 60mg Syringes" in Japan (Press release issued by Maruho on August 8, 2022)

<https://www.maruho.co.jp/english/information/20220808.html>

Maruho Obtained Regulatory Approval for Mitchga, the First Antibody Targeting IL-31 for Itching Associated with Atopic Dermatitis (Press release issued by Chugai on March 28, 2022)

[https://www.chugai-pharm.co.jp/english/news/detail/20220328160001\\_908.html](https://www.chugai-pharm.co.jp/english/news/detail/20220328160001_908.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](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 <sup>1)</sup>.

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 <sup>2)</sup>. The prevalence of the disease in Japanese adults is estimated to be about 5.5 million <sup>3)</sup>.

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### **Sources**

- 1 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
- 2 Japanese guidelines for atopic dermatitis 2021
- 3 T Muto, et al. Prevalence of atopic dermatitis in Japanese adults. *British Journal of Dermatology.* 2003; Volume148, Issue1

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