

News Release

August 8, 2022
Maruho Co., Ltd.

Maruho Launches the First Antibody Treatment Targeting Itch Associated with Atopic Dermatitis "Mitchga[®] Subcutaneous Injection 60mg Syringes" in Japan

Osaka (Japan), August 8, 2022 – Maruho Co., Ltd. ("Maruho", Head Office: Osaka, Japan, President and CEO: Atsushi Sugita) announces that it has launched "Mitchga[®] Subcutaneous Injection 60mg Syringes" (Japanese Accepted Name (JAN): Nemolizumab (Genetical Recombination), hereinafter referred to as "the product"), for the treatment of itching associated with atopic dermatitis (only when existing treatment is insufficiently effective) in Japan.

The product is a world first-in-class anti-IL-31 receptor A humanized monoclonal antibody created by Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan, CEO: Osamu Okuda, hereinafter referred to as Chugai). In September 2016, Maruho entered into a license agreement with Chugai in the skin disease area for the Japanese market. Since then Maruho has developed the product and received manufacturing and marketing approval on March 28, 2022.

Atopic dermatitis is a chronic skin disease with repetitive exacerbations and remissions, characterized with an itchy skin rash as the main lesion. Itching associated with atopic dermatitis can cause poor concentration at work or school, sleep disorder, etc., significantly reducing a patient's Quality of Life (QOL)¹. Moreover, the scratching behavior associated with itching leads to worsening of skin symptoms and causes the negative "itch scratch cycle" that further enhances itch and skin inflammation.

IL-31 is a neuroimmune cytokine² that has been reported to play a central role in pruritus and skin inflammation in the development of atopic dermatitis^{3,4}. The product competitively inhibits the binding of IL-31 on its receptor, and exhibits an inhibitory effect on itch and skin inflammation associated with atopic dermatitis. By preventing the negative cycle caused by itching, skin symptoms and the patient's QOL) are expected to improve.

Current existing treatments include mainly anti-inflammatory topical drugs. However, some patients are unable to find relief from itching with existing treatments. For this reason, new treatment options are required.

Maruho, specializing in dermatology, hopes that with the proper use of the product it can contribute to improving the QOL of patients suffering from itching caused by atopic dermatitis.

Product Profile

Brand Name	Mitchga® Subcutaneous Injection 60mg Syringes
JAN	Nemolizumab (Genetical Recombination)
Indication	The treatment of itch associated with atopic dermatitis (only when existing treatment is insufficiently effective).
Dosage and Administration	Generally, for adults and children over 13 years old, 60 mg of nemolizumab (genetical recombination) is subcutaneously administered at intervals of 4 weeks.
Date of Approval	March 28, 2022
Date of NHI Price Listing	May 25, 2022
Date of Launch	August 8, 2022
NHI Drug Price Standard	117,181yen/1 vial

[Reference information]

- Chugai and Maruho Announce License Agreement of Nemolizumab (CIM331), a Novel Biologic in the Skin Disease Area for the Japanese Market (2016-09-28 News Release) https://www.maruho.co.jp/english/information/20160928_pr_eng_1.pdf
- Maruho Announces New England Journal of Medicine Publication of Results from Phase 3 Clinical Study (Comparative Study) in Japan of Nemolizumab for the Treatment of Atopic Dermatitis (2020-07-09 News Release) <https://www.maruho.co.jp/english/information/2020070902.html>
- Maruho Acquires Manufacturing and Marketing Approval in Japan for "Mitchga® Subcutaneous Injection 60mg Syringes", a New Treatment Targeting Itch Associated with Atopic Dermatitis (2022-03-28 News Release) <https://www.maruho.co.jp/english/information/20220328.html>

[References]

1. Nakahara M. : Rinsho Derma 2019; 61: 740-747.
2. Dillon SR, et al. Interleukin 31, a cytokine produced by activated T cells, induces dermatitis in mice. Nat Immunol 2004; 5: 752-60.
3. Sonkoly E, et al. IL-31: a new link between T cells and pruritus in atopic skin inflammation. J Allergy Clin Immunol 2006; 117: 411-7.
4. Ko MJ, et al. Interleukin-31 is associated with uremic pruritus in patients receiving hemodialysis. J Am Acad Dermatol 2014; 71: 1151-9.

About Maruho

Maruho Co., Ltd. has its head office in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,546 employees (as of the end of September 2021), and net sales were approximately 87.03 billion yen in its fiscal year ended September 30, 2021. Pursuing its long-term corporate vision of "Excellence in Dermatology," Maruho is striving to improve the health and quality of life of people all over the world.

For more information, please visit <https://www.maruho.co.jp/english/>

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