News Release

March 28 2022
Maruho Co., Ltd.

Maruho Acquires Manufacturing and Marketing Approval in Japan for "Mitchga® Subcutaneous Injection 60mg Syringes", a New Treatment Targeting Itch Associated with Atopic Dermatitis

Osaka (Japan), March 28, 2022 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Atsushi Sugita) announces that it has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for "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.

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 disorders, psychosocial distress, etc., significantly reducing a patient's Quality of Life (QOL).[1] Moreover, the scratching behavior that accompanies itching leads to worsening of skin symptoms and causes the negative “itch scratch cycle” that further enhances itch and skin inflammation. Some patients are unable to find relief from itching with existing treatments. For this reason, new treatment options are required.

The product is a subcutaneous injection containing nemolizumab as an active ingredient. Nemolizumab is the first and only 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). IL-31 is a neuroimmune cytokine that induces itch[2], inflammation and skin barrier disfunction and has been reported to play a central role in the development of atopic dermatitis.[3, 4]

This drug competitively inhibits the binding of IL-31 with its receptor, thereby exhibiting an inhibitory effect on itching associated with atopic dermatitis. By blocking the negative cycle caused by itching, it is expected that skin symptoms and the QOL of patients will be improved. As demonstrated in clinical trials, nemolizumab 60mg administered with concomitant topical treatments led to sustained improvements in itch, skin lesions and quality of life in patients with uncontrolled atopic dermatitis, with a favorable safety profile.

In September 2016, Maruho entered a license agreement with Chugai to develop and market the product in the skin disease area for the Japanese market, and since then has proceeded

with development. This approval is based on the results of Phase III clinical studies conducted in Japan and marks the first approval of nemolizumab globally.

Maruho, specializing in dermatology, hopes that the approval of this drug will lead to the provision of new treatment options for 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.

[Reference information]

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

[References]

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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 headquarters 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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