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Mitchga Approved for Itching in Pediatric Atopic Dermatitis and Prurigo Nodularis, for its Subcutaneous Injection 30mg Vials

- Maruho, the out-license partner of Chugai originated Mitchga in Japan, received approval for the drug in itching in pediatric atopic dermatitis and prurigo nodularis, for 30 mg vials for subcutaneous injection, a new dosage form
- Prurigo nodularis is a new indication, and for itching of atopic dermatitis, the target age was expanded from the indication approved for 60 mg syringe

TOKYO, March 26, 2024 -- 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 30 mg Vials [generic name: nemolizumab (genetical recombination)] for the treatment for the following diseases in patients only when existing treatment is insufficiently effective: pruritus associated with atopic dermatitis (children aged ≥6 and <13 years), prurigo nodularis (adults and children aged ≥13 years) in Japan.

“We are very pleased that by this time’s approval of Mitchga, originated by Chugai, the medicine would be able to contribute to the treatment for younger patients with atopic dermatitis, and for patients with prurigo nodularis. Itching caused by atopic dermatitis affects many aspects of patients’ daily lives. With this approval, the medicine may be used by children aged 6-12 years, in addition to the age group for which the brand has already been approved. Prurigo nodularis is a new indication for the Mitchga brand. This disease also affects patients’ daily lives and mental health. With the medicine’s unique approach to blocking the action of IL-31, which is involved in itching and inflammation in a variety of skin conditions, we hope it will help to improve symptoms and quality of life in patients,” said Chugai’s President and CEO Dr. Osamu Okuda.

The approval is based on the results of Maruho's phase III clinical study in Japanese patients aged ≥6 and <13 years with atopic dermatitis of moderate or severe pruritus who have had an inadequate response to conventional therapies, and its Japanese phase II/III clinical study in Japanese patients aged ≥13 years with prurigo nodularis who have had an inadequate response to conventional therapies.

[Reference information]

Maruho Acquires Manufacturing and Marketing Approval in Japan for "Mitchga Subcutaneous Injection 30mg Vials", an Antibody Treatment for Pruritus Associated with Atopic Dermatitis (Pediatric) and Prurigo Nodularis (Press release issued by Maruho on March 26, 2024)
https://www.maruho.co.jp/english/information/20220328.html

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About nemolizumab

Nemolizumab is a humanized anti-human IL-31 receptor A (IL-31RA) monoclonal antibody originating from Chugai. By binding to IL-31RA competitively with IL-31, it inhibits the binding of IL-31 to its receptors and the subsequent intracellular signal transduction, thereby suppressing pruritus.[1]

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 Japan, Maruho obtained manufacturing and marketing approval for Mitchga® Subcutaneous Injection 60 mg Syringe in March 2022, ahead of other countries, for the treatment of pruritus associated with atopic dermatitis in adults and children aged ≥13 years (only when existing treatment is insufficiently effective). The product was launched in Japan in August 2022. Overseas, Galderma announced that its two global phase III clinical trials for atopic dermatitis and prurigo nodularis had achieved their primary endpoints, and filed new drug applications in Europe and the United States. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation, as well as Priority Review Designation on acceptance of approval application, for prurigo nodularis.

About atopic dermatitis

Atopic dermatitis 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.[2] The prevalence of the disease in Japanese adults is estimated to be about 5.5 million.[3]

About prurigo nodularis[4]

Prurigo nodularis is a disorder characterized by thick, dome-like and warty scratches on the skin accompanied by severe itching, which appear in scattering patterns. It is mainly seen on the outside of the arms and legs but it may be seen on a wide area, such as the trunk. Symptoms can last from weeks to months, and the itching can be emotionally distressing for patients, affecting their daily lives. Although the definite cause of prurigo nodularis is unknown, it is considered that there are factors such as stress and atopic diathesis.

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 Wahlgren CF. Itch and atopic dermatitis: An overview. J Dermatol 1999;26:770-9

3 T Muto, et al. Prevalence of atopic dermatitis in Japanese adults. British Journal of Dermatology. 2003; Volume148, Issue1

4 T Satoh, et al. 2020 guidelines for the diagnosis and treatment of cutaneous pruritus. J Dermatol. 2021;48(9):e399-e413.

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