

News Release

June 11, 2024
Maruho, Co., Ltd.

Maruho Launches "Mitchga® Subcutaneous Injection 30mg Vials", an Antibody Treatment for Pruritus Associated with Atopic Dermatitis (Pediatric) and Prurigo Nodularis in Japan

Osaka (Japan), June 11, 2024 - Maruho Co., Ltd. ("Maruho"; Head Office: Osaka; President and CEO, Atsushi Sugita) announces that it has launched Mitchga® Subcutaneous Injection 30mg Vials (Japanese Accepted Name (JAN): Nemolizumab (Genetical Recombination), hereinafter referred to as "the product") in Japan for the treatment of the following diseases 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).

The product is a vial for subcutaneous injection containing nemolizumab, a humanized anti-interleukin-31 (IL-31) receptor A monoclonal antibody discovered and developed by Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan, CEO: Osamu Okuda, hereinafter referred to as Chugai), as an active ingredient. In September 2016, Maruho entered into a license agreement with Chugai to develop and market the product in the skin disease area for the Japanese market. Maruho developed the product in Japan and acquired approval for manufacturing and marketing in March 2024, followed by the NHI drug price listing in May 2024, leading to the launch of the product.

IL-31 is a cytokine that induces itch¹ and is involved in the development of pruritus caused by atopic dermatitis^{2,3}. It has also been shown to induce itch in prurigo nodularis⁴ and to be involved in its pathogenesis⁵⁻⁷. By competitively inhibiting the binding of IL-31 to its receptor, this product is expected to improve the pruritus and skin symptoms associated with atopic dermatitis (pediatric patients) and prurigo nodularis, thereby improving patients' Quality of Life (QOL).

In March 2022, Maruho acquired the world's first manufacturing and marketing approval for "Mitchga® Subcutaneous Injection 60mg Syringes" for the treatment of pruritus associated with atopic dermatitis in adults and children over 13 years old (only when existing treatment is insufficiently effective) in Japan. Maruho launched "Mitchga® Subcutaneous Injection 60mg Syringes" in August 2022 in Japan.

Maruho, specializing in dermatology, is committed to contributing to the smiles of patients suffering from itching caused by atopic dermatitis and patients suffering from prurigo nodularis by promoting the appropriate use of the product and "Mitchga® Subcutaneous Injection 60mg Syringes".

Note

The information contained in this news release in regard to pharmaceutical and developmental products is not intended for the purpose of promotion, advertising or medical advice.

Product Profile

Brand Name	Mitchga® Subcutaneous Injection 30mg Vials
JAN	Nemolizumab (Genetical Recombination)
Indications	<p>The following diseases only when existing treatment is insufficiently effective</p> <ul style="list-style-type: none"> - Pruritus associated with atopic dermatitis* - Prurigo nodularis <p>*Subject to Japanese "Optimal Clinical Use Guidelines"</p>
Dosage and Administration	<p><Pruritus associated with atopic dermatitis> Generally, for children aged ≥ 6 and < 13 years, is 30mg of nemolizumab (genetical recombination) is subcutaneously administered at intervals of 4 weeks.</p> <p><Prurigo nodularis> Generally, for adults and children aged ≥ 13 years, 60mg of nemolizumab (genetical recombination) is subcutaneously administered for the first dose, and thereafter 30mg is administered at intervals of 4 weeks.</p>
Date of Approval	March 26, 2024
Date of NHI Price Listing	May 22, 2024
Date of Launch	June 11, 2024
NHI Drug Price Standard	67,112yen/1 vial

[Reference information]

Maruho Launches the First Antibody Treatment Targeting Itch Associated with Atopic Dermatitis "Mitchga Subcutaneous Injection 60mg Syringes" in Japan
(2022.08.08) <https://www.maruho.co.jp/english/information/20220808.html>

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
(2024.03.26) <https://www.maruho.co.jp/english/information/20240326.html>

About Atopic Dermatitis

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 QOL⁸. Particularly when the patient is a child, it has been reported to significantly affect the daily lives of parents⁹. Currently, treatment options for pruritus associated with atopic dermatitis in children are limited, and there are patients whose itching is not adequately controlled with existing treatments.

About Prurigo Nodularis

Prurigo nodularis is a chronic skin disorder characterized by numerous dome-shaped raised skin lesions (nodules) with intense itching. Itching and skin lesions have been reported to affect a patient's QOL, leading to sleep disturbance, psychological distress, and decreased work productivity¹⁰⁻¹³. In terms of treatment, no highly recommended therapy has been established and new options are needed.

[References]

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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 1,566 employees (as of the end of September 2023), and net sales were approximately 85.71 billion yen in its fiscal year ended September 30, 2023. With the mission "More smiles, brighter life for you.", Maruho aims to help realize a society where everyone can live with a smile.

For more information, please visit www.maruho.co.jp/english/

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