News Release

March 26, 2024
Maruho, Co., Ltd.

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

Osaka (Japan), March 26, 2024 - Maruho Co., Ltd. ("Maruho"; Head Office: Osaka; President and CEO, Atsushi Sugita) announces that it has received approval to manufacture and market “Mitchga® Subcutaneous Injection 30mg Vials” (Japanese Accepted Name (JAN): Nemolizumab (Genetical Recombination), hereinafter referred to as "the product") 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) 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]. In particular, when the patient is a child, it has also been reported to affect the daily lives of parents[2]. 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.
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 productivity[3-6]. In terms of treatment, no highly recommended therapy has been established and new options are needed.

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. IL-31 is a cytokine that induces itch[7] and is involved in the development of pruritus caused by atopic dermatitis[8,9]. It has also been shown to induce itch in prurigo nodularis[10] and to be involved in its pathogenesis[11-13]. By competitively inhibiting the binding of IL-31 to its receptor, the product is expected to improve the pruritus and skin symptoms associated with atopic dermatitis (pediatric patients) and prurigo nodularis, thereby improving patients' QOL.

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, and 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, hopes that the approval of this drug will lead to the provision of new treatment options for pediatric patients suffering from itching caused by atopic dermatitis and for patients suffering from itching and other skin symptoms of prurigo nodularis.

Product Profile

Brand Name	Mitchga® Subcutaneous Injection 30mg Vials
JAN	Nemolizumab (Genetical Recombination)
Indications	The following diseases only when existing treatment is insufficiently effective - Pruritus associated with atopic dermatitis* - Prurigo nodularis *Subject to Japanese “Optimal Clinical Use Guidelines”
Dosage and Administration	<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. <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.

[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

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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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