News Release

July 9, 2020
Maruho Co., Ltd.

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

Osaka (Japan), July 9, 2020 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that the results of a phase 3 study in Japan of nemolizumab (comparative study) for pruritus associated with atopic dermatitis (hereinafter referred to as “the study”) have been published in the New England Journal of Medicine.

The study included 215 Japanese patients over 13 years of age with atopic dermatitis who had moderate to severe pruritus (median of baseline scores was 75.4 (pruritus VAS)). Patients were randomly assigned in a 2:1 ratio to receive subcutaneous nemolizumab 60 mg or placebo every 4 weeks until week 16 (nemolizumab, n = 143; placebo, n = 72). In the study, the efficacy and safety of nemolizumab was evaluated when administered concomitantly with topical inflammatory agents and compared to placebo 16 weeks after administration.

- The primary efficacy endpoint, week 16 percent change from baseline in pruritus VAS score, was −42.8% with nemolizumab vs −21.4% with placebo. A statistically significant difference was seen in the nemolizumab group, (p-value <0.001).
- In secondary efficacy endpoints, a percent reduction in daily pruritus VAS score from baseline up to 4 weeks after administration was reported as early as day 2 (nemolizumab, -10.3%; placebo, -4.4%). The percent change in EASI score at week 16 was −45.9% in the nemolizumab group and −33.2% in the placebo group. The percent of patients achieving a DLQI score of ≤4 was 40% in the nemolizumab group and 22% in the placebo group. An ISI score of ≤7 was achieved by 55% in the nemolizumab group and 21% in the placebo group.

- Overall, 71% of patients in both groups reported adverse events; most were mild or moderate in severity. Severe adverse events were reported by three (2%) patients in the nemolizumab group (Meniere's disease, acute pancreatitis, and atopic dermatitis). Three nemolizumab-treated patients reported four treatment-related adverse events resulting in discontinuation of trial medication: atopic dermatitis, Meniere's disease, alopecia, and peripheral edema. The most commonly reported adverse event was worsening atopic dermatitis, occurring in 24% of the nemolizumab group and 21% of the placebo group. The incidence of injection-related reactions was 8% with nemolizumab versus 3% with placebo.
- An increase in thymus and activation-regulated chemokine (TARC) occurred only in the nemolizumab group, but there was no correlation between this increase and changes in EASI.

For the full article, please visit https://www.nejm.org/doi/full/10.1056/NEJMoa1917006

The first author of this publication, Kenji Kabashima, M.D., Ph.D., Department of Dermatology, Graduate School of Medicine, Kyoto University said, "Itching causes patients with atopic dermatitis to suffer from decreased quality of life including difficulty concentrating at work and school and sleep disturbances. Important results from the study may lead to identifying the mechanism of action for itch associated with atopic dermatitis. Nemolizumab may contribute to reducing the suffering and social loss experienced by patients with atopic dermatitis and their families.

Yasuhiko Kito, Director of the Board, Executive Corporate Officer, Research & Development, Reliability Assurance & Medical Affairs of Maruho said, "In this study, the effect of nemolizumab on pruritus in patients with atopic dermatitis was verified in Japan. Through the development of nemolizumab, Maruho will contribute to improving the quality of life of patients suffering from pruritus as a result of atopic dermatitis".

[Reference]

Nemolizumab Achieves Primary Endpoint in Phase 3 Clinical Study (Comparative Study) in Japan for the Treatment of Atopic Dermatitis (2019-04-18 News Release)
https://www.maruho.co.jp/english/release/nek5p40000004lm8-att/20190418_pr_eng.pdf

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/release/index.html

About nemolizumab
Nemolizumab is an anti-IL-31 receptor A humanized monoclonal antibody created by Chugai Pharmaceutical. IL-31 is a pruritus-inducing cytokine and has been reported to be involved in the development of pruritus in atopic dermatitis and dialysis patients. Nemolizumab is thought to work by inhibiting biological activity of IL-31 through competitively blocking the binding of IL-31 to its receptor.

About Pruritus VAS
An abbreviation of (Visual Analogue Scale), an evaluation index that determines the degree of itch by drawing a line on the scale of 10cm (0: no itch, 10: worst imaginable itch).

About EASI
EASI (Eczema Area and Severity Index) is an evaluation index to demonstrate the extent (area) and severity of atopic dermatitis.

About DLQI
DLQI (Dermatology Life Quality Index), is a quality of life index specific to skin diseases.

About ISI
ISI (Insomnia Severity Index), is a patient's subjective evaluation index in regard to sleep.

About DLQI
Serum TARC level is used as a short-term condition marker for atopic dermatitis patients.

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 1,537 employees (as of the end of September 2019), and net sales were approximately 80.37 billion yen in its fiscal year ending September 30, 2019. 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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