News Release

April 18, 2019
Maruho Co., Ltd.

Nemolizumab Achieves Primary Endpoint in Phase 3 Clinical Study (Comparative Study) in Japan for the Treatment of Atopic Dermatitis

Osaka (Japan), April 18, 2019 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that a phase 3 clinical study (comparative study) of nemolizumab conducted in Japan for the treatment of pruritus associated with atopic dermatitis (hereinafter referred to as “the study”) has achieved its primary endpoint.

The study included 215 subjects over 13 years of age with atopic dermatitis who had moderate to severe pruritus, and compared the efficacy and safety of nemolizumab with placebo 16 weeks after administration. The nemolizumab-treated subjects showed statistically significant improvements compared with the placebo group at the primary endpoint, the change rate of Pruritus VAS 16 weeks after administration, and at the secondary endpoint, the rate of change in EASI 16 weeks after administration. Also, nemolizumab was found to be well-tolerable in this study.

In the future, Maruho aims to apply for marketing approval in Japan, including the results of other clinical trials currently being conducted.

As a pharmaceutical company specializing in dermatology, Maruho hopes to further contribute to patients suffering from itching from atopic dermatitis through the development of nemolizumab.

[Reference]

Chugai and Maruho Announce License Agreement of Nemolizumab (CIM331), a Novel Biologic in the Skin Disease Area for the Japanese Market

https://www.maruho.co.jp/english/release/

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 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 1,512 employees (as of the end of September 2018), and net sales were approximately 78.6 billion yen in its 2018 fiscal year. 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 www.maruho.co.jp/english

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