

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

TOKYO and OSAKA, September 28, 2016 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) and [Maruho Co., Ltd.](#) announced that they have entered into a license agreement where Chugai grants Maruho the rights for the development and marketing of “nemolizumab” (CIM331) in the skin disease area for the Japanese market. Nemolizumab is an anti-IL-31 receptor A humanized monoclonal antibody, currently under development for the indications of atopic dermatitis and pruritus in hemodialysis patients by Chugai.

“Chugai and Maruho have a long history of collaboration for the development and marketing of the topical preparations such as Oxarol[®] Ointment. This time, I am pleased to sign an additional new agreement with Maruho for the development and marketing of nemolizumab,” said Chugai’s Representative Director, President and COO, Tatsuro Kosaka. “We are committed to maximize the value of this innovative drug in the Japanese market by combining Maruho’s established expertise in the skin disease area and Chugai’s cutting-edge antibody technologies.”

“For Maruho, aiming to make an outstanding contribution in the dermatology area, this agreement for an innovative drug with a novel mechanism of action developed by Chugai has great significance,” said Koichi Takagi, President and CEO of Maruho. “Using Maruho’s strengths, we will deliver this treatment to patients suffering from skin disease as soon as possible.”

Nemolizumab was created by Chugai utilizing its proprietary antibody engineering technology called ACT-Ig, which can extend the biological half-life of antibodies in the blood. IL-31 has been identified as a pruritogenic cytokine¹⁾, and reported to be involved in the generation of pruritus in atopic dermatitis and hemodialysis^{2,3)}. Nemolizumab is designed to inhibit the biological activities of IL-31 by competitively blocking binding with its receptor. Chugai has obtained positive results for both efficacy and safety at 12 weeks in a global phase II study with moderate-to-severe atopic dermatitis patients in five countries including US, Europe and Japan. Currently, a phase II study for pruritus in hemodialysis patients is ongoing in Japan as well.

Under the agreement, Chugai will grant Maruho a license for the development and marketing of nemolizumab for the skin disease area in Japan. Chugai will continue to be responsible for product manufacturing and supply of nemolizumab. Under the terms of the agreement, Chugai will receive an upfront and other payments from Maruho. The development and marketing of nemolizumab for pruritus in hemodialysis patients will be continued solely by Chugai.

For the overseas market, Chugai has out-licensed nemolizumab to Galderma Pharma S.A. and granted it an exclusive license for the development and marketing of the drug worldwide, with the exception of Japan and Taiwan.

About Chugai Pharmaceutical

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area. The consolidated revenue in 2015 of Chugai totaled 498.8 billion yen and the operating income was 90.7 billion yen (IFRS Core basis). Additional information is available on the internet at <http://www.chugai-pharm.co.jp/english>.

About Maruho

Maruho has its headquarters in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,335 employees (as of the end of September 2015) and net sales were 67.0 billion yen in its 2015 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.

Additional information is available on the internet at <https://www.maruho.co.jp/english>.

Reference

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2. Sonkoly E, et al. IL-31: a new link between T cells and pruritus in atopic skin inflammation. *J Allergy Clin Immunol* 2006;117:411-7.
3. Ko MJ, et al. Interleukin-31 is associated with uremic pruritus in patients receiving hemodialysis. *J Am Acad Dermatol* 2014;71:1151-9.

For inquiries

Chugai Pharmaceutical Co., Ltd.
Media Relations Group
Corporate Communications Dept.
Tel: +81-(0)3-3273-0881
Fax: +81-(0)3-3281-6607
pr@chugai-pharm.co.jp

Maruho Co., Ltd.
Shuhei Inokuchi
Public Relations Dept.
Tel: +81-(0)6-6371-8831
Fax: +81-(0)6-6371-8679
kouhou@mii.maruho.co.jp