Chugai and Galderma Announce Global License Agreement for Nemolizumab (CIM331), Novel Biologic for Skin Diseases

TOKYO/LAUSANNE, July 21, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) and Galderma Pharma S.A. today announced that they have entered into a global license agreement for "nemolizumab" (CIM331), the anti-IL-31 receptor A humanized monoclonal antibody created by Chugai, which is currently under development for atopic dermatitis and pruritus in hemodialysis patients.

"This agreement highlights the great expectation for nemolizumab which possesses a novel mechanism of action to improve atopic dermatitis by breaking the itch-scratch cycle," said Chugai's Representative Director, President and Chief Operating Officer, Tatsuro Kosaka. "Along with Galderma, we are committed to the development of nemolizumab to bring this innovative drug to patients with atopic dermatitis worldwide."

"Our vision is to provide a new medicine to patients suffering from many diseases with itch as the main symptom. This agreement is a great step forward towards the realization of this vision," said Dr. Athos Gianella-Borradori, Chief Medical Officer of Chugai Pharma USA, Inc. "This partnership with Galderma will ensure that the full potential of nemolizumab will be realized."

"This new strategic agreement marks another important step in our journey to meet the needs of patients and healthcare professionals all around the world by delivering breakthrough innovative medical solutions along the entire spectrum of technological options," said Stuart Raetzman, Chief Executive Officer of Galderma Pharma S.A. "Nemolizumab is a new innovative biotherapy candidate which will be developed as a clearly differentiated first in class solution for patients with moderate-to-severe atopic dermatitis," added Dr. Thibaud Portal, Vice President of Galderma's Prescription Business. "This first foray for Galderma in the field of biotherapies will be truly transformational for our prescription business and illustrates our ambitions to fulfill all the needs of our patients, from diagnosis to treatment, maintenance and prevention."

Nemolizumab was discovered by Chugai, and uses Chugai's proprietary antibody engineering technology ACT-Ig, which can extend the biological half-life of antibodies in blood. IL-31 has been identified as a pruritogenic cytokine,[1] and reported to be associated with pruritus in many diseases including atopic dermatitis and hemodialysis.[2,3] Nemolizumab is designed to inhibit the activities of IL-31 by competitively blocking binding with its receptor. Chugai has obtained positive results in a global phase II study in patients with moderate-to-severe atopic dermatitis in five countries in US, Europe and Japan. Currently, a phase II study for pruritus in hemodialysis patients is ongoing in Japan.

Under the agreement, Chugai will grant Galderma an exclusive license for the development and marketing of nemolizumab worldwide, with the exception of Japan and Taiwan. Chugai will continue to be responsible for product manufacturing and supply of nemolizumab. Under the terms of the agreement, Chugai will receive an upfront, milestone and royalty payments from Galderma.

This transaction is subject to potential competition authority clearances and other customary closing conditions.

About Atopic Dermatitis

Atopic dermatitis (AD) is a complex multi-factorial disease combining two types of anomalies: alteration of the epidermal barrier and sensibility to allergens. It is a chronic, pruriginous, inflammatory dermatitis manifesting itself under the form of flares. It is the most common dermatitis among children but can subsist at any age: patient types vary widely and range from infants to seniors, acute to chronic, and mild to severe. It is caused by genetic and environmental factors: new discoveries are elucidating the pathogenic pathways that drive AD.

About itch-scratch cycle

Skin itchiness causes scratch, which enhances inflammation and further aggregation of itchiness. This vicious cycle called the itch-scratch cycle is known as an exacerbating factor for dermatitis.

About Chugai

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.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2015 of Chugai totalled 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 Galderma

Dating back to 1981, Galderma is now present in 100 countries with an extensive product

portfolio to treat a range of dermatological conditions. The company partners with health care professionals around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in research and development of scientifically-defined and medically-proven solutions for the skin, hair and nails.
For more information, please visit http://www.galderma.com/.

Reference

1. Dillon SR, Sprecher C, Hammond A, Bilsborough J, Rosenfeld-Franklin M, Presnell SR, Haugen HS, Maurer M, Harder B, Johnston J, Bort S, Mudri S, Kuijper JL, Bukowski T, Shea P, Dong DL, Dasovich M, Grant FJ, Lockwood L, Levin SD, LeCiel C, Waggie K, Day H, Topouzis S, Kramer J, Kuestner R, Chen Z, Foster D, Parrish-Novak J, Gross JA. Interleukin 31, a cytokine produced by activated T cells, induces dermatitis in mice. Nat Immunol 2004;5:752-60.
2. Sonkoly E, Muller A, Lauerma AI, Pivarcsi A, Soto H, Kemeny L, Alenius H, Cieu-Nosjean MC, Meller S, Ricker J, Steinhoff M, Hoffmann TK, Ruzicka T, Zlotnik A, Homey B. 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, Peng YS, Chen HY, Hsu SP, Pai MF, Yang JY, et al. Interleukin-31 is associated with uremic pruritus in patients receiving hemodialysis. J Am Acad Dermatol 2014;71:1151-9.

Contact:

Galderma

Yvan Deurbroeck, Global Vice President Communications

Phone +41792543824

Email: yvan.deurbroeck@galderma.com

Chugai

For Media

Chugai Pharmaceutical Co., Ltd.

Media Relations Group, Corporate Communications Dept.,

Koki Harada

Tel: +81-3-3273-0881

E-mail: pr@chugai-pharm.co.jp

For US media

Chugai Pharma USA Inc.

Casey Astringer

Tel: +1-908-516-1350

E-mail: pr@chugai-pharm.com

For European media

Chugai Pharma France SAS

Nathalie Leroy
Tel: +33-1-56-37-05-21
E-mail: pr@chugai.eu

For Taiwanese media
Chugai Pharma Taiwan Ltd.
Susan Chou, Osamu Kagawa
Tel: +886-2-2715-2000
E-mail: pr@chugai.com.tw

For Investors
Chugai Pharmaceutical Co., Ltd.
Investor Relations Group, Corporate Communications Dept.,
Toshiya Sasai
Tel: +81-3-3273-0554
E-mail: ir@chugai-pharm.co.jp