

## Chugai and Maruho Announce Marketing Approval of "Marduox<sup>®</sup> Ointment," a Preparation for the Treatment of Psoriasis Vulgaris (Combination Topical Ointment)

TOKYO, March 28, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) and Maruho Co., Ltd. announced today that Chugai has acquired the marketing approval of "Marduox<sup>®</sup> Ointment" (Marduox) for the indication of psoriasis vulgaris, which has been jointly developed by Chugai and Maruho.

Marduox is a topical preparation combining maxacalcitol, an active vitamin D<sub>3</sub> derivative developed by Chugai, and the corticosteroid betamethasone butyrate propionate. Both drugs are indicated for psoriasis vulgaris and are clinically used together or individually for the treatment of the disease. Marduox has been developed as an easy-to-use combination drug that leverages the advantages of these drugs and at the same time improves the issues associated with concomitant uses of multiple topical drugs.

In a phase III study in Japanese patients with psoriasis vulgaris, Marduox with once-daily topical application was confirmed to be superior to both a single use of maxacalcitol ointment (twice-daily topical application) and a single use of betamethasone butyrate propionate ointment (once-daily topical application) in terms of efficacy. With regards to safety, decrease in blood cortisol was observed as an adverse reaction; however, its severity was mild, and no significant difference was found between the single use of each individual drug.

The collaboration between Chugai and Maruho started with the launch of "Oxarol<sup>®</sup> Ointment 25µg/g" in 2001, which is a product of maxacalcitol, and followed by the launch of "Oxarol<sup>®</sup> Lotion 25µg/g" in 2007. Maruho which specializes in the dermatology area and Chugai, the originator of this product, are convinced that Marduox will provide better treatment for patients suffering from psoriasis vulgaris.

### Product summary of "Marduox<sup>®</sup> Ointment"

Nonproprietary name:	Maxacalcitol/Betamethasone butyrate propionate
Dosage form and strength:	Marduox is an ointment that contains (per 1 g) 25 µg of maxacalcitol and 0.5 mg of betamethasone butyrate propionate.
Indication:	Psoriasis vulgaris
Dosage and administration:	Apply a proper quantity of Marduox once daily on the affected site.
Conditions for approval:	Prepare and appropriately execute a Risk Management Plan.

### **About psoriasis**

Psoriasis is a chronic skin disease classified under the inflammatory keratosis category. It is a disease having two aspects: inflammation of the skin and abnormal metabolism of the epidermis (the outermost layer of the skin). It is divided into five types according to symptoms, and approximately 90% of cases are psoriasis vulgaris. In Japan, 430,000 people, accounting for 0.3% of the population, are reported to be affected. As a typical symptom, silver-white scales resembling thin scabs are attached to red-colored eruptions elevated slightly from the skin, and these scales flake off like dandruff. In Japanese, psoriasis is called kansen, which phonetically can also mean "infection or infectious disease." Thus, psoriasis is often misunderstood to be infectious. However, it is not a contagious disease. It is a chronic disease, and difficult to be cured with currently available treatment. Topical medicine and other drugs are mainly used to control the symptoms.

### **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.

For more information about Maruho Co., Ltd., please refer to <http://www.maruho.co.jp/english>.

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