

Translation

Chugai Pharmaceutical Co., Ltd.
Maruho Co., Ltd.

Filing of New Drug Application for M8010, a Topical Preparation Combining an Active Vitamin D₃ Derivative and a Corticosteroid

May 25, 2015 (Tokyo) -Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] (hereafter “Chugai”) announced today that it has submitted a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare for a combination topical drug preparation of maxacalcitol and betamethasone butyrate propionate (Development Code: M8010). M8010 has been co-developed with Maruho Co., Ltd. [Head Office: Kita-ku, Osaka; President and CEO: Koichi Takagi] (hereafter “Maruho”) for the indication of psoriasis vulgaris.

M8010 is a topical preparation combining maxacalcitol, an active vitamin D₃ derivative created by Chugai, and the corticosteroid betamethasone butyrate propionate. Both drugs are indicated for psoriasis vulgaris and are used together to treat the disease in medical practice.

A Japanese phase III clinical study was conducted to evaluate a once-daily topical application of M8010 against maxacalcitol ointment monotherapy (twice daily inunction) and betamethasone butyrate propionate ointment monotherapy (once daily application). The result showed superiority over both monotherapies in terms of primary endpoint (total score of PSI* at four weeks), and secondary endpoint (rate of reduction of mPASI** at four weeks). As for safety, rhinopharyngitis and reduction of blood cortisol were observed as major adverse events during the study. However, these were mild and no major difference was observed in the rate of occurrence compared with both monotherapies, so safety of M8010 was similar to that of both drugs.

The collaboration between Chugai and Maruho started with the launch of Oxarol[®] Ointment, a product of maxacalcitol in 2001. Both companies will make efforts to obtain early approval and make sure that M8010 can be delivered to patients and healthcare professionals as soon as possible. Maruho will be responsible for providing information and marketing activities after an approval is obtained, the same responsibilities Maruho has for Oxarol[®] Ointment and Lotion, which are already on the market.

- ***PSI (Psoriasis Severity Index):** An evaluation index that converts the degree of severity of the psoriatic lesions' skin findings (erythema, infiltration and thickening, scales) into scores.
- ****mPASI (modified Psoriasis Area and Severity Index):** An evaluation index that converts the degree of severity and the scope of the lesions of the psoriatic lesions' skin findings (erythema, infiltration and thickening, and scales), in areas excluding the head and the neck, into scores.

[References]

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 afflicted. As a typical symptom, silver-white scales resembling thin scabs adhere to red-colored eruptions that have become elevated slightly from the skin. 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 cannot 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 2014 of Chugai totaled 461.1 billion yen and the operating income was 77.3 billion yen (IFRS Core basis).

Additional information is available on the internet at <http://www.chugai-pharm.co.jp/english>.

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 1,297 employees (as of the end of September 2014) and net sales were approximately 63.3 billion yen in the previous 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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