



News Release

September 25, 2015
Maruho Co., Ltd.

Maruho submits a New Drug Application for Propranolol as the first drug for Infantile Hemangioma in Japan

Osaka (Japan), September 25, 2015 – Maruho Co., Ltd (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that it has submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labor and Welfare (MHLW), based on clinical trial results carried out in Japan and overseas data, for an infantile hemangioma treatment product (“the product”, INN: propranolol hydrochloride) in Japan.

The active ingredient propranolol hydrochloride is widely used in clinical practice as a treatment for hypertension, angina pectoris, arrhythmias and other disorders. In 2008, the first report of its efficacy against infantile hemangioma was published in the New England Journal of Medicine. Pierre Fabre Dermatologie (PFD) developed the new formulation of propranolol specially designed for pediatric use. The product is currently approved in 34 countries after receiving approval in the US, the EU and Australia in 2014.

In December 2012, Maruho entered into an exclusive license agreement with PFD to develop and market the product in Japan for the treatment of infantile hemangioma. In November 2013 the MHLW designated the product as an orphan drug. Now Maruho has submitted an NDA for the product as the first drug for infantile hemangioma in Japan.

Infantile hemangioma is a disease where often a small bruise swells to form a vivid, crimson, strawberry-like lesion. Hemangiomas are benign tumors that develop most often in infancy. The incidence in Japan is estimated to be about 1% of the population of infants.^{1,2} Generally, infantile hemangioma develops from 1 to 4 weeks after birth, grow to maximum size in about 1 year, then naturally shrink and regress by 5-7 years old.³ Almost all infantile hemangiomas are followed without treatment, but in some cases treatment is required. If the infantile hemangioma may cause a life threatening problem, may interfere with body functions or cause permanent cosmetic damage, treatment should be considered. Current treatments are considered to be unsatisfactory in regard to safety and efficacy, and a new treatment is desired.



With this application, Maruho hopes to provide a new treatment option to improve the lives of patients and their families suffering from infantile hemangioma.

References

- ¹ Hidano A, Nakajima S: Earliest features of the strawberry mark in the newborn. Br J Dermatol. 1972;87:138-144
- ² Miyasaka M, Tanaka R: Strawberry Hemangioma. PEPARS. 2006; 7:6-15.
- ³ The Japanese Clinical Practice Guidelines for Hemangioma and Vascular Malformation 2013

About Pierre Fabre and Pierre Fabre Dermatologie

Pierre Fabre is the 3rd largest French pharmaceutical group and the 2nd largest dermo-cosmetics laboratory in the world. Pierre Fabre Laboratories employ over 10,000 people worldwide. Created in 1983, present in 84 countries, Pierre Fabre Dermatologie has become a major player in dermatology over the last 30 years. Its product portfolio covers the management of major dermatological disorders including acne, psoriasis, inflammatory dermatitis, fungal infections, and alopecia. Benefiting from the Group's pharmaceutical expertise, Pierre Fabre Dermatologie is committed to the absolute requirement of quality, efficacy and safety of its drugs, research into the pharmaceutical forms best suited to dermatology and partnering with dermatologists. To find out more, please visit www.pierre-fabre.com

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 www.maruho.co.jp/english

Contact Information:

Maruho Co., Ltd.

Public Relations Department

Shuhei Inokuchi

Tel: +81-(0)6-6371-8831 Fax: +81-(0)6-6376-1724

E-mail: kouhou@mii.maruho.co.jp