



## News Release

July 04, 2016  
Maruho Co., Ltd.

### **Maruho receives manufacturing and marketing approval in Japan for infantile hemangioma treatment “Hemangiol<sup>®</sup> Syrup for Pediatric 0.375%” under a license from Pierre Fabre Laboratories**

Osaka (Japan), July 04, 2016 – Maruho Co., Ltd (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that it has received manufacturing and marketing approval in Japan from the Japanese Ministry of Health, Labor and Welfare (MHLW), for infantile hemangioma treatment “Hemangiol<sup>®</sup> Syrup for Pediatric 0.375%” (“Hemangiol” INN: propranolol hydrochloride).

Hemangiol is an oral solution formulation of a treatment using the active ingredient propranolol hydrochloride developed by Laboratoires Pierre Fabre Dermatologie (“PFD”, France, Boulogne, CEO: Jean-Jacques VOISARD). Hemangiol is currently approved in 36 countries.

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.

Infantile hemangiomas are benign tumors that develop most often in infancy. 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.<sup>1</sup> 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 in Japan are considered to be unsatisfactory in regard to safety and efficacy, and a new treatment is desired. However, a treatment indicated for infantile hemangioma has not been approved until now.

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



## Product Profile: Hemangiol<sup>®</sup>

INN	Propranolol hydrochloride
Formulation/Dose	An oral solution formulation containing 3.75mg of propranolol (Japanese Pharmacopoeia: propranolol hydrochloride 4.28mg) per 1mL.
Indication	Infantile hemangioma
Dosage and Administration	General administration is 1mg/kg~3mg/kg of propranolol a day, divided into two doses administered orally on an empty stomach. Administration starts from 1mg/1kg a day increasing by 1mg/kg a day after two day intervals, then maintained at 3mg/kg a day. Dosage is reduced as appropriate according to the patient's condition.
Approval Requirements	A pharmaceutical risk management plan should be properly designed and implemented

### About infantile Hemangioma

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.<sup>2,3</sup> In 90% of cases, infantile hemangioma develop 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.<sup>1</sup>

### References

<sup>1</sup> [The Japanese Clinical Practice Guidelines for Hemangioma and Vascular Malformation 2013](#)

<sup>2</sup> [Hidano A, Nakajima S: Earliest features of the strawberry mark in the newborn. Br J Dermatol. 1972;87:138-144](#)

<sup>3</sup> [Miyasaka M, Tanaka R: Strawberry Hemangioma. PEPARS. 2006; 7:6-15.](#)

### 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](http://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 1,335 employees (as of the end of September 2015), and net sales were approximately 67.0 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](http://www.maruho.co.jp/english)

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