



Pierre Fabre obtains FDA Approval to market Hemangeol™ for the Treatment of Infantile Hemangioma

Castres (Tarn) – France, Parsippany (NJ) – USA, March 17th, 2014 – Pierre Fabre Dermatologie has obtained marketing authorization from the FDA* for the pediatric drug Hemangeol™ (propranolol hydrochloride), which is the first and only approved treatment for “proliferating infantile hemangioma requiring systemic therapy”. Hemangeol is an oral solution specially developed for safe and effective use in children. Hemangeol will be available June 2014.

This marketing authorization comes after the new drug application for Hemangeol was submitted to the US FDA in May 2013. The application was also submitted to the European Medicines Agency, receiving positive opinion on February 21st, 2014 from the CHMP**, with marketing authorization expected for April 28th, 2014.

The efficacy of propranolol in the treatment of infantile hemangioma (IH) was first discovered in 2007 by Dr. Christine Léauté-Labreze, a dermatologist at the Bordeaux University Hospital. Subsequently, the off-label use of this molecule became the first-line treatment for IH. While propranolol has long been known and used in cardiology, its use in infants with IH had never been properly studied and there was no pharmaceutical form approved for pediatric use. In 2009, Pierre Fabre Dermatologie undertook the pharmaceutical and clinical development required to make the Bordeaux University Hospital discovery accessible to infants with IH, with proven clinical safety and efficacy.

“This collaboration has endowed pediatric dermatology with a new therapy that fulfills an unmet medical need and thousands of American children may now benefit from this new therapy each year,” declared Dr. Jean-Jacques Voisard, Dermatologist, General Manager of Pierre Fabre Dermatologie.

“As Pierre Fabre US representatives we are proud to be part of a Group able to develop children dedicated medicines and to be the first Pierre Fabre subsidiary to obtain marketing approval for Hemangeol,” underlined Laurent-Emmanuel Saffré, General Manager of Pierre Fabre Pharmaceuticals, Inc. (USA).

“The marketing authorization granted by the FDA rewards a public-private partnership developed over the last six years by Pierre Fabre Laboratories and the Bordeaux University Hospital, with the support from Aquitaine Science Transfert,” stated Eric Ducournau, CEO of Pierre Fabre Dermo-cosmetics SAS, parent company of Pierre Fabre Dermatologie.

“Following the marketing authorization approved by the FDA in July last year for Fetzima (levomilnacipran extended-release capsules), a drug created by Pierre Fabre research and developed in partnership with Forest Laboratories, the Hemangeol marketing authorization is yet further recognition for our R&D on the world’s most demanding pharmaceutical market. This is a tremendous encouragement to pursue our R&D effort in oncology, dermatology and neuropsychiatry which are our prioritized therapeutic areas of innovation,” commented Bertrand Parmentier, CEO of the Pierre Fabre Laboratories.

* FDA (Food and Drug Administration) ** CHMP (Committee for Medicinal Products for Human Use)

About infantile hemangiomas

Infantile hemangioma is the most common vascular benign tumor of infancy, affecting 3% to 10% of newborns. This benign tumor is characterized by abnormal proliferation of the endothelial tissue. The lesions are rarely detectable at birth and start growing noticeably during the first 4 to 6 weeks of life. While most infantile hemangiomas do not require treatment, approximately 12% require treatment. Some infantile hemangiomas based on their location can be functionally impairing (breathing, eating, vision) or life-threatening. Ulceration is the most common complication (with incidence of 16%). Other major complications are airway obstruction, cardiovascular risk or permanent disfigurement.

For more information, visit www.infantilehemangioma.com

About Hemangeol™

Hemangeol™ (propranolol hydrochloride) formulation was specifically developed for the use in pediatric population following the guidelines of health regulatory agencies. Hemangeol was studied in infants 5 weeks to 5 months old (at therapy initiation) with a proliferative infantile hemangioma requiring systemic treatment in a randomized, double blind placebo controlled, multi-dose and multi-center adaptive phase II/III trial, which compared four propranolol treatment protocols (1 or 3 mg/kg/day for 3 or 6 months) versus placebo. The treatment protocol of 3 mg/kg/day dose for the duration of 6 months had a 60.4% success rate versus 3.6% in the placebo group ($p < 0.0001$) reaching the primary endpoint: complete or nearly-complete resolution of the target hemangioma. In 11.4% of patients needed to be retreated after stopping the treatment.

Important Safety Information

Hemangeol is contraindicated in premature infants with corrected age < 5 weeks; infants weighing less than 2 kg; known hypersensitivity to propranolol or any of the excipients, has asthma or history of bronchospasm, heart rate <80 beats per minute, greater than first degree heart block, or decompensated heart failure ; blood pressure <50/30 mmHg; or pheochromocytoma.

Hemangeol can cause serious side effects including hypoglycemia, bradycardia, hypotension, bronchospasm, worsen congestive heart failure, and may increase the risk of stroke in children with PHACE syndrome.

The most frequently reported adverse reactions (>10%) in infants treated with Hemangeol were sleep disorders, aggravated respiratory tract infections such as bronchitis and bronchiolitis associated with cough and fever, diarrhea, and vomiting. Adverse reactions led to treatment discontinuation in fewer than 2 % of treated patients.

About Pierre Fabre and Pierre Fabre Dermatologie

Pierre Fabre Laboratories is the second largest independent pharmaceutical group in France with revenue of over 2 billion Euros in 2013, 56% of which comes from international business. Pierre Fabre is present in 42 countries and its products are distributed in more than 130 countries.

Through its two branches, Pierre Fabre Pharmaceuticals and Pierre Fabre Dermo-cosmetics, Pierre Fabre's activities cover all areas of healthcare from prescription and OTC drugs to dermo-cosmetic treatments and natural health products. Pierre Fabre has 10,000 employees around the world, including 1400 in R&D, and devotes almost 20% of its pharmaceuticals turnover to R&D.

With its well-known brands such as Avène, A-Derma, Ducray, Glytone, Klorane, Naturactive, René Furterer, and Pierre Fabre Oral Care, Pierre Fabre Laboratories is the French market's leading producer of dermo-cosmetics, hair care and oral care products sold in pharmacies and drugstores. Avène is the world's best-selling dermo-cosmetics brand. In pharmaceuticals, Pierre Fabre focuses on four key treatment franchises: oncology, dermatology, neuropsychiatry, and women's health.

Created in 1983, present in 84 countries, the subsidiary 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. With the Group's pharmaceutical expertise behind it, 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

Press contacts :

US : Pierre Fabre USA 973-647-1610 // lsaffre@PFDCUSA.com

France : +33 (0)1 49 10 83 84 valerie.roucoules@pierre-fabre.com