Pierre Fabre obtains European Commission Marketing Authorization for Hemangiol®, the first and only drug approved for the treatment of Proliferating Infantile Hemangioma

Castres (Tarn) - France, 5th May, 2014 – Pierre Fabre Dermatologie Laboratories have obtained European Commission authorization to market Hemangiol® (propranolol), the first and only drug to be approved for the treatment of “proliferating infantile hemangioma requiring systemic treatment”. Hemangiol® is an oral solution specially developed for pediatric use. It will be launched firstly in France and Germany, and gradually throughout other European markets.

This European agreement follows the FDA* approval obtained on March 14th for Hemangeol™, the trade name of the identical drug to be launched on in the US in June.

This PUMA (Paediatric Use Marketing Authorization) is only the second of its type, for all pathologies, that the European Medicines Agency (EMA) has issued since the system was established in 2007.

From a discovery to a trusted drug

The efficacy of propranolol for the treatment of infantile hemangioma was first discovered in 2007 by Christine Léauté-Labreze MD, a dermatologist at Bordeaux University Hospital Center. “12% of hemangiomas are severe forms that can lead to complications such as airway obstruction, vision problems or irreversible disfigurement. Yet there was no treatment available for this pathology that offered adequate efficacy and tolerance. The marketing authorization provides a legal framework that protects the child, family members and the prescribing practitioner,” explained Christine Léauté-Labreze MD, a dermatologist at Bordeaux University Hospital Center.

In 2009, Pierre Fabre Dermatologie and the University of Bordeaux had formed a partnership to make this discovery available to infants with infantile hemangioma (IT) under conditions specifically adapted to pediatric use. Within this framework, Pierre Fabre Dermatologie took charge of the pharmaceutical, toxicological, clinical and industrial development aspects, including:

- Developing a formula for infants - containing no excipients known to have a recognized effect (such as alcohol and sugar), and flavored to allow for better acceptability of the treatment;
- Setting up three clinical trials, including a Phase II / III trial, conducted on 460 babies between five weeks and five months of age, to confirm the appropriate treatment regimen, and the efficacy and tolerance of the formula;
- Designing a product presentation aimed at safe and easy use, thanks notably to a graduated (in mg) oral syringe and a non-movable adaptor on the bottle,
- The industrial adaptation and manufacturing in accordance with pharmaceutical standards in order to ensure the quality and reproducibility of the drug.

“Every year, thousands of children will be able to benefit from this new pediatric dermatology treatment specially formulated, developed, tested and produced for safe pediatric use,” stated Jean-Jacques Voisard MD, Dermatologist, General Manager of Pierre Fabre Dermatologie.

“The approvals obtained from the American and now the European agency are testimony to the capacity for innovation in French research and reward a public-private partnership formed six years ago between the University, the Bordeaux University Hospital Center and Pierre Fabre Laboratories, with support from the innovation agency, Aquitaine Science Transfert,” commented Eric Ducournau, CEO of Pierre Fabre Dermo-Cosmétique. “This achievement is a source of great encouragement to maintain the focus of on R&D efforts on oncology, dermatology and neuropsychiatry, our three priority therapeutic franchises” stated Bertrand Parmentier, Group CEO of Pierre Fabre Laboratories.
About infantile hemangiomas
Infantile hemangiomas are the most common tumor among infants. They affect 3 to 10% of newborns. They are vascular tumors, most often benign, and characterized by abnormal proliferation of the endothelial tissue. The lesions are rarely detectable at birth but develop during the first 4 to 6 weeks of life. While most infantile hemangiomas are benign, approximately 12% are severe, requiring treatment by a specialist. In some cases, such as when they develop in sensitive areas (near the eyes, nose and throat), hemangiomas can be debilitating or life-threatening. Ulceration is the most common complication (with incidence of 16%). Other major complications are airway obstruction, cardiovascular risk or disfiguration.

For more information, visit www.infantilehemangiomas.com

About Hemangiol®
Hemangiol® (propranolol base) oral solution contains the beta-blocker propranolol hydrochloride and is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy. The efficacy of Hemangiol® in infants (from 5 weeks to 5 months of age at start of treatment) has been demonstrated in a pivotal randomized, controlled, multi-dose and multicenter adaptive Phase II/III trial.

Important Safety Information
Hemangiol® is contraindicated in premature infants who have not reached the adjusted age of 5 weeks, in case of hypersensitivity to the active substance or any of the excipients, asthma or history of bronchospasm, bradycardia, second and third degree atrioventricular blocks, cardiac failure not controlled with treatment, low blood pressure, or pheochromocytoma.

In clinical trials conducted on proliferative infantile hemangiomas, the most commonly reported side effects in children treated with Hemangiol® were trouble sleeping, increased respiratory infections such as bronchitis and bronchiolitis associated with cough and fever, diarrhea and vomiting. The most severe side effects reported during the experimental use program and in the literature were hypoglycemia (and associated events such as hypoglycemic seizures) and increased respiratory infections associated with respiratory distress.

About Pierre Fabre and Pierre Fabre Dermatologie
Pierre Fabre is the 3rd largest French pharmaceutical group. In 2013, its sales reached €2.008 Billion, with international revenues accounting for 56%. Founded, and its headquarters still based in the South-west of France, Pierre Fabre currently has branches in 44 countries and distribution agreements in over 130 countries.

Covering all aspects of healthcare, from prescription drugs and OTC products to dermo-cosmetics, Pierre Fabre employs over 10,000 people worldwide. In 2013, Pierre Fabre allocated 17% of its drug revenues to R&D, focusing on three main areas: oncology, dermatology and neuropsychiatry.

Through the Pierre Fabre Participations holding company, the Pierre Fabre Foundation, a government-recognized public-interest foundation, owns 86% of Pierre Fabre. Remaining shares are owned by employees (7%) and through treasury stock (7%).

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

Press contacts
Valérie Roucoules Deputy Director Media Relations Pierre Fabre Médicament
+33 (0)1 49 10 83 84 // valerie.roucoules@pierre-fabre.com

Juliette Billaroch Agence PRPA // +33 (0)1 77 35 60 94 // juliette.billaroch@prpa.fr