

Pierre Fabre and Maruho sign a licensing agreement in the treatment of severe infantile haemangioma

Maruho obtains exclusive license for Japan

Castres (France) - Osaka (Japan), January 17th, 2013 – Laboratoires Pierre Fabre Dermatologie (PFD), a subsidiary of Laboratoires Pierre Fabre and Maruho Co., Ltd. (Maruho), today announced that an exclusive licensing agreement has been reached to develop and market in Japan, an oral formulation of paediatric beta-blocker for the treatment of infantile haemangioma requiring a systematic therapy. Laboratoires Pierre Fabre Dermatologie recently completed a worldwide Phase III study with this oral formulation of beta-blocker which resulted in complete or nearly complete resolution of the haemangioma for a large majority of the infants treated, compared to an almost complete lack of effect for the placebo.

Under the terms of this agreement, Maruho will be responsible for developing and registering this oral formulation in Japan. Maruho has been granted an exclusive licence to import, distribute and promote the product in the country. Pierre Fabre Dermatologie will manufacture and supply the drug.

Asked about this agreement, Eric Ducournau, C.E.O. Pierre Fabre Dermo-Cosmetics, said: *"we are excited about this partnership with Maruho, Japan's leading dermatological company. It's the best guarantee of success for our oral formulation of paediatric beta-blocker, the first effective and safe treatment for infantile haemangioma, in the world's second biggest pharmaceutical market. Our determination to make dermatology one of our priority growth franchises can only benefit from this agreement"*.

Koichi Takagi, President and Chief Executive Officer of Maruho, said: *"We are very glad to be able to make this agreement with Pierre Fabre Dermatologie. In Japan, there are currently no therapies available with an indication for infantile haemangioma. This agreement meets an unmet medical need for infantile haemangioma patients in Japan, and will contribute to the progress of the field of dermatology"*.

As a reminder, the oral formulation of paediatric beta-blocker was developed by Pierre Fabre Dermatologie in compliance with the European Paediatric Regulations, which promotes the development of drugs specially designed for children.

About beta-blockers

The beta-blocker family, a well known molecule, has been used in the past for several infantile heart indications. The 2007 discovery by Dr Christine Léauté-Labrèze (paediatric dermatology team at the Bordeaux University Hospital) of its efficacy in the treatment of infantile haemangioma provides a powerful alternative to the reference treatments, corticotherapy and interferon.

In 2008, Pierre Fabre Dermatologie signed an exclusive worldwide licence agreement with the University of Bordeaux to develop, produce and market a paediatric beta-blocker for the treatment of severe infantile haemangioma with the aim of obtaining marketing authorisation (MA / NDA) both in Europe and the USA.

On October 10th 2012, Pierre Fabre Dermatologie announced positive results in a Phase III clinical trial and expects to shortly file an application for marketing authorisation specific to children (PUMA, Paediatric Use Marketing Authorisation) with the European Medicines Agency (EMA). In the United States, where this treatment benefits from orphan drug status, an application will be similarly filed with the Food and Drug Administration (FDA).

About Pierre Fabre Laboratories

Pierre Fabre, the second largest independent pharmaceutical group in France, achieved a turnover of 1.9 billion Euros in 2011, with international sales accounting for 52%. Pierre Fabre has branches in 42 countries and markets its products in over 130 countries. Their activities cover all aspects of healthcare, from prescription drugs and family health products to dermo-cosmetics.

The Pierre Fabre Laboratories employ some 10,000 people worldwide, 1,300 of whom are dedicated to R&D. In 2011, the group allocated 20% of its Pharmaceuticals business revenues to R&D, focusing on three main areas: oncology, dermatology and neuropsychiatry.

With brands including Avène, A-Derma, Ducray, Glytone, Klorane, René Furterer, Pierre Fabre Dermatology or Pierre Fabre Oral Care, Pierre Fabre is market leader in France when it comes to cosmetics, hair care, oral products and dermatological products sold in pharmacies. Avène is marketed in over 100 countries, and is the leading dermo-cosmetics brand sold in Europe, Japan and China. In the oncology area, 85% of Pierre Fabre's sales are achieved outside France.

Established in 1983, Pierre Fabre Dermatologie Laboratories have become a major player in dermatology with active presence in 84 countries around the world. Their product portfolio provides support for all major dermatological diseases such as acne, psoriasis, inflammatory dermatoses, fungal infections, alopecia, etc.

About Maruho Co., Ltd.

Maruho Co., Ltd., founded in 1915 in Osaka, leads Japan in development and commercialisation of dermatological products with sales of almost 550 million euro in FY 2011, 98% of which came from prescription drug sales. Still based in Osaka, Maruho employs about 1,160 people, and has an office in Düsseldorf that conducts European market research.

Maruho Group includes three overseas subsidiaries. Maruho North America Inc. (in New York) and Maruho Europe Ltd., (in London) focus on clinical development and market research, and Cutanea Life Sciences, Inc. (in Pennsylvania, USA) is developing pharmaceuticals in the field of dermatology.

As part of its commitment to advancing Excellence in Dermatology, Maruho has more than 10 dermatological programmes in its pipeline, including treatments for atopic dermatitis, psoriasis, acne and other disorders.

Maruho's long-term vision is to provide innovative pharmaceutical products to treat a wide range of skin disorders in the global marketplace.

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