

Debiopharm Group's Triptorelin 6-month Formulation Receives Approval for the Treatment of Central Precocious Puberty (CPP) in Europe

Triptorelin is the first 6-month formulation treatment registered in the EU for CPP

Lausanne, Switzerland – January 9, 2017 – Debiopharm International SA (Debiopharm – www.debiopharm.com), a Swiss-based company, part of Debiopharm Group™, today announced that triptorelin 6-month formulation (Decapeptyl® and Pamorelin® 22.5 mg) received approval for the treatment of central precocious puberty (CPP) in 22 European countries where the 6-month formulation has already been registered for the treatment of prostate cancer.

Triptorelin is the first 6-month GnRH agonist formulation approved for the treatment of CPP. Developed by Debiopharm, the product is manufactured in Switzerland by Debiopharm Research & Manufacturing SA and licensed for distribution under exclusive rights to Ipsen for Europe and other parts of the world.

“We are extremely pleased to make the triptorelin 6-month formulation available for this pediatric population in need of more treatment options”, said Eija Lundstrom, Medical Director, Debiopharm International SA. “The further reduced injection frequency will increase the comfort for children with CPP, allowing them to benefit from an established safe and effective treatment and so with only two injections per year.”

About Central Precocious Puberty (CPP)

GnRH-dependent CPP is defined by pubertal development occurring before the age of 8 years in girls and 9 years in boys. It is characterized by early pubertal changes such as breast development and start of menses in girls and increased testicular and penile growth in boys, appearance of pubic hair, as well as acceleration of growth velocity and bone maturation and tall stature during childhood, which often results in reduced adult height due to premature fusion of the growth plates.

Reliable epidemiological data on CPP worldwide are not available. The condition is a rare disease occurring in about 1 out of every 5,000 to 10,000 children. Central precocious puberty is more common in girls than in boys, with a female: male ratio estimated to be between 3:1 and 23:1.

About Triptorelin

Triptorelin is a synthetic decapeptide agonist analogue that was first registered in France in 1986 and is currently marketed in more than 80 countries in various indications including CPP.

Numerous published studies over more than 30 years involving large series of children around the world have reported efficacy and safety results with different triptorelin 1- and 3-month formulations consistent with those of other approved GnRH agonists in this indication. None of these studies has revealed any safety issues.

About Debiopharm International SA

Debiopharm Group™ is a Swiss-headquartered global biopharmaceutical group of five companies active in drug development, GMP manufacturing of proprietary drugs, diagnostics tools and investment management. Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses and develops promising drug candidates. The products are commercialized by pharmaceutical out-licensing partners to give access to the largest number of patients worldwide.

For more information, please visit www.debiopharm.com

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