PRESS RELEASE

Debiopharm International SA Announces Phase III Positive Results for Triptorelin 6-month Formulation in the Management of Central Precocious Puberty (CPP)

Triptorelin 6-month formulation phase III trial demonstrates good efficacy in terms of pituitary and gonadal suppression and in arresting or reversing progression of clinical signs of puberty and slowing down of accelerated bone maturation in children with CPP

Lausanne, Switzerland – May 19, 2015 – Debiopharm International SA (Debiopharm), part of Debiopharm Group™**,** a Swiss-based global biopharmaceutical company developing prescription drugs that target unmet medical needs as well as companion diagnostics, today announced the completion of an international, multicenter, non-comparative phase III study with triptorelin embonate (pamoate) 22.5 mg 6-month formulation in 44 patients (39 girls and 5 boys) with central precocious puberty (CPP). The mean age of the patients at the time of diagnosis was 7 years (range 1 to 9 years).

The results of this 12-month study show that the triptorelin 6-month formulation is efficacious in suppressing the pituitary release of LH (luteinizing hormone) and FSH (follicle-stimulating hormone), and consequently the gonadal secretion of estradiol in girls and testosterone in boys to prepubertal levels, with favorable effects on progression of clinical signs of puberty and bone maturation. The percentage of children with prepubertal LH levels exceeded 93% at each time point on-treatment and reached 98% at month 12 when all but one patient were suppressed. The clinical signs of puberty (Tanner) were stable or reduced in the vast majority of patients (89%) between baseline and month 12. Administration of the triptorelin 6-month formulation was well tolerated and safe with no unexpected adverse events reported.

“The reduced injection frequency has the potential advantage of improving compliance to treatment and increasing comfort for children with CPP, for which no other 6-month GnRH agonist formulation is currently approved.” says Dr Eija Lundstrom, Medical Director at Debiopharm. “We remain committed to developing treatments that improve the quality of life of patients”.

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, which often results in reduced adult height and disproportioned body appearance due to premature fusion of the growth plates.
Reliable epidemiological data on CPP worldwide are not available. The condition occurs in about 1 out of every 5,000 to 10,000 children (leading to an estimated prevalence of 10,000 to 20,000 children in the USA). These numbers show that CPP is a rare disease. 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. Except for injection site reactions or rare immunoallergic reactions, the side effects of triptorelin are mostly due to the initial increase in testosterone/estrogen levels (e.g. vaginal bleeding in girls) followed by almost complete suppression of testosterone/estrogen (e.g. hot flushes and headaches).

However, numerous published studies over more than 25 years involving large series of children (≥ 20 studies) around the world have reported efficacy and safety results with different triptorelin acetate and pamoate (embonate) 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-based global biopharmaceutical group of four companies active in drug development, GMP manufacturing of proprietary drugs, diagnostics, and investments. 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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