

**PRESS RELEASE**

**Debiopharm Group™ Announces Completion of Recruitment for Phase III Clinical Study with Triptorelin 22.5 mg in Central Precocious Puberty**

**Lausanne, Switzerland – January 13, 2014** – Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs and companion diagnostics, announces that it has completed the recruitment of patients for its Phase III clinical study in Central Precocious Puberty (CPP) with triptorelin 22.5 mg.

Debiopharm is investigating the efficacy and safety of the gonadotropin releasing hormone (GnRH) agonist analog triptorelin pamoate 6-month formulation in the treatment of children suffering from central (GnRH-dependent) precocious puberty (CPP). CPP is defined by pubertal development occurring before the age of 8 years in girls and 9 years in boys, which is not secondary to exposure to sex steroids of adrenal or gonadal origin (peripheral precocious puberty). This 6-month formulation offers an excellent treatment option in a pediatric indication due to less frequent injections. No GnRH agonist 6-month formulation is currently approved for treatment of precocious puberty. The study is an international, multicenter, non-controlled phase III study on the efficacy, pharmacokinetics and safety of two consecutive intramuscular injections of the triptorelin pamoate 22.5 mg 6-month formulation over 12 months. The protocol has gone through the US Food and Drug Administration (FDA) Special Protocol Assessment procedure. The recruitment has been completed and the results are expected in Q4 2014.

“We are very happy to have completed the recruitment in this study,” said Eija Lundström, Medical Director responsible for this project at Debiopharm International. “We are looking forward to the results at the end of this year as we believe that the 6-month formulation will simplify the treatment of CPP and make it more tolerable for this young population of patients.”

**About CPP**

The onset of precocious pubertal development is the result of a premature activation of the pulsatile secretion of hypothalamic GnRH leading to an increase in pituitary LH (luteinising hormone) and to a lesser degree FSH (follicle stimulating hormone) secretion. It is characterized by early pubertal changes as well as acceleration of growth velocity and bone maturation. The condition is estimated to occur in about 1 out of every 5'000 to 10'000 children and is more common in girls than in boys.

**About GnRH agonists in CPP**

GnRH agonists have been the standard of care in the management of CPP for almost 30 years, including the triptorelin 1- and 3-month formulations manufactured by Debiopharm or its licensees. Chronic administration of triptorelin causes down- and dys-regulation of the pituitary GnRH receptors and suppresses LH and FSH secretion and ultimately the release of sex-hormones. The goal of the therapy is to stop the premature bone maturation and to avoid a compromised adult height and the social and psychological difficulties associated with premature sexual development. The treatment is generally well tolerated with acceptable adverse effects of minor severity.

**About triptorelin**

Triptorelin is an agonist analogue of the natural gonadotropin-releasing hormone (GnRH). Debiopharm signed a licensing agreement for triptorelin with Tulane University in the US. Triptorelin was discovered by Prof. Andrew Schally who received the Nobel Prize in 1977. Debiopharm has since developed three slow-release formulations (1, 3 and 6 months) of triptorelin pamoate. The 1- and 3-month-formulations have been registered in most countries and are currently available under the names of Trelstar® in North America, Decapeptyl®/Pamorelin® in

Europe, Latin America and Pamorelin® in India. The 6-month-formulation has been registered and is available in Europe and the US in prostate cancer.

### **About Debiopharm Group™**

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™ is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses, develops and/or co-develops promising biological and small molecule drug candidates for global registration. The products are commercialized through out-licensing to pharmaceutical partners to give access to the largest number of patients worldwide.

For more information about Debiopharm Group™, please visit: [www.debiopharm.com](http://www.debiopharm.com).

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