Debiopharm International SA and Arbor Pharmaceuticals, LLC Announce U.S. FDA Approval for Triptodur™, Triptorelin 6-month Formulation, in the Treatment of Central Precocious Puberty (CPP)

Triptodur ™, (triptorelin) for extended release injectable suspension, has been shown to arrest or reverse the clinical signs of puberty with once every six-month intramuscular injection (IM) dosing for children with CPP

Approval brings new CPP treatment formulation to U.S. children for the first time in six years

Lausanne, Switzerland and Atlanta, GA – June 30, 2017 – Debiopharm International SA, part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, and Arbor Pharmaceuticals, LLC, a U.S.-based specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved Triptodur™ for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP). CPP occurs when a child shows signs of puberty sooner than normal - before age 8 in girls and age 9 in boys.

“We are extremely pleased to provide this pediatric population with the option of the triptorelin six-month formulation", said Eija Lundstrom, Medical Director, Debiopharm International SA. "This will allow children to benefit from an effective and well tolerated treatment with only two injections per year."

Triptodur™, a gonadotropin-releasing hormone (GnRH) agonist administered through intramuscular injection (IM), is the first GnRH agonist to offer once-every six-month dosing approved for the treatment of CPP in the U.S. In a phase III clinical trial, Triptodur™ demonstrated a return to pre-pubertal luteinizing hormone (LH) levels in 93 percent of patients, with pre-pubertal LH suppression maintained at 12 months by 98 percent of patients.[1] The most common adverse reactions are injection site reactions and menstrual (vaginal) bleeding.

“Early puberty in a child can pose significant physical and emotional challenges throughout their life, including shorter adult stature, social, psychological and emotional effects,” said Karen Klein, M.D., Pediatric Endocrinologist, University of California San Diego and Rady Children’s Hospital. “With treatment, hormone levels in children with CPP are returned to a normal level, slowing the clinical signs of puberty until an age appropriate time.”

“We are excited to be bringing Triptodur™, a new treatment option for children impacted by the disruptive effects of CPP, to the U.S. market,” said Ed Schutter, President and CEO of Arbor. “Triptodur™ adds to our growing portfolio of approved medications that may help to improve the lives of our patients.”

Triptorelin was developed by Debiopharm and will be manufactured in Switzerland by Debiopharm Research & Manufacturing SA. Arbor acquired exclusive U.S. commercial rights to Triptorelin 6-month for CPP in November 2015. Triptodur™ is expected to be available in the fourth quarter of 2017.

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.[2,3] 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.[4]

Reliable epidemiological data on CPP worldwide is not available. The condition is a rare disease occurring in about 1 out of every 5,000 to 10,000 children.[5] 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.[3]

About Triptorelin

Triptorelin is an agonist analogue of the natural gonadotropin-releasing hormone (GnRH). Debiopharm has developed three sustained-release formulations (1, 3 and 6 months) of triptorelin pamoate. The 1-, 3- and 6-month formulations have been registered in numerous countries for several indications.

Triptorelin was first registered in France in 1986 and is currently marketed in more than 80 countries for various indications including CPP.

About TRIPTODUR

INDICATIONS

TRIPTODUR is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty.

IMPORTANT SAFETY INFORMATION

Contraindications

TRIPTODUR is contraindicated in:

- Individuals with a known hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH.
- Women who are or may become pregnant. Expected hormonal changes that occur with TRIPTODUR treatment increase the risk for pregnancy loss and fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Warnings and Precautions

Initial Rise of Gonadotropins and Sex Steroid Levels - During the early phase of therapy, gonadotrophins and sex steroids rise above baseline because of the initial stimulatory effect of the drug. Therefore, a transient increase in clinical signs and symptoms of puberty, including vaginal bleeding, may be observed during the first weeks of therapy.

Psychiatric Events - Psychiatric events have been reported in patients taking GnRH agonists. Post-marketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment with TRIPTODUR.

Convulsions – Post-marketing reports of convulsions have been observed in patients receiving GnRH agonists, including triptorelin. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

Adverse Reactions

The most common adverse reactions are injection site pain, menstrual disorder and vaginal bleeding.

For additional safety information, consult the TRIPTODUR full Prescribing Information

http://arborpharma.com/docs/TriptodurFullProductInformation.pdf

About Arbor Pharmaceuticals LLC

Arbor Pharmaceuticals, headquartered in Atlanta, Georgia, is a specialty pharmaceutical company currently focused on the cardiovascular, neurology, hospital and pediatric markets as well as generics through its Wilshire division. The company has approximately 750 employees, with over 625 sales professionals that promote its products to hospitals and physicians. In addition to its extensive pipeline, the company continues to actively pursue growth through acquisition or licensing of marketed or late-stage development products. Arbor currently markets twenty-two approved NDA and ANDA products, and, along with Wilshire, has over forty products in development. For more information regarding Arbor Pharmaceuticals or any of its products, visit www.arborpharma.com or send email inquiries to info@arborpharma.com.

About Debiopharm International SA

Part of Debiopharm Group™ – a Swiss-headquartered global biopharmaceutical group including five companies active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic 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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