PRESS RELEASE

Arbor Pharmaceuticals, LLC and Debiopharm International SA Announce Commercial Availability of Triptodur™, Triptorelin 6-month Formulation, for Treatment of Central Precocious Puberty (CPP)

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

Atlanta, GA, USA and Lausanne, Switzerland – October 3, 2017 – Arbor Pharmaceuticals, LLC, a U.S. based specialty pharmaceutical company, and Debiopharm International SA, part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, announced today that Triptodur™ (triptorelin) is now commercially available in the U.S. for the treatment of pediatric patients 2 years and older diagnosed with central precocious puberty (CPP) – a rare condition that affects one in every 5,000 to 10,000 children.[1]

"We are pleased to be providing this important new treatment option for children diagnosed with CPP," said Ed Schutter, President and CEO of Arbor. "We believe that many providers, patients and parents will appreciate the convenience Triptodur™ offers through a once-every six-month dosing schedule."

CPP is a condition that occurs when a child shows signs of puberty earlier than normal: before age 8 in girls and age 9 in boys.[2,3] Without appropriate treatment, children with CPP will be shorter in height than their peers due to premature fusion of growth plates.[4] CPP has also been associated with low self-esteem and higher anxiety, irritability or withdrawal.[5-7,12]

"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 may be returned to a normal level, slowing the clinical signs of puberty until an age appropriate time."

Triptodur™ (triptorelin) is the first gonadotropin-releasing hormone (GnRH) agonist administered through intramuscular injection (IM) to offer once-every six-month dosing.[8] This treatment helps to return hormone levels in children to a normal prepubertal level, pausing the clinical signs of puberty until an age appropriate time. GnRH agonists are the primary treatment for CPP and can help preserve time in childhood.[9]

"We are very pleased to offer this well tolerated and efficacious triptorelin formulation to children suffering from central precocious puberty, for which no other 6-month GnRH agonist formulation is approved", said Eija Lundstrom, Medical Director, Debiopharm International SA.[8]

Triptodur™ (triptorelin) has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of children with CPP. In a phase III clinical trial, Triptodur™ (triptorelin) demonstrated a return to pre-pubertal luteinizing hormone (LH) levels in 93 percent of patients after 6 months of treatment, and in 98 percent of patients after 12 months.[10] The most common adverse reactions in clinical studies were injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection). Please see Important Safety Information below.

Triptorelin extended release formulations were developed by Debiopharm and are manufactured in Switzerland by Debiopharm Research & Manufacturing SA. Arbor acquired exclusive U.S. commercial rights to Triptorelin 6-month for CPP in November 2015 and it was approved by the U.S. FDA in June 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.[1-2] 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.[11]

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.[3] 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.[10]

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 indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

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 advised of the potential risk to the fetus.

Warnings and Precautions
Initial Rise of Gonadotropins and Sex Steroid Levels - During the early phase of therapy, gonadotropins 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 or after subsequent doses.

Psychiatric Events - Psychiatric events have been reported in patients taking GnRH agonists. Postmarketing 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

In clinical trials for TRIPTODUR™, the most common adverse reactions (≥4.5%) are injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection).

For additional safety information, consult the TRIPTODUR™ full Prescribing Information: http://arborpharma.com/docs/TriptodurFullProductInformation.pdf

For More Information

For additional news or information about Triptodur™ (triptorelin), please visit www.Triptodur.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.
We are on Twitter. Follow us @DebiopharmNews at http://twitter.com/DebiopharmNews.

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.

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