Triptodur™ (triptorelin) – New drug approval

- On June 30, 2017, Arbor Pharmaceuticals announced the FDA approval of Triptodur (triptorelin) extended-release injectable suspension for the treatment of pediatric patients ≥ 2 years of age with central precocious puberty (CPP).

- Gonadotropin-releasing hormone (GnRH)-dependent CPP is defined by pubertal development occurring before the age of 8 years in girls and 9 years in boys. CPP is a rare disease occurring in about 1 out of every 5,000 to 10,000 children and is more common in girls than boys.

- Triptorelin is the first GnRH agonist to offer once-every 6 month dosing for the treatment of CPP in the U.S.

- The efficacy and safety of Triptodur were based on a single-arm, open-label study of 44 children with CPP and naïve to previous GnRH treatment administered Triptodur every 24 weeks over a 12 month period. Triptodur demonstrated a return to pre-pubertal luteinizing hormone (LH) levels in 93% of patients, with pre-pubertal LH suppression maintained at 12 months by 98% of patients.

- Triptodur is contraindicated during pregnancy, and in individuals with a known hypersensitivity to triptorelin, any other component of the product, or other GnRH agonists or GnRH.

- Warnings and precautions of Triptodur include initial rise of gonadotropins and sex steroid levels, psychiatric events, and convulsions.

- The most common adverse reactions (≥ 4.5%) with Triptodur use 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).

- The recommended dosage of Triptodur is 22.5 mg administered as a single intramuscular injection once every 24 weeks.

    - Triptodur must be administered under the supervision of a physician.
    - Triptodur treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician.
    - Response to Triptodur should be monitored with LH levels after a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels beginning 1 to 2 months following initiation of therapy, during therapy as necessary to confirm maintenance of efficacy, and with each subsequent dose.
    - Height should be measured every 3 to 6 months and bone age should be monitored periodically.

- Arbor Pharmaceuticals plans to launch Triptodur in the 4th quarter of 2017. Triptodur will be available as a kit containing one single dose vial of Triptodur 22.5 mg, one glass syringe prefilled with 2 mL of sterile water for injection, and two sterile 21 gauge, 1½" needles.