Fensolvi® (leuprolide acetate) – New drug approval

- On May 4, 2020, Tolmar Pharmaceuticals announced the FDA approval of Fensolvi (leuprolide acetate), for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

- Other injectable formulations of leuprolide acetate are also available generically and as branded Lupron Depot-PED® and Eligard®.

    - Generic leuprolide acetate and Eligard are approved for palliative treatment of advanced prostate cancer.
    - Lupron Depot-PED is approved for treatment of children with CPP.

- The efficacy of Fensolvi was established in an uncontrolled, open-label, single-arm study in 64 pediatric patients with CPP. Fensolvi reduced stimulated and basal gonadotropins to prepubertal levels.

    - Suppression of peak stimulated luteinizing hormone concentrations to < 4 IU/L was achieved in 87% of pediatric patients by month 6 and in 86% of patients by month 12.
    - Suppression of estradiol or testosterone concentration to prepubertal levels at the 6-month assessment was achieved in 97% and 100% of patients, respectively. Suppression of estradiol or testosterone was maintained at the 12-month assessment with 98% (55/56 females) and 50% (1/2 males) maintaining suppression.
    - Fensolvi arrested or reversed progression of clinical signs of puberty with reductions in growth velocity and bone age.

- Fensolvi is contraindicated in patients with:

    - Hypersensitivity to gonadotropin releasing hormone (GnRH), GnRH agonists or any of the components of Fensolvi. Anaphylactic reactions to synthetic GnRH or GnRH agonists have been reported
    - Pregnancy

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

- The most common adverse reactions (≥ 5%) with Fensolvi use were injection site pain, nasopharyngitis, pyrexia, headache, cough, abdominal pain, injection site erythema, nausea, constipation, vomiting, upper respiratory tract infection, bronchospasm, productive cough, and hot flush.

- The recommended dose of Fensolvi is 45 mg administered by subcutaneous injection once every six months.

    - Fensolvi treatment should be discontinued at the appropriate age of onset of puberty.
    - Fensolvi must be administered by a healthcare professional.

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- Tolmar Pharmaceuticals' launch plans for Fensolvi are pending. Fensolvi will be available as a 45 mg powder for suspension supplied in a kit.