Vigafyde™ (vigabatrin) – New orphan drug approval

- On June 17, 2024, Pyros Pharmaceuticals announced the FDA approval of Vigafyde (vigabatrin), as monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

- Vigafyde is a ready-to-use oral solution formulation of vigabatrin. Vigabatrin is available generically as a tablet and a powder for oral solution.

    - Vigabatrin powder for oral solution is approved for infantile spasms and refractory complex partial seizures.
    - Vigabatrin tablets are only approved for refractory complex partial seizures.

- The efficacy of Vigafyde is based upon a comparison of the compositional differences between vigabatrin powder for oral solution and Vigafyde oral solution.

- Vigafyde carries a boxed warning for permanent vision loss.

    - Vigafyde is available only through a restricted program called the Vigabatrin REMS.

- Additional warnings and precautions for Vigafyde include magnetic resonance imaging abnormalities in infants, neurotoxicity, withdrawal of antiepileptic drugs, anemia, somnolence and fatigue, peripheral neuropathy, weight gain, edema, and suicidal behavior and ideation with unapproved use in adolescents and adults.

- The most common adverse reactions (> 5% and greater than on placebo) with Vigafyde use for infantile spasms were somnolence, bronchitis, ear infection, and acute otitis media.

- The recommended initial daily dosing of Vigafyde is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily); subsequent dosing can be titrated by 25 mg/kg/day to 50 mg/kg/day increments every 3 days, up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).

    - In patients with infantile spasms, Vigafyde should be withdrawn if a substantial clinical benefit is not observed within 2 to 4 weeks. If, in the clinical judgment of the prescriber, evidence of treatment failure becomes obvious earlier than 2 to 4 weeks, treatment should be discontinued at that time.
    - As compared to other vigabatrin products, Vigafyde is a concentrated solution that requires a smaller volume than other vigabatrin products to obtain the same dosage (ie, Vigafyde is 100 mg/mL and currently available vigabatrin for oral solution products have a final concentration of 50 mg/mL).

- Pyros Pharmaceuticals plans to launch Vigafyde in the second half of 2024. Vigafyde will be available as a 100 mg/mL oral solution.