Fycompa® (perampanel) – Expanded indication

- On September 28, 2018, Eisai announced the FDA approval of Fycompa (perampanel), for the treatment of partial-onset seizures (POS) with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.
    - Previously, Fycompa was approved for use in patients ≥ 12 years of age for this indication.
- Fycompa is also indicated as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.
- The approval of Fycompa for the treatment of POS in adolescents and children 4 to < 12 years is supported by evidence extrapolated from adequate and well-controlled studies of Fycompa in patients ≥ 12 years of age, pharmacokinetic data from adult and pediatric patients, and safety data in 225 pediatric patients 4 years to less than < 12 years of age.
- Fycompa carries a boxed warning for serious psychiatric and behavioral reactions.
- The recommended starting dose of Fycompa is 2 mg once daily taken orally at bedtime for both indications.
    - For POS, the recommended maintenance dose range is 8 mg to 12 mg once daily, although some patients may respond to a dose of 4 mg daily. A dose of 12 mg once daily resulted in somewhat greater reductions in seizure rates than the dose of 8 mg once daily, but with a substantial increase in adverse reactions.