Fycompa® (perampanel) – Expanded indication

- On July 26, 2017, Eisai announced the FDA approval of Fycompa (perampanel) as monotherapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older.
    - Previously, Fycompa was only approved for use as adjunctive therapy in partial-onset seizures.
    - Fycompa is also approved as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.
- Fycompa's approval for monotherapy use was extrapolated based on comparable exposures to those obtained with adjunctive use in clinical trials for the treatment of partial-onset seizures.
- Fycompa carries a boxed warning for serious psychiatric and behavioral reactions.
- The recommended starting dose of Fycompa for monotherapy or adjunctive therapy for partial onset seizures is 2 mg once daily taken orally at bedtime.
    - The dose may be increased by increments of 2 mg once daily based on individual clinical response and tolerability, no more frequently than at weekly intervals.
    - 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.
    - Refer to the prescribing information for dosing recommendations for tonic-clonic seizures.