Latuda® (lurasidone) – Expanded indication

- On March 6, 2018, Sunovion announced the FDA approval of Latuda (lurasidone) for monotherapy treatment of pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression).
    - Previously, Latuda was only approved for monotherapy treatment of adults with major depressive episode associated with bipolar I disorder.
    - Latuda is also indicted for the treatment of adult and adolescent patients (13 to 17 years) with schizophrenia and as adjunctive treatment with lithium or valproate [eg, Depakote® (divalproex sodium)] in adult patients with major depressive episode associated with bipolar I disorder.
- The efficacy of Latuda for the expanded indication was established in a placebo-controlled study of 343 pediatric patients with major depressive episode associated with bipolar I disorder. The primary endpoint was the change from baseline in Children's Depression Rating Scale, Revised (CDRS-R) score at week 6.
    - Latuda was superior to placebo in reduction of CDRS-R score (placebo subtracted difference in CDRS-R score: -5.7; 95% CI: -8.4, -3.0).
- Latuda carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis, and suicidal thoughts and behaviors.
- The most common adverse reactions (≥ 5% and at least twice the rate for placebo) with Latuda use for pediatric patients with bipolar depression were nausea, weight increase, and insomnia.
- The recommended starting dose of Latuda for monotherapy treatment of bipolar depression in pediatric and adult patients is 20 mg orally once daily. Initial dose titration is not required. The daily dose may be increased up to 120 mg for adults and 80 mg for children.
- Refer to the Latuda prescribing information for dosing recommendations for all other indications.