Vraylar™ (cariprazine) – Expanded indication

- On November 13, 2017, Allergan announced the FDA approval of Vraylar (cariprazine) for the maintenance treatment of adults with schizophrenia.
    - Vraylar is also approved in adults for the acute treatment of schizophrenia and acute treatment of manic or mixed episodes of bipolar I disorder.
- Without maintenance treatment, an estimated 60% – 70% of schizophrenia patients relapse within 1 year.
- The efficacy of Vraylar in the maintenance treatment of schizophrenia was demonstrated in a withdrawal trial involving 200 adult patients who were clinically stable following 20 weeks of cariprazine. Patients were randomized either to continue Vraylar or switch to placebo for up to 72 weeks or until a relapse occurred. The primary endpoint was the time to relapse.
    - The time to relapse was statistically significantly longer in the Vraylar-treated group vs. the placebo-treated group ($p = 0.0010$).
    - In addition, relapse occurred in nearly twice as many placebo-treated patients (49.5%) vs. Vraylar-treated (29.7%) patients.
- Vraylar carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis.
- The dosing range for Vraylar in schizophrenia is 1.5 mg to 6 mg orally once daily. The recommended starting dosage is 1.5 mg.
    - The maximum recommended dose is 6 mg daily. Doses > 6 mg per day do not confer significant benefit but increase the risk of dose-related adverse reactions.
    - Because of the long half-life of Vraylar and its active metabolites, changes in dose will not be fully reflected in plasma for several weeks.
    - For the dosage of Vraylar in manic or mixed episodes of bipolar I disorder, please refer to the drug label.