## Saphris® (asenapine) – Expanded Indication

- On January 13, 2017, the FDA approved Allergan's Saphris (asenapine) for maintenance monotherapy treatment of bipolar I disorder in adults.

- Saphris is also FDA approved for:

    - Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age with bipolar I disorder
    - Adjunctive treatment to lithium or valproate [eg, Depakote® (divalproex)] in adults with bipolar I disorder
    - Schizophrenia in adults

- Efficacy of Saphris for the maintenance monotherapy treatment of bipolar I disorder was demonstrated in a clinical study of 252 patients randomized to treatment with Saphris or placebo for a period of 12 to 16 weeks. All patients were initially administered 5 or 10 mg twice daily, and the option to titrate down to 5 mg twice daily was provided based on tolerability.

    - Saphris was statistically superior to placebo in time to relapse as measured by bipolar disorder symptoms; requirement or initiation of an antipsychotic, antidepressant, or mood-stabilizing agent; requirement or initiation of psychiatric hospitalization; and investigator judgment to discontinue the study due to a mood event.

- The Saphris drug label was also updated with a dosing recommendation for bipolar I maintenance monotherapy.

    - Patients should continue on the Saphris dose that the patient received during stabilization (5 mg - 10 mg twice daily). Depending on the clinical response and tolerability in the individual patient, a dose of 10 mg twice daily can be decreased to 5 mg twice daily.
    - Refer to the Saphris drug label for the recommended doses for all other indications.

- Saphris carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis.