TrendsRx® Approval Alert

Saphris® (asenapine)*

Drug Approval

- Saphris (asenapine, Schering-Plough Corporation) received FDA approval on August 14, 2009 for
  - the acute treatment of schizophrenia in adults; and
  - the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
- Phase III studies have shown that patients who received asenapine 5 mg twice daily achieved significantly greater reductions in symptoms of schizophrenia than with placebo.
- A Phase III extension study showed that asenapine was significantly more effective at reducing predominant, persistent negative symptoms of schizophrenia after one year than olanzapine.
- Studies of acute bipolar I disorder showed that asenapine 10 mg twice daily significantly reduced bipolar mania symptoms compared to placebo.
- Saphris is not approved for the treatment of patients with dementia-related psychosis.

Mechanism of Action

- The exact mechanism by which asenapine works is unknown.
- The medicine appears to work by blocking the activity of dopamine and serotonin neurotransmitters in the brain.
- Hyperactivity of these neurotransmitters may be responsible for the development of psychotic symptoms.

Adverse Effects

- Common side effects experienced by patients taking Saphris in clinical trials:
  - Patients with schizophrenia: dose-related akathisia (the inability to sit still or remain motionless), extrapyramidal symptoms other than akathisia, oral hypoesthesia (decreased oral sensitivity), and somnolence
  - Patients with bipolar disorder: somnolence, dizziness, extrapyramidal symptoms other than akathisia, and weight gain
- Saphris carries a Boxed Warning stating that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

Available Dosage Form and Strengths

- Sublingual tablets: 5 mg and 10 mg

Anticipated Launch Date†

- Fourth quarter 2009

Selected Medications Available in the Class

- Generics (various manufacturers): risperidone
- Brands: Risperdal® (risperidone, Ortho-McNeil-Janssen Pharmaceuticals, Inc.); Zyprexa® (olanzepine, Eli Lilly); Seroquel® (quetiapine, AstraZeneca Pharmaceuticals LP); Geodon® (ziprasidone, Pfizer Inc.); Abilify® (aripiprazole, Otsuka America Pharmaceutical, Inc.)

Background

- An estimated 1% of Americans suffer from schizophrenia. The disorder occurs equally across gender and ethnic groups and symptoms usually emerge in early adulthood.
- Patients with schizophrenia usually present with a range of positive and negative symptoms and cognitive impairments. Positive symptoms that indicate psychosis include auditory and visual hallucinations, delusions and thought disorganization. Negative symptoms include a loss of verbal and emotional expression and a lack of personal motivation or social drive.
- Because schizophrenia includes both the presence of psychotic symptoms and the absence of normal expression, many patients try several antipsychotic medications before responding to one.
- Bipolar disorder is also known as manic-depressive illness. It is characterized by unusual shifts in mood and activity levels, namely, depression alternating with exhuberance, restlessness, impulsive behaviors, and difficulty concentrating.
- Bipolar disorder often develops in the late teens or early adulthood.
- Long-term treatment is necessary to control the symptoms of this disorder. Mood-stabilizing medications are recommended for first-line and maintenance therapy. Frequently, atypical antipsychotics are added to treat acute manifestations of mania and other behavioral disturbances.

Budget Impact‡

- National brand utilization of the selected medications available in the class:
  - Risperdal: $783 Million
  - risperidone: $1.6 Billion
  - Seroquel: $4.3 Billion
  - Abilify: $3.6 Billion
  - Zyprexa: $2.5 Billion
  - Geodon: $1 Billion
- CVS Caremark anticipates moderate utilization of Saphris. Physicians may consider this medication for patients with persistent negative symptoms of schizophrenia or for patients who are at risk of metabolic syndrome.
- CVS Caremark will continue to monitor the long-term budget effects of Saphris's introduction into the pharmaceutical marketplace.

CVS Caremark Response

- CVS Caremark recognizes the unique needs of plan participants with schizophrenia and bipolar disorder.
- Subsequent to FDA approval, Saphris will be considered for inclusion into the following clinical solution: Adherence to Drug Therapy
- CVS Caremark will continue to monitor Saphris to determine if any additional clinical solutions are needed.
- For more information, call your CVS Caremark account representative.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only and is based in part on information derived from third parties.

* This information is current as of August 25, 2009. The information presented is subject to change and is represented to the best of our knowledge at the time of this publication.

† A launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes. This medication is expected to be available in pharmacies within a few days of launch.

‡ Industry sales data from the last 12 months

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

References

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