Vanda Receives FDA Letter Regarding Corporate Webpage

November 1, 2018

WASHINGTON, Nov. 1, 2018 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that it received a letter from the U.S. Food and Drug Administration (FDA) Office of Prescription Drug Promotion on October 22, 2018 regarding the content on a single page of its corporate website. Vanda modified the content of this webpage on October 23, 2018. The webpage is shown here in its prior and current forms.

To access the FDA letter, which was published on October 31, 2018, please refer to the FDA's website here. Vanda intends to meet with the FDA to better understand the reasoning of the letter.

About Vanda

Vanda is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

About Fanapt®

Fanapt® is an atypical antipsychotic approved for the treatment of schizophrenia in adults.

Fanapt® is a serotonin (5-HT2) receptor and dopamine receptor antagonist.

Fanapt® received US Market Approval by the FDA in May 2009. In addition, Vanda currently has Fanapt® distribution partnerships in Israel and Mexico. In 2012, Fanapt® was approved for marketing in Israel and Argentina.

Indication and Important Safety Information About Fanapt®

Indication

Fanapt® (iloperidone) tablets are indicated for the treatment of schizophrenia in adults.

Deciding to look at alternate medications is something your doctor may do. Your doctor needs to consider that Fanapt® may change your heart rhythm (meaning there is more time between heartbeats). When taking other drugs that may cause this same change in heart rhythm, you are at a higher risk of a serious, even life-threatening medical issue (torsade de pointes), which may result in sudden death. In many cases, your doctor may prescribe another medication like Fanapt® first.

Fanapt® needs to be taken as directed starting at a low dose and slowly increasing the strength. This may delay the control of symptoms in the first 1 to 2 weeks of treatment.

Important Safety Information

BOXED WARNING: Elderly patients with psychosis related to dementia (having lost touch with reality due to memory loss and experiencing a decline in day-to-day functioning) who are treated with antipsychotic medications are at an increased risk of death compared to patients treated with a placebo. Fanapt® is not approved for the treatment of people with dementia-related psychosis.

Patients should not use Fanapt® if they have a known allergy to Fanapt® or its ingredients. Allergic reactions, including anaphylaxis, rapid swelling of the skin (angioedema), and other symptoms of allergy (eg, throat tightness; swelling of the throat, face, lips, mouth and tongue; hives; rash; and itching) have been reported.

An increased risk of stroke (including death) has been reported in clinical studies of elderly people with dementia-related psychosis. **Fanapt® is not approved for the treatment of people with dementia-related psychosis.**

Fanapt® may change your heart rhythm (mean there is more time between heartbeats). Heart rhythm changes have occurred in patients taking Fanapt® and are a risk factor for serious, even life-threatening medical issues. You should tell your doctor if you have or have had heart problems. Contact your doctor right away if you feel faint or have unpleasant feelings of irregular or forceful heartbeats as any of these feelings could be a sign of a rare, but serious side effect that could be fatal. You should not use Fanapt® with other drugs that are known to cause these same heart rhythm issues.

Tell your doctor if you have some or all of the following symptoms; Very high fever, rigid muscles, shaking, confusion, sweating or increased heart rate and blood pressure. These may be signs of a condition called neuroleptic malignant syndrome (NMS), a rare but serious side effect that could be fatal. This may happen with Fanapt® or drugs like it.

Abnormal or uncontrollable movements of the face, tongue, or other parts of the body may be signs of a serious condition called tardive dyskinesia (TD), which could become permanent. The chance of this condition going away decreases, depending on how long and how much medication has been taken. Tell your doctor if you have body movements you can't control.

Fanapt® and medicines like it have been associated with metabolic changes (high blood sugar, high cholesterol and triglycerides, and weight gain) that can increase cardiovascular/cerebrovascular risks.

Tell your doctor if you have diabetes or risk factors for diabetes (for example, obesity, family history of diabetes), or if you have unexpected increases in thirst, urination, or hunger. If so, your blood sugar should be monitored. Increases in blood sugar levels (hyperglycemia), which in some cases can be serious and associated with coma or death, have been reported in patients taking Fanapt® and medicines like it.

Changes in cholesterol and triglycerides have been seen in patients taking Fanapt® and medicines like it. Check with your doctor while on treatment.

Some patients may gain weight while taking Fanapt®. Your doctor should check your weight regularly.

Tell your doctor about any medical conditions that you have including problems with your liver. Fanapt® is not recommended for patients with severe liver problems.

Tell your doctor if you have a history of or have a condition that may increase your risk for seizures before you begin taking Fanapt®.

Light-headedness or faintness caused by a sudden change in heart rate and blood pressure when rising quickly from a sitting or lying position (orthostatic hypotension) has been reported with Fanapt®. This condition is most common when you start therapy, when re-starting treatment, or when the dose of Fanapt® is increased. You should consult your doctor if you have or have had heart problems or conditions that lead to these sudden changes since Fanapt® should be used with caution in these patients.

Fanapt® may increase the risk of falls, which could cause fractures or other injuries.

Decreases in infection-fighting white blood cells (WBCs) have been reported in some patients taking antipsychotic agents. Patients with a preexisting history of low WBC count or who have experienced a low WBC count due to drug therapy should have their blood tested and monitored during the first few months of therapy. Some (including fatal) cases of agranulocytosis, a serious decrease in specific types of WBCs called neutrophils or granulocytes, have been reported in drugs like Fanapt®.

Fanapt® can increase the level of the hormone prolactin. Tell your doctor if you experience breast enlargement, breast pain, or breast discharge, abnormal menstrual cycles in females or impotence in males. If elevated levels of prolactin persist, this may lead to bone loss.

Medicines like Fanapt® can impact your body's ability to reduce your body temperature. You should avoid overheating and dehydration.

Fanapt® and medicines like it have been associated with swallowing problems (dysphagia). If you have or have had swallowing problems, you should tell your doctor.

As with many conditions that affect the way you think or feel, thoughts of suicide may occur. If you get these feelings, seek help immediately from your doctor, or local emergency room.

For males, in the rare event you have a painful or prolonged erection (priapism), lasting 4 or more hours, stop using Fanapt® and seek immediate medical attention.

Fanapt® and medicines like it can affect your judgment, thinking, or motor skills. You should not drive or operate hazardous machinery, including automobiles, until you know how Fanapt® affects you.

The most common side effects for Fanapt® versus placebo were dizziness, dry mouth, feeling unusually tired or sleepy, stuffy nose, feeling faint/light-headed when standing quickly, racing heartbeat, and weight gain. The average weight gain in clinical studies lasting 4-6 weeks was 5 lbs. If you experience any of these symptoms, talk with your doctor.

When taking Fanapt®, you should avoid drinking alcohol, and you should not breastfeed. You should notify your doctor if you become pregnant or intend to become pregnant while taking Fanapt®. Tell your doctor about all prescription and nonprescription medicines and supplements you are taking. Some medications may interact with Fanapt®.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Full U.S. prescribing information, including box warnings and safety information, can be found at: www.fanapt.com.

About Hetlioz®

HETLIOZ® is a melatonin receptor agonist. HETLIOZ® received U.S. Food and Drug Administration approval in January 2014 for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). HETLIOZ® received European Commission approval in July 2015 for the treatment of Non-24 in totally blind adults in the European Union.

Non-24 is a chronic, circadian rhythm disorder resulting from the misalignment of the endogenous master body clock to the 24-hour day, disrupting the sleep-wake cycle. The sleep disturbance causes significant distress or impairment in social, occupational and other important areas of functioning. Non-24 affects the majority of totally blind individuals and it is estimated that approximately 80,000 Americans have the disorder.

For more information about HETLIOZ® call 1-844-HETLIOZ (1-844-438-5469).

Indication and Important Safety Information About HETLIOZ®

Indication

HETLIOZ® is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Important Safety Information

HETLIOZ® may cause somnolence: After taking HETLIOZ®, patients should limit their activity to preparing for going to bed, because HETLIOZ® can impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ® than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ® is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ® should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ®, and a greater risk of adverse reactions. HETLIOZ® should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ®, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ® in pregnant women. Based on animal data, HETLIOZ® may cause fetal harm. HETLIOZ® should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ® is administered to a nursing woman.

HETLIOZ® has not been studied in patients with severe hepatic impairment and is not recommended in these patients.

Safety and effectiveness of HETLIOZ® in pediatric patients have not been established.

Full HETLIOZ® Prescribing Information can be found at: www.hetlioz.com.

HETLIOZ® is a registered trademark of Vanda Pharmaceuticals Inc.

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