Endo Begins Shipment of Generic SEROQUEL XR®

November 1, 2016

DUBLIN, Nov. 1, 2016 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) announced today that one of its operating companies, Par Pharmaceutical, has begun shipping four dosage strengths (50 mg, 150 mg, 200 mg and 300 mg) of quetiapine fumarate extended release (ER) tablets, the generic version of AstraZeneca's SEROQUEL XR®. As marketer and distributor of the product, Par will have 180 days of marketing exclusivity for these four strengths and will share profits with its partners Handa Pharmaceuticals, Inc. and Deerfield Generics, L.P., a portfolio company of Deerfield Management Company, L.P.

SEROQUEL XR® is a once-daily tablet approved in adults for add-on treatment to an antidepressant for patients with major depressive disorder (MDD) who did not have an adequate response to antidepressant therapy; acute depressive episodes in bipolar disorder; acute manic or mixed episodes in bipolar disorder alone or with lithium or divalproex; long-term treatment of bipolar disorder with lithium or divalproex; and schizophrenia.

According to IMS Health data, U.S. sales of SEROQUEL XR® for the four dosage strengths to be marketed by Par are approximately $911 million for the 12 months ended September 30, 2016.

Important Safety Information

Elderly patients with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) treated with this type of medicine are at an increased risk of death, compared to placebo (sugar pill). SEROQUEL XR® is not approved for treating these patients.

Antidepressants have increased the risk of suicidal thoughts and actions in some children, teenagers, and young adults. Patients of all ages starting treatment should be watched closely for worsening of depression, suicidal thoughts or actions, unusual changes in behavior, agitation, and irritability. Patients, families, and caregivers should pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. These symptoms should be reported immediately to the doctor. SEROQUEL XR® is not approved for children under the age of 10 years.

- Do not take SEROQUEL XR® if you are allergic to quetiapine fumarate or any of the ingredients in SEROQUEL XR®
- Stroke that can lead to death can happen in elderly people with dementia who take medicines like SEROQUEL XR®
- Stop SEROQUEL XR® and call your doctor right away if you have some or all of the following symptoms: high fever; excessive sweating; stiff muscles; confusion; changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare, but very serious and potentially fatal, side effect called neuroleptic malignant syndrome (NMS)
- High blood sugar and diabetes have been reported with SEROQUEL XR® and medicines like it. If you have diabetes or risk factors such as obesity or a family history of diabetes, your doctor should check your blood sugar before you start taking SEROQUEL XR® and also during therapy. If you develop symptoms of high blood sugar or diabetes, such as excessive thirst or hunger, increased urination, or weakness, contact your doctor. Complications from diabetes can be serious and even life threatening
- Increases in triglycerides and in LDL (bad) cholesterol and decreases in HDL (good) cholesterol have been reported with SEROQUEL XR®. Your doctor should check your cholesterol levels before you start SEROQUEL XR® and during therapy
- Weight gain has been reported with SEROQUEL XR®. Your doctor should check your weight regularly
- Tell your doctor about any movements you cannot control in your face, tongue, or other body parts, as they may be signs of a serious condition called tardive dyskinesia (TD). TD may not go away, even if you stop taking SEROQUEL XR®. TD may also start after you stop taking SEROQUEL XR®
- Other risks include feeling dizzy or lightheaded upon standing, decreases in white blood cells (which can be fatal), or trouble swallowing. Tell your doctor if you experience any of these
- Before starting treatment, tell your doctor about all prescription and nonprescription medicines you are taking. Also tell your doctor if you have or have had low white blood cell count, seizures, abnormal thyroid tests, high prolactin levels, heart or liver problems, or cataracts. An eye exam for cataracts is recommended at the beginning of treatment and every 6 months thereafter
- Since drowsiness has been reported with SEROQUEL XR®, you should not participate in activities such as driving or operating machinery until you know that you can do so safely. Avoid becoming overheated or dehydrated while taking SEROQUEL XR®. Do not drink alcohol while taking SEROQUEL XR®
- Tell your doctor if you are pregnant or intend to become pregnant. Avoid breast-feeding while taking SEROQUEL XR®
- The most common side effects are drowsiness, dry mouth, constipation, dizziness, increased appetite, upset stomach, weight gain, fatigue, disturbance in speech and language, and stuffy nose
- Do not stop taking SEROQUEL XR® without talking to your doctor. Stopping SEROQUEL XR® suddenly may cause side effects

This is not a complete summary of safety information. Please discuss the full Prescribing Information with your health care provider.

About Endo International plc

Endo International plc (NASDAQ: ENDP) (TSX: ENL) is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded and generic pharmaceutical products as well as over-the-counter medications through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR), and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo does not assume any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/endo-begins-shipment-of-generic-seroquel-xr-300354795.html

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