PRESS RELEASE

Issued: Monday, May 11, 2009, Research Triangle Park, NC

FDA approves Lamictal® ODT™ Orally Disintegrating Tablets

- Easy-to-swallow formulation provides important new alternative for patients

GlaxoSmithKline (NYSE: GSK) announced today that the U.S. Food and Drug Administration (FDA) has approved Lamictal® ODT™ (lamotrigine) Orally Disintegrating Tablets. *Lamictal ODT* uses a novel drug-delivery formulation to provide *Lamictal* in a tablet that has a pleasant taste and disintegrates on the tongue.

One factor physicians should consider when treating chronic disorders is whether patients can swallow the medications they need. In one large survey study, 23 percent of patients in a general practice setting reported difficulty swallowing.

"Patients with epilepsy or bipolar disorder can have difficulty swallowing tablets. Unfortunately, this problem may go unrecognized, because many patients don't discuss this issue with their healthcare providers," said Daniel Lieberman, M.D., associate professor and clinical director of the George Washington University Department of Psychiatry and Behavioral Sciences." Orally disintegrating tablets, like *Lamictal ODT*, offer an option for patients who have difficulty swallowing tablets."

Lamictal ODT was approved based on the demonstrated bioequivalence of *Lamictal ODT* to *Lamictal* Tablets and was developed in collaboration with Eurand N.V. (NASDAQ: EURX). *Lamictal ODT* is the only antiepileptic treatment that is available in an orally disintegrating formulation.

Lamictal ODT is indicated for the long-term treatment of Bipolar I Disorder to lengthen the time between mood episodes in people 18 years or older who have been treated for mood episodes with other medicine. It is not known if *Lamictal ODT* is safe or effective in children or teenagers under the age of 18 with mood disorders such as bipolar disorder or depression. *Lamictal ODT* is also used together with other medicines to treat certain types of seizures (partial seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in people two years or older or alone when changing from other medicines used to treat partial seizures in people 16 years or older. It is not known if *Lamictal ODT* is safe or effective when used alone as the first treatment of seizures in adults.

Lamictal ODT will be available in 25 mg, 50 mg, 100 mg, and 200 mg strengths and is expected to be available in pharmacies in June. For patients switching from *Lamictal* Tablets to the ODT formulation, the recommended dose of *Lamictal ODT* matches the dose of *Lamictal* Tablets. For patients new to *Lamictal*, Patient Titration Kits containing five weeks of treatment will be available. *Lamictal ODT* will also be available in four Maintenance Packs, one Pack for each dose strength.

These Packs each contain 30 tablets and are designed to help make it easy for patients to keep up with their daily dose.

Safety Information

Prescription *Lamictal ODT Tablets* are not for everyone. *Lamictal ODT* is another form of *Lamictal. Lamictal* may cause a serious skin rash that may cause the patient to be hospitalized or to stop *Lamictal*; it may rarely cause death. There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when the patient begins taking *Lamictal,* within the first two to eight weeks of treatment. But it can happen in people who have taken *Lamictal* for any period of time. Children between two to 16 years of age have a higher chance of getting this serious skin reaction while taking *Lamictal.*

The risk of getting a rash is higher if taking *Lamictal* while taking valproate (Depakene® (valproic acid) or Depakote® (divalproex sodium)), taking a higher starting dose of *Lamictal* than a healthcare provider prescribed or increasing the dose of *Lamictal* faster than prescribed.

Lamictal can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. The patient may or may not have a rash with these types of reactions.

The patient should call their healthcare provider right away if they have any of the following: a skin rash, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of the lips or tongue, yellowing of the skin or eyes, unusual bruising or bleeding, severe fatigue or weakness, severe muscle pain or frequent infections. These symptoms may be the first signs of a serious reaction. A healthcare provider should examine the patient to decide if they should continue taking *Lamictal.*

Antiepileptic drugs, including *Lamictal,* increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any antiepileptic drug for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

Patients, their caregivers, and families should be informed that antiepileptic drugs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Medication errors involving *Lamictal* have occurred. In particular, the name *Lamictal* or lamotrigine can be confused with the names of other commonly used medications. Medication errors may also occur between the different formulations of *Lamictal.* To reduce the potential of medication errors, healthcare professionals should write and say *Lamictal* clearly. Depictions of the *Lamictal* Tablets, Chewable Dispersible Tablets, and Orally Disintegrating Tablets can be found in the Medication Guide that accompanies the product to highlight the distinctive markings, colors, and shapes that serve to identify the different presentations of the drug and thus may help reduce the risk of medication errors. To avoid the medication error of using the wrong drug or formulation, patients should be strongly advised to visually inspect their tablets to verify that they are *Lamictal,* as well as the correct formulation of *Lamictal,* each time they fill their prescription.

Patients should not take *Lamictal* or *Lamictal ODT* if they have had an allergic reaction to lamotrigine or to any of the inactive ingredients.

Common side effects include dizziness, headache, blurred or double vision, lack of coordination, sleepiness, nausea, vomiting, insomnia, tremor, rash, fever, abdominal pain, back pain, tiredness, and dry mouth. Patients should tell their healthcare provider about any side effect that bothers them or does not go away; patients should tell their healthcare provider if they have any changes in their menstrual pattern, such as breakthrough bleeding, while taking *Lamictal* and birth control pills. These are not all the possible side effects of *Lamictal.*

*Depakene and Depakote are registered trademarks of Abbott Laboratories

For full prescribing information including Boxed Warning, please visit www.lamictal.com and click on "Complete Prescribing Information for *Lamictal*" to view prescribing information for all formulations, including *Lamictal ODT*.

Eurand is a specialty pharmaceutical company that develops, manufactures and commercializes enhanced pharmaceutical and biopharmaceutical products based on its proprietary drug formulation technologies. Eurand has had four partnered products approved by the FDA since 2001 and has a pipeline of product candidates in development for itself and its collaboration partners. Eurand's technology platforms include bioavailability enhancement of poorly soluble drugs, customized drug release profiles, taste-masking orally disintegrating tablet (ODT) formulations, and drug conjugation. Eurand is a global company with facilities in the U.S. and Europe. For more information, visit Eurand's website at www.eurand.com.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

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Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2008.

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