FOR IMMEDIATE RELEASE

Lundbeck’s SABRIL® (vigabatrin) Now Approved by U.S. FDA as an Adjunctive Treatment Option for Children 10 and older with Refractory Complex Partial Seizures

Deerfield, Ill., October 28, 2013 – The U.S. Food and Drug Administration (FDA) approved SABRIL (vigabatrin) as add-on therapy for the treatment of refractory complex partial seizures (CPS) in children 10 years of age and older who have inadequately responded to several other treatments and if the possible benefit outweighs the risk of vision loss.¹ This approval expands upon the age range of SABRIL’s previous indication as adjunctive therapy for adults with refractory CPS. SABRIL is not indicated as a first-line agent for refractory CPS.

Of the more than two million Americans affected by epilepsy,² approximately 35 percent have CPS, which originates from a single region of the brain and can cause impaired consciousness.³ Approximately 30 to 36 percent of those with CPS continue to have seizures despite trying multiple therapies, and are considered to have refractory CPS.⁴,⁵,⁶

“It is crucially important for people with challenging seizures like refractory CPS to not give up and continue striving for improved seizure management, and this expanded Sabril indication provides another consideration for the treatment of those ten and older with refractory CPS,” said Philip Gattone, president and CEO of the Epilepsy Foundation. “We encourage people living with such challenging seizures and their loved ones to have ongoing conversations with their doctor about available options to help manage this intractable seizure disorder.”

When SABRIL was first approved in 2009, a patient registry was established to collect information on all patients who are prescribed SABRIL. To date, more than 5,600 patients have been treated with SABRIL, a substantial number of whom have been treated for refractory CPS.⁷ In evaluating whether to start SABRIL, doctors, patients and their caregivers work together to assess the risk of permanent vision loss versus the benefit of seizure reduction. There are other serious risks associated with SABRIL. Please see the important safety information below for more details.

“With so many children still having seizures due to refractory CPS, we are very pleased that the FDA has approved SABRIL for patients 10 and older who may benefit from a new add-on treatment option,” said Amy Magro, Director of Epilepsy Marketing at Lundbeck. “For those caring for a child as young as 10, we hope this new indication provides encouragement to speak with their child’s doctor about the risks and potential benefits of adding SABRIL for refractory CPS.”

In addition to its refractory CPS indication, SABRIL is approved for use in babies one month to two years of age with infantile spasms if the possible benefit outweighs the potential risk of vision loss.

For more information, please visit www.SABRIL.net.

About SABRIL® (vigabatrin)¹
SABRIL is a prescription oral antiepileptic drug developed in the United States by Lundbeck. SABRIL is available in 500-mg tablets or 500-mg packets of powder for oral suspension. Because of the risk of permanent vision loss, SABRIL is available only through a restricted program under a REMS called the SHARE Program. (1-888-45-SHARE).

Use
SABRIL (vigabatrin) is a prescription medicine used with other treatments in adults and children 10 years of age and older with refractory complex partial seizures (CPS), who have not responded well enough to several other treatments, and if the possible benefits outweigh the risk of vision loss. SABRIL should not be the first medicine used to treat CPS.
SABRIL (vigabatrin) is a prescription medicine used in babies, 1 month to 2 years old, with infantile spasms (IS), if the possible benefits outweigh the possible risk of vision loss.

Important Safety Information

**WARNING: VISION LOSS**

| See Medication Guide and full Prescribing Information for complete information |

In all people who take SABRIL:
- You are at risk for vision loss with any amount of SABRIL
- Your risk of vision loss may be higher the more SABRIL you take daily and the longer you take it
- It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting SABRIL or any time during treatment. It may even happen after treatment has stopped.

- SABRIL can permanently damage the vision of anyone who takes it. The most noticeable loss is in the ability to see to the side when looking straight ahead (peripheral vision). If this happens, it will not get better. People who take SABRIL do not lose all of their vision, but some people can have severe loss and may only be able to see things straight in front of them (sometimes called “tunnel vision”), and they may also have blurry vision.

- Tell your healthcare provider right away if you (or your child): might not be seeing as well as before starting SABRIL; start to trip, bump into things, or are more clumsy than usual; are surprised by people or things coming in front of you that seem to come out of nowhere; or if your baby is acting differently than normal. These changes can mean that vision damage has occurred.

- Your healthcare provider will test your (or your child’s) vision before or within 4 weeks after starting SABRIL, and at least every 3 months during treatment until SABRIL is stopped. Vision should also be tested about 3 to 6 months after SABRIL is stopped. You (or your child) may not be able to be tested in certain situations. It is difficult to test vision in babies, but to the extent possible, all babies should have their vision tested. Your healthcare provider will determine if testing can be done. Regular vision testing is important because damage can happen before any changes are noticed.

- Vision tests cannot prevent the vision damage that can happen with SABRIL, but they do allow SABRIL to be stopped if vision has gotten worse, which usually will lessen further damage. Even these regular vision tests may not show vision damage before it is serious and permanent. Parents, caregivers, and healthcare providers may not recognize the symptoms, or find vision loss in babies, until it is severe.

- If vision tests are not done regularly, your healthcare provider may stop prescribing SABRIL for you (or your child). Some people are not able to complete vision testing. If vision testing cannot be done, your healthcare provider may continue prescribing SABRIL, but will not be able to watch for any vision loss.

- Brain pictures taken by magnetic resonance imaging (MRI) show changes in some babies after they are given SABRIL. It is not known if these changes are harmful.

- Like other antiepileptic drugs, SABRIL may cause suicidal thoughts and actions in some people. Call a healthcare provider right away if you (or your child) have any symptoms, especially sudden changes in mood, behaviors, thoughts or feelings, and especially if they are new, worse, or worry you.

- Do not stop SABRIL without first talking to a healthcare provider. Stopping SABRIL suddenly can cause seizures that will not stop.
• SABRIL can cause serious side effects such as low red blood cell counts, sleepiness and tiredness, nerve problems, weight gain, and edema. Because SABRIL causes sleepiness and tiredness, do not drive, operate machinery, or perform hazardous tasks, unless it is decided that these things can be done safely. SABRIL may make certain types of seizures worse. Tell your healthcare provider right away if seizures get worse.

• Before starting SABRIL, tell your doctor about all of your (or your child’s) medical conditions including depression, mood problems, suicidal thoughts or behavior, any allergic reaction to SABRIL, vision problems, kidney problems, low red blood cell counts, and any nervous or mental illness. Tell your doctor about all the medicines you (or your child) take.

• If you are breastfeeding or plan to breastfeed, SABRIL can pass into breast milk and may harm your baby. If you are pregnant or plan to become pregnant, it is not known if SABRIL will harm your unborn baby. You and your healthcare provider will have to decide if you should take SABRIL while you are pregnant.

• The most common side effects of SABRIL in adults include: problems walking or feeling uncoordinated, feeling dizzy, shaking (tremor), joint pain, memory problems and not thinking clearly, eye problems like blurry vision, double vision, and eye movements that cannot be controlled. The most common side effects of SABRIL in children 10 to 16 years of age include weight gain, upper respiratory tract infection, tiredness, and aggression. Also expect side effects like those seen in adults.

• The most common side effects of SABRIL in babies include: sleepiness—some babies may have a harder time suckling and feeding or may be irritable, swelling in the bronchial tubes (bronchitis), ear infection, and irritability.

• Tell your healthcare provider if you or your child has any side effect that bothers you or that does not go away. These are not all of the possible side effects of SABRIL. For more information, ask your healthcare provider or pharmacist.

Please see SABRIL Medication Guide, full Prescribing Information including Boxed Warning, and Instructions for Use; go to www.sabril.net, or call toll-free 1-888-45-SHARE (1-888-457-4273).

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.

About Lundbeck in the U.S.

A wholly owned subsidiary of H. Lundbeck A/S of Denmark, Lundbeck in the United States is headquartered in Deerfield, Illinois, and is committed to providing innovative specialty therapies that fulfill unmet medical needs of people with central nervous system (CNS) disorders, including several therapies for people with challenging seizure disorders.

With a special commitment to the epilepsy community, Lundbeck actively supports and participates in hundreds of community-based initiatives. Learn more about our epilepsy community programs at http://www.lundbeck.com/us/our-commitment/community-involvement.

About H. Lundbeck A/S
Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company’s products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington’s, Alzheimer’s and Parkinson’s diseases. Lundbeck’s pipeline consists of several mid- to late-stage development programs.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have employees in 57 countries and our products are registered in more than 100 countries. We have research centers in Denmark, China and the United States and production facilities in Italy, France,
Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012.
Lundbeck’s shares are listed on the stock exchange in Copenhagen under the symbol “LUN.” Lundbeck
has a sponsored Level 1 ADR programme listed in the US (OTC) under the symbol “HLUYY.” For
additional information, we encourage you to visit our corporate site www.lundbeck.com.

Sources

1. SABRIL® (vigabatrin) full Prescribing Information, Deerfield, IL. Lundbeck. 2013.
2. Epilepsy Foundation. About Epilepsy: Statistics.
7. Data on File.

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