



**For Immediate Release**

**Five-Year Data From SABRIL® (vigabatrin) Registry Presented  
at American Epilepsy Society Annual Meeting**

**Seattle, Wash., Dec. 8, 2014** – A late-breaking poster presentation focused on five-year vision data from Lundbeck’s SABRIL (vigabatrin) patient registry was presented at the annual meeting of the American Epilepsy Society (AES). The data set includes 6,823 patients enrolled from August 21, 2009 through August 26, 2014.<sup>1</sup> The U.S. Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) due to the risk of SABRIL-induced permanent vision loss, including an ongoing patient registry.

SABRIL is indicated as adjunctive therapy for patients 10 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. SABRIL is not indicated as a first line agent for CPS.<sup>2</sup> SABRIL is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.<sup>2</sup>

The registry provides important usage data on SABRIL since it became available in the United States in 2009, including the number of patients who have received the therapy, patient demographics, and recent testing results. It also collects information on HCP-reported reasons why patients have discontinued SABRIL, including visual field defect. Of the total patients enrolled in the registry, 4,309 had IS and 2,055 had refractory CPS.<sup>1</sup> Because of the nature of the registry and vision testing variability, no comparison can be drawn between registry data and clinical trial results.<sup>1</sup>

“The importance of the registry is that it is the largest database of SABRIL-treated patients to date and is set up to collect ongoing data on all patients who receive SABRIL,” said Robert C. Sergott, MD, lead author of the poster presentation, director of neuro-ophthalmology at the Wills Eye Institute, and professor of ophthalmology, neurology and neurosurgery at Thomas Jefferson University Medical College. Dr. Sergott is also one of two expert neuro-ophthalmologists who are part of the SABRIL registry steering committee and who reviewed detailed vision test findings.

Adults in the registry frequently had attempted more than four epilepsy medications, and most were receiving multiple epilepsy medications when SABRIL was initiated.<sup>1</sup>

“The goal of the REMS is to ensure regular vision monitoring and to facilitate ongoing benefit-risk discussions. From my perspective, it is important to know that every patient who receives SABRIL will be included in the registry,” said John M. Pellock, MD, an author on the poster presentation and professor of neurology, pediatrics and pharmacy and pharmaceuticals at Virginia Commonwealth University.

**About the Presentation**

This study was presented at AES on Sunday, Dec. 7, 12:00 p.m.-2:00 p.m., during Poster Session 2 at the Washington State Convention Center in Exhibit Hall 4, Level 4.

**About the SABRIL Registry**

All patients using SABRIL are enrolled in a registry. The registry collects prescriber specialty, patient demographics, diagnosis, prior and concurrent anti-seizure medications, periodic ophthalmologic assessment data (i.e., the results of mandatory monitoring every three months, unless otherwise exempted), and the proportion of patients with refractory CPS and IS who continue/discontinue receiving SABRIL after the treatment initiation phase.

**About SABRIL® (vigabatrin)<sup>2</sup>**

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). For more information, please visit [www.SABRIL.net](http://www.SABRIL.net).

### **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.**
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- **Because SABRIL might cause vision loss, it is available to healthcare providers and patients only under a special program called the Support, Help And Resources for Epilepsy (SHARE) Program. Your healthcare provider will explain the details of the SHARE Program to you.**
  - **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 swelling. 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 have 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.sabrill.net](http://www.sabrill.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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

### **About Lundbeck in the U.S.**

Lundbeck in the U.S., headquartered in Deerfield, Illinois, is a wholly-owned subsidiary of H. Lundbeck A/S in Denmark. Globally, our mission is to help people suffering from psychiatric and neurologic disorders. To drive this mission in the U.S., nearly 800 employees are engaged in the research, development, production, marketing and sale of innovative specialty therapies that fulfill unmet medical needs. We see the person behind the disease and how it affects the lives of patients, families and caregivers. Lundbeck is actively involved with hundreds of local and national U.S. events each year that support our patient communities. To learn more, visit us at [www.LundbeckUS.com](http://www.LundbeckUS.com) and connect with us on Twitter at @LundbeckUS.

### **About Lundbeck**

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our nearly 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more than 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com).

**CONTACT:**

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**Sources**

1. Sergott R, Foroozan R, Pellock J, et al. Late-Breaking Abstract 2.387. Presented at the 68th Annual Meeting of the American Epilepsy Society, Dec. 7, 2014, Seattle.
2. SABRIL® (vigabatrin) full Prescribing Information, Deerfield, IL. Lundbeck. 2013.

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