



SABRIL® (vigabatrin) Vision Data Presented in Two Late-Breaking Posters at American Epilepsy Society Annual Meeting

Washington D.C., Dec. 9, 2013 – Two late-breaking presentations focused on SABRIL vision data were presented today at the annual meeting of the American Epilepsy Society (AES). One presentation includes interim results from a prospective, open-label trial of retinal structure and function in adult patients with refractory complex partial seizures (CPS), and the other presents four-year data from Lundbeck's SABRIL patient registry.^{1,2} Because of the risk of permanent vision loss, the U.S. Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) for SABRIL which includes the ongoing registry.

SABRIL is indicated as adjunctive therapy for patients 10 years of age and older with refractory 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. 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.³

Initial results of the SABRIL® Vision Study (Poster 3.302, Hall D, Level 2)

Currently, much of the published SABRIL vision data are derived from cross-sectional studies without baseline values. This study includes baseline values and aims to longitudinally measure changes in optic nerve and retinal structure and function using static perimetry and spectral optical coherence tomography (OCT). It is an ongoing, one-year, open-label clinical study, and the first prospective, long-term study evaluating SABRIL vision effects. Interim results presented at AES cover the first 30 patients who reached their first post-reference vision assessments, which occurred at Month 3.¹

Four-Year Results from the SABRIL® Registry (Poster 3.303, Hall D, Level 2)

Of the 5,487 patients enrolled in the registry through August 27, 2013, 3,436 had IS and 1,696 had refractory CPS. Median duration of treatment in the registry was 9.9 months. A small data subset of patients with detailed vision results reviewed by independent, expert neuro-ophthalmologists is included in the poster presentation. This subset included results from all physicians who voluntarily submitted vision results for expert analysis. Because of the nature of the registry and vision testing variability, clear comparisons cannot be drawn between registry data and clinical trial data.²

“Sabril is an important therapeutic option for people living with refractory complex partial seizures or infantile spasms, and it’s essential that we continue studying its potential benefits and risks,” said Robert C. Sergott, MD, an author on both late-breaking poster presentations, director of neuro-ophthalmology at the Wills Eye Institute, and professor of ophthalmology, neurology and neurosurgery at Thomas Jefferson University Medical College. “It’s encouraging to see the Sabril Vision Study enroll patients and begin to yield results. Prospective studies with baseline measures, consistent evaluation methods, and longitudinal analyses are critical to evaluating this therapy. Meanwhile, the registry continues to collect information on Sabril use since it became available in the United States in 2009.”

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.

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About SABRIL® (vigabatrin)

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 distribution program under a REMS called the SHARE Program (1-888-45-SHARE). For more information, please visit www.SABRIL.net.

Important Safety Information

WARNING: VISION LOSS

See full Prescribing Information for complete boxed warning

- **SABRIL causes progressive and permanent bilateral concentric visual field constriction in a high percentage of patients. In some cases, SABRIL may also reduce visual acuity.**
 - **Risk increases with total dose and duration of use, but no exposure to SABRIL is known that is free of risk of vision loss**
 - **Risk of new and worsening vision loss continues as long as SABRIL is used, and possibly after discontinuing SABRIL**
 - **Unless a patient is formally exempted, periodic vision assessment is required for patients on SABRIL. However, this assessment cannot always prevent vision damage.**
 - **SABRIL can cause permanent vision loss. SABRIL is available only through a restricted program called the SHARE Program.**
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- **SABRIL causes permanent bilateral concentric visual field constriction. Because assessing vision may be difficult in infants and children, the frequency and extent of vision loss in pediatric patients are poorly characterized. In adults, 30% or more of patients can be affected, ranging in severity from mild to severe, including tunnel vision to within 10° of visual fixation, and can result in disability. SABRIL can also damage the central retina and may decrease visual acuity.**
 - **The onset of vision loss is unpredictable and can occur soon after starting treatment, at any time during treatment, even after months or years, or possibly after discontinuation. Symptoms of vision loss from SABRIL are unlikely to be recognized by patients or caregivers before it is severe. Vision loss of milder severity may still adversely affect function.**
 - **Unless a patient is formally exempted from periodic ophthalmologic assessment as documented in the SHARE Program, vision should be assessed at baseline (no later than 4 weeks after starting SABRIL), every 3 months during therapy, and at 3 to 6 months after discontinuing therapy. Once detected, vision loss is not reversible. Even with frequent monitoring, some patients will develop severe vision loss. Consider drug discontinuation, balancing benefit and risk, if vision loss is documented.**
 - **Because of the risk of permanent vision loss, withdraw SABRIL from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation, and from patients with infantile spasms who fail to show substantial clinical benefit within 2 to 4 weeks of initiation, or sooner, if treatment failure becomes obvious. Periodically reassess patient response and continued need for SABRIL.**
 - **Do not use SABRIL in patients with, or at high risk of, other types of irreversible vision loss, or, with other drugs associated with serious adverse ophthalmic effects, unless the benefits clearly outweigh the risks. The interaction in these situations has not been well characterized, but is likely adverse.**
 - **Use the lowest dose and shortest exposure to SABRIL that is consistent with clinical objectives. Adjust the dose in patients with renal impairment.**

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- Abnormal magnetic resonance imaging (MRI) signal changes have been observed in some infants treated for IS with SABRIL. These changes generally resolved with discontinuation of treatment, and resolved in a few patients despite continued use.
- Antiepileptic drugs (AEDs), including SABRIL, increase the risk of suicidal thoughts and behavior. Monitor appropriate patients for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.
- As with all AEDs, discontinue SABRIL gradually to avoid withdrawal seizures.
- SABRIL can cause anemia, peripheral neuropathy, weight gain, and edema. SABRIL can cause somnolence and fatigue. Advise patients not to drive or operate machinery until they know how it will affect them.
- Vigabatrin is excreted in human milk and may cause serious adverse events in nursing infants. Do not use SABRIL during pregnancy unless the potential benefit justifies the potential risk to the fetus. **Pregnancy Registry:** To provide information regarding the effects of *in utero* exposure to SABRIL, physicians should recommend that pregnant patients taking SABRIL enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Patients must call the toll-free number 1-888-233-2334 to enroll. Registry information can be found at <http://www.aedpregnancyregistry.org/>.
- The most common adverse reactions in controlled studies ($\geq 5\%$ over placebo) include:
 - Adults >16 years of age: fatigue, somnolence, nystagmus, tremor, blurred vision, memory impairment, weight gain, arthralgia, abnormal coordination, and confusional state
 - Pediatrics 10 to 16 years of age: increased weight, upper respiratory tract infection, tremor, fatigue, aggression, and diplopia
- In infants, the most common adverse reactions in a controlled clinical study (incidence >5%) were somnolence, bronchitis, ear infection, and acute otitis media.

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

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.

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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. Johnson CA, Sergott RC, Laxer KD, et al. Late-Breaking Abstract 3.302. Presented at the 67th Annual Meeting of the American Epilepsy Society, Dec. 9, 2013, Washington, DC.
2. Sergott RC, Foroozan R, Pellock J, et al. Late-Breaking Abstract 3.303. Presented at the 67th Annual Meeting of the American Epilepsy Society, Dec. 9, 2013, Washington, DC.
3. SABRIL® (vigabatrin) full Prescribing Information, Deerfield, IL. Lundbeck. 2013.

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