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First Post-Baseline Data from the Sabril® (vigabatrin) Registry Presented at the American Epilepsy Society Annual Meeting

Baltimore, Md., Dec. 2, 2011 — Post-baseline vision data from Lundbeck's Sabril® patient registry is available for the first time today as a late-breaking poster presentation at the annual meeting of the American Epilepsy Society (AES). The data set includes 3,093 patients who enrolled in the mandatory patient registry during the two-year period between Aug. 21, 2009 and Aug. 22, 2011.[1] Because of the risk of Sabril-induced permanent vision loss, the U.S. Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) which includes an ongoing patient registry.

"These registry findings represent the first longitudinal data on Sabril therapy since its FDA approval, and include post-baseline vision data collected from a subset of patients who were reported as either having previously received Sabril or were Sabril naïve prior to entering the registry," said Robert C. Sergott, MD, lead author of the poster, director of neuro-ophthalmology at the Wills Eye Institute and professor of ophthalmology, neurology and neurosurgery at Thomas Jefferson University Medical College. Dr. Sergott was also one of two expert neuro-opthalmologists who are members of the Sabril registry steering committee and who independently reviewed detailed vision test findings for technical adequacy and clinical significance.

"The Sabril patient registry collects information on every U.S. patient who has received treatment with Sabril since it was approved by the FDA,"[1] said John M. Pellock, MD, an author on the poster presentation and chairman of the Division of Child Neurology and professor of neurology, pediatrics and pharmacy and pharmaceutics at Virginia Commonwealth University. "We look forward to furthering our knowledge of Sabril through continued analysis of this data."

Of the total patients enrolled in the registry, 1,046 had refractory complex partial seizures (CPS) and 1,880 had infantile spasms (IS).[1]

Sabril is indicated as adjunctive therapy for adult patients with refractory CPS who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss.[2] Sabril is not indicated as a first-line agent for complex partial seizures. Sabril is indicated as monotherapy for pediatric patients 1 month to 2 years of age with IS for whom the potential benefits outweigh the potential risk of vision loss.[3]

This poster presentation (poster #: 3.330) will be made available at AES as part of the Lundbeck Scientific Exhibit (Room 337, Baltimore Convention Center, Sunday, Dec. 4, 8 a.m. – 11 a.m.) and as part of the AES official poster sessions (Convention Center Hall E, Level 100, 11 a.m. – 4 p.m., Monday, Dec. 5).

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 every 3-month monitoring), and the proportion of patients receiving Sabril for refractory CPS and IS who respond/do not respond to Sabril during the treatment initiation phase.

About Infantile Spasms
Infantile spasms is a difficult-to-treat epilepsy syndrome that usually strikes infants between four to eight months old.[4] Infants suffer spasms that typically last for one to five seconds[5] and occur in clusters of up to 100 spasms at a time.[4] An estimated 8,500 infants in the U.S. have been diagnosed with IS,[6] and each year approximately 2,500 new cases of IS are reported in the U.S. Sabril may not be appropriate for use in all patients with IS.

About Complex Partial Seizures
There are three million Americans affected by epilepsy[7] and approximately 35 percent have CPS,[8] the single largest seizure type, which originates from a single region of the brain and can cause impaired consciousness.[8] Despite the availability of many antiepileptic drugs, approximately 30 to 36 percent of adults with CPS continue to have seizures.[9,10,11]

About Sabril® (vigabatrin)
Sabril is an oral antiepileptic drug developed in the United States by Lundbeck. Sabril is available in two formulations—in 500 mg tablets for use as add-on therapy for adults with refractory CPS and in 500 mg packets of powder for oral solution for infants with IS.

About Lundbeck in the U.S.
A wholly-owned subsidiary of H. Lundbeck A/S of Denmark, Lundbeck in the U.S. 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 challenging seizure disorders.

With a special commitment to addressing the needs of the epilepsy community, Lundbeck makes several therapies available in the U.S. for people with difficult-to-treat seizure disorders and actively participates in many community-based initiatives. Each year, Lundbeck employees actively support and participate in more than 100 epilepsy awareness events as part of their ongoing commitment to make a difference for those impacted by epilepsy.

For more information, please visit www.lundbeckus.com.

About Lundbeck
H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from brain disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, schizophrenia, insomnia, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 5,900 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with brain disorders. In 2010, the company's revenue was DKK 14.8 billion (approximately EUR 2.0 billion or USD 2.6 billion). For more information, please visit www.lundbeck.com.

Important Safety Information

WARNING: VISION LOSS
See Medication Guide 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 doctor 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 particularly to their peripheral vision. With severe vision loss you may only be able to see things straight in front of you (sometimes called 'tunnel vision'). You may also have blurry vision.

Because of the risk of vision loss in adults, SABRIL is used to treat CPS only in people who do not respond well enough to several other medications. Tell your doctor right away if you think you are not seeing as well as before you started taking SABRIL; start to trip, bump into things, or are more clumsy than usual; or are surprised by people or things coming in front of you that seem to come out of nowhere.

These changes can mean that you have damage to your vision. Your doctor will test your visual fields (including peripheral vision) and visual acuity (ability to read an eye chart) before you start SABRIL or within 4 weeks after starting SABRIL, and at least every 3 months after that until SABRIL is stopped You may not be able to be tested in certain situations. Your doctor will determine if you can be tested. Even if your vision seems fine, it is important that you get these regular vision tests because damage can happen to your vision before you notice any changes. These vision tests cannot prevent the vision damage that can happen with SABRIL, but they do allow you to stop SABRIL if vision has gotten worse, which usually will lessen further damage. If you do not have these vision tests regularly, your doctor may stop prescribing SABRIL for you. You should also have a vision test after SABRIL is stopped. Some people are not able to complete testing of vision for medical reasons. If you cannot complete vision testing, your doctor may continue prescribing SABRIL, but your doctor will not be able to watch for any vision loss you may get.

Because of the risk of vision loss, SABRIL is used in babies with IS only when you and your doctor decide that the possible benefits of SABRIL are more important than the risks. Parents or caregivers are not likely to recognize the symptoms of vision loss in babies until it is severe. Doctors may not find vision loss in babies until it is severe. It is difficult to test vision in babies, but all babies should have their vision tested before starting SABRIL or within 4 weeks after starting SABRIL, and every 3 months after that until SABRIL is stopped. Your baby should have a vision test after SABRIL is stopped. Your baby may not be able to be tested in certain situations. Your doctor will determine if your baby can be tested.

Tell your doctor right away if you think that your baby is not seeing as well as before taking SABRIL or is acting differently than normal. Even if your baby's vision seems fine, it is important to get regular vision tests because damage can happen before your baby acts differently. Even these regular vision tests may not show the damage to your baby's vision before it is serious and permanent. If your baby does not have these vision tests regularly, your doctor may stop prescribing SABRIL for your baby. If your baby is not able to complete vision testing, your doctor may continue prescribing SABRIL for your baby. But, your doctor will not be able to watch for vision loss in your baby.

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 or actions in a very small number of people, about 1 in 500 people taking it. Call a doctor right away if you 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 serious problems. Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures.

If you are an adult with CPS, tell your doctor about all of your medical conditions including depression, mood problems, suicidal thoughts or behavior, an allergic reaction to SABRIL, any vision problems, any kidney problems, low red blood cell counts and any nervous or mental illness. 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.

Before giving SABRIL to your baby, tell the doctor about all of your baby's medical conditions including if your baby has or ever had an allergic reaction to SABRIL, or any vision or kidney problems.

Tell your doctor about all the medicines you or your baby take.

SABRIL causes sleepiness and tiredness. Adults taking SABRIL should not drive, operate machinery, or perform any hazardous task, unless you and your doctor have decided that you can do these things safely. SABRIL can cause serious side effects in adults such as low red blood cell counts, sleepiness and tiredness, nerve problems, weight gain that happens without swelling, and swelling. It is not known if these side effects also happen in babies who take SABRIL. SABRIL may make certain types of seizures worse. You should tell your or your baby's doctor right away if the seizures get worse.

The most common side effects of SABRIL in adults include: problems walking or feeling uncoordinated, feeling dizzy, shaking, joint pain, memory problems and not thinking clearly, and eye problems such as blurry vision, double vision, and eye movements you cannot control. The most common side effects of SABRIL in babies and young children include: sleepiness—some babies may have a harder time suckling and feeding or may be irritable, ear infection, and irritability. Tell your doctor if you or your baby 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 doctor or pharmacist.

Please see SABRIL Medication Guide and full Prescribing Information including Boxed Warning and dosing instructions for SABRIL for Oral Solution on this website or call toll-free 1-888-45-SHARE (1-888-457-4273).

Oral Solution: For more information, please see the full Prescribing Information including Boxed Warning, Medication Guide and Dosing Instructions.

Solución oral: Para más información, vea por favor la información que prescribe completa incluyendo la advertencia encajonada, guía de la medicación y las instrucciones de la dosificación.

Tablets: For more information, please see the full Prescribing Information including Boxed Warning and Medication Guide.

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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.

Sources

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