ADDING MULTIMEDIA Lundbeck Inc. Announces FDA Marketing Approval for Sabril for the Treatment of Two Difficult-to-Treat Epilepsies

First FDA-approved treatment for infantile spasms and a new adjunctive treatment for adults with refractory complex partial seizures

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DEERFIELD, Ill.--(EON: Enhanced Online News)--Lundbeck Inc. ("Lundbeck"), a wholly owned subsidiary of H. Lundbeck A/S in Denmark (Copenhagen: LUN), announced today that the U.S. Food and Drug Administration (FDA) has granted two New Drug Application (NDA) approvals for Sabril® (vigabatrin) Tablets and Oral Solution. Lundbeck plans to launch Sabril in the United States in the third quarter.

Sabril is indicated as monotherapy for pediatric patients one month to two years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss, and as adjunctive (add-on) therapy for adult patients 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.[1,2] Sabril is not indicated as a first line agent for CPS.

"Having more than a decade of experience with Sabril, I have felt this drug was important to the epilepsy community. Lundbeck shared my commitment to getting this important therapy approved and without their support, Sabril would not be available today in the U.S."

Sabril causes permanent bilateral concentric visual field constriction in 30 percent or more of patients that ranges in severity from mild to severe, including tunnel vision to within 10 degrees of visual fixation and can result in disability. In some cases, Sabril also can damage the central retina and may decrease visual acuity. Sabril causes permanent vision loss in infants, children and adults. The onset is unpredictable and can occur within weeks of starting treatment, or sooner, or at any time during treatment, even after months or years. Because of this risk of permanent vision loss, Sabril approval is accompanied by an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) and is available only through a special restricted distribution program called SHARE (Support Help and Resources for Epilepsy).

Sabril is the first therapy approved for the treatment of IS and an important new option as add-on therapy for the approximately 30 to 36 percent of adults with CPS whose seizures remain uncontrolled in spite of having many antiepileptic therapies already available.[3,4]

"The approval of Sabril is great news for patients and their families who have been waiting a long time for access to this new therapy," said Dr. W. Donald Shields, Director of the Pediatric Epilepsy Program at the University of California at Los Angeles. "Having more than a decade of experience with Sabril, I have felt this drug was important to the epilepsy community. Lundbeck shared my commitment to getting this important therapy approved and without their support, Sabril would not be available today in the U.S."

Commenting on the approval of the lead compound in its central nervous system (CNS) pipeline, Jeffrey S. Aronin, President and Chief Executive Officer of Lundbeck Inc., said, "We have been working hard to address the unmet medical needs of patients faced with infantile spasms and to offer a new add-on option for treating refractory complex partial seizures. FDA approval of Sabril is an important victory for the entire epilepsy community."

In conjunction with marketing approval of Sabril, Lundbeck has developed an FDA-mandated REMS to manage the risk of permanent vision loss associated with Sabril. The Sabril REMS, a critical component in receiving FDA approval, specifies elements, such as restricted product distribution, required vision testing and mandatory benefit-risk assessments, to manage the risk of permanent vision loss associated with Sabril. The Sabril REMS is administered through Lundbeck's SHARE program, a comprehensive patient and physician support program designed to provide tools and resources for all of Lundbeck's epilepsy products, including Sabril. Through SHARE and the recently established SHARE Call Center, patients, caregivers and physicians will have access to information and tools to help manage severe and uncontrolled epilepsy, programs to help facilitate initial and ongoing use of Sabril, and support from a team dedicated to helping people fully understand and navigate the Sabril prescribing process.

About Complex Partial Seizures

There are three million Americans affected by epilepsy[5] and approximately 35 percent have CPS, the single largest seizure type, which originates from a single region of the brain and can cause impaired consciousness.[6] Despite the availability of many antiepileptic drugs, approximately 30 to 36 percent of adults with CPS continue to have seizures.[3,4] Sabril provides a new and valuable add-on treatment option for adult CPS patients who have not responded to several alternative treatments and are considered 'refractory' to treatment. Given the potential benefit compared to the risk of permanent vision loss, it is expected that only a small percentage of refractory CPS patients will initiate and maintain treatment with Sabril as add-on therapy.

About Infantile Spasms

Infantile spasms is a difficult-to-treat epilepsy syndrome that usually strikes infants between three to six months old.[8] An estimated 8,500 infants in the U.S. have been diagnosed with IS,[9] 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 Sabril® (vigabatrin) Tablets and Oral Solution

Sabril is an oral antiepileptic drug developed in the United States by Lundbeck Inc. 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. The precise mechanism of Sabril's antiseizure effect is unknown, but is believed to be the result of its action as an irreversible inhibitor of gamma-aminobutyric acid transaminase (GABA-T), the enzyme responsible for the metabolism of the inhibitory neurotransmitter GABA. This action results in increased levels of GABA in the central nervous system. No direct correlation between plasma concentration and efficacy has been established. The duration of drug effect is presumed to be dependent on the rate of enzyme re-synthesis rather than on the rate of elimination of the drug from the systemic circulation.[1]

For full Prescribing Information, including Boxed Warning, please see:

- Sabril Tablets full Prescribing Information, including Boxed Warning: *http://www.lundbeckinc.com/USA/products/CNS/Sabril/sabril_PI_CPS.pdf*
- Sabril Oral Solution full Prescribing Information, including Boxed Warning: *http://www.lundbeckinc.com/USA/products/CNS/Sabril/sabril_PI_IS.pdf*
- Sabril Medication Guide: *http://www.lundbeckinc.com/USA/products/CNS/Sabril/sabril_medication_guide.pdf*

Additional information is available at www.sabril.net or by calling toll-free 1-888-45-SHARE (1-888-457-4273).

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
- Periodic vision testing is required for patients on SABRIL, but cannot reliably prevent vision damage
- Because of the risk of permanent vision loss, SABRIL is available only through a special restricted distribution program

SABRIL causes permanent vision loss in infants, children and adults. Because assessing vision loss is difficult in children, the frequency and extent of vision loss in infants and children is poorly characterized.

In adults, SABRIL causes progressive and permanent bilateral concentric visual field constriction in 30% or more of patients that ranges in severity from mild to severe, including tunnel vision to within 10° of visual fixation, and can result in disability. In some cases, SABRIL also can damage the central retina and may decrease visual acuity. The lowest dose and shortest exposure to SABRIL should be used that is consistent with clinical objectives.

Because of the risk of permanent vision loss, a pediatric patient treated for IS (1 month to 2 years of age) who fails to show substantial clinical benefit within 2 to 4 weeks of treatment initiation or an adult patient treated for refractory CPS as adjunctive therapy who fails to show substantial clinical benefit within 3 months of treatment initiation should be withdrawn from SABRIL.

Vision testing for adults treated for refractory CPS as adjunctive therapy is required at baseline and at least every 3 months while on therapy. Vision testing for pediatric patients treated for IS is required to the extent possible at baseline and at least every 3 months while on therapy. Vision testing for adults and pediatric patients is also required about 3 to 6 months after discontinuing SABRIL therapy. The onset of vision loss from SABRIL is unpredictable and can occur within weeks of starting treatment or sooner, or at any time during treatment, even after months or years. Patient response to and continued need for SABRIL should be periodically reassessed.

Symptoms of vision loss from SABRIL are unlikely to be recognized by the patient, parent or caregiver before vision loss is severe. Vision loss of milder severity, although unrecognized by the patient, parent or caregiver may still adversely affect function. The possibility that vision loss from SABRIL may be more common or more severe, or have more severe functional consequences in infants and children than in adults, cannot be excluded.

SABRIL should not be used in patients with, or at high risk of, other types of irreversible vision loss or with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefits clearly outweigh the risks. In adult patients treated for CPS, dose adjustment, including initiating treatment with a lower dose, is necessary in patients with renal impairment.

Abnormal MRI signal changes have been observed in some infants treated for IS with SABRIL. These changes generally resolved with discontinuation of treatment and in a few patients the lesion resolved despite continued use. SABRIL should be discontinued gradually to avoid withdrawal seizures.

Antiepileptic drugs (AEDs), including SABRIL, increase the risk of suicidal thoughts or behavior. Adult patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior and/or any unusual changes in mood or behavior.

SABRIL has been shown to cause anemia, somnolence, fatigue, weight gain, edema, and symptoms of peripheral neuropathy. SABRIL should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Vigabatrin is excreted in human milk and may cause serious adverse events in nursing infants.

The most commonly observed adverse reactions reported in 2 add-on clinical studies of adults with refractory CPS treated with SABRIL as adjunctive therapy with the recommended dose of 3 g/day (≥10% and at least 5% greater than placebo) were dizziness (SABRIL 24% vs placebo 17%), fatigue (SABRIL 23% vs placebo 16%), somnolence (SABRIL 22% vs placebo 13%), tremor (SABRIL 15% vs placebo 8%), blurred vision (SABRIL 13% vs placebo 5%), and arthralgia (SABRIL 10% vs placebo 3%). A 6 g/day dose has not been shown to confer additional benefit compared to the 3 g/day dose and is associated with an increased incidence of adverse events.

The most common adverse events reported by >5% of infants taking SABRIL for IS occurring more frequently than placebo in a randomized, placebo-controlled IS study with a 5-day double-blind treatment phase (n=40) were somnolence (SABRIL 45% vs placebo 30%), bronchitis (SABRIL 30% vs placebo 15%), ear infection (SABRIL 10% vs placebo 5%), and acute otitis media (SABRIL 10% vs placebo 0%).

About Lundbeck Inc.

Lundbeck Inc. was established in March 2009 following the acquisition of Ovation Pharmaceuticals, Inc. by Lundbeck and has proven success in developing and commercializing high-need treatments. The company is committed to providing innovative therapies that fulfill unmet medical needs of people with CNS disorders and rare diseases for which few, if any, effective treatments are available. For more information, please visit www.lundbeckinc.com.

About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improve the quality of life for people suffering from CNS disorders. For this purpose Lundbeck is engaged in the research and development, production, marketing and sale of pharmaceuticals across the world, targeted at disorders like depression and anxiety, schizophrenia, insomnia, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark, and employs today over 5,500 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with CNS disorders. In 2008, the company's revenue was DKK 11.3 billion (approximately EUR 1.5 billion or USD 2.2 billion). For more information, please visit www.lundbeck.com.

Sources:

1. Sabril® (vigabatrin) for Oral Solution full Prescribing Information, including Boxed Warning.

2. Sabril® (vigabatrin) Tablets full Prescribing Information, including Boxed Warning.

3. Kwan P, Brodie MJ. Early identification of refractory epilepsy. *New England Journal of Medicine*. February 3, 2000;342:314-319.

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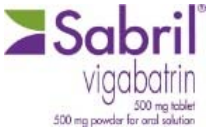

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