H. Lundbeck A/S

Ottiliavej 9
DK-2500 Valby, Copenhagen

Tel +45 36 30 13 11
Fax +45 36 43 82 62

E-mail investor@lundbeck.com
www.lundbeck.com

Corporate Release No 383

21 August 2009

FDA grants marketing approval for Lundbeck's Sabril® (vigabatrin)

- *First FDA-approved treatment for infantile spasms*
- *New adjunctive treatment for adults with refractory complex partial seizures*

H. Lundbeck A/S today announced that the US Food and Drug Administration (FDA) has granted two New Drug Application (NDA) approvals for Sabril® (vigabatrin) Tablets and Oral Solution.

Lundbeck Inc. plans to launch Sabril in the US during the third quarter of 2009, with an extensive Risk Evaluation and Mitigation Strategy (REMS) program as required by the FDA and created in collaboration with the agency.

Sabril is the first therapy approved by the FDA for the treatment of infantile spasms (IS) and an important new adjunctive therapeutic option for the approximately 30 to 36 percent of adults with complex partial seizures (CPS) whose seizures remain uncontrolled in spite of having many antiepileptic therapies already available[i] [ii].

Sabril is indicated as monotherapy for paediatric patients one month to two years of age with IS for whom the potential benefits outweigh the potential risk of vision loss. IS is characterized by spasms that may occur in clusters of up to 100 at a time. Sabril represents the only treatment approved by the FDA to help manage this difficult-to-treat condition.

Sabril is also 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. Sabril is not indicated as a first-line agent for CPS. This patient group is inherently difficult to treat and is in need of additional treatment alternatives to help reduce the number of seizures.

Commenting on the approval of the lead compound in its CNS pipeline, Ulf Wiinberg, President and CEO at Lundbeck said, "Infantile spasms and refractory complex partial seizures in adults are difficult-to-treat epilepsies and we are pleased to be able to address the unmet medical need patients with infantile spasms have faced and to offer an additional choice in treating refractory complex partial seizures. FDA approval of Sabril is an important step forward for the entire epilepsy community and provides patients with a new treatment option that could reduce seizures among these adult patients and may eliminate spasms in a certain proportion of children with infantile spasms."

Lundbeck has together with the FDA established a comprehensive REMS to manage the risk of permanent vision loss associated with the product. The Sabril REMS, which was a critical component in receiving FDA approval, specifies elements, such as restricted product distribution, required vision testing and mandatory risk-benefit assessments, to manage the risk of vision loss associated with Sabril. Like all other antiepileptic drugs, the REMS also addresses the risk for suicidality associated with the class.

The Sabril REMS is administered through Lundbeck's SHARE (Support, Help and Resources for Epilepsy) 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.

Sabril causes permanent vision loss in infants, children and adults. Sabril-induced vision loss includes progressive and permanent bilateral concentric visual field constriction in 30 percent or more of patients on the therapy that ranges in severity from mild to severe, including tunnel vision to within 10 degrees of visual fixation, and can result in disability. There are also some reports that Sabril can damage the central retina and decrease visual acuity. The onset is unpredictable and can occur within weeks of starting treatment, or sooner, or at anytime during treatment even after months or years.

Financial guidance
The content of this release will have no influence on the Lundbeck Group's financial result for 2009.

Lundbeck made an upfront payment of USD 600 million (or approximately DKK 3.5 billion) immediately upon closing of the acquisition of Ovation Pharmaceuticals, Inc. An additional payment of USD 300 million (or approximately DKK 1.6 billion) will now be paid in connection with the approval of Sabril by the FDA.

About complex partial seizures
There are three million Americans affected by epilepsy[iii] 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[iv]. Despite the availability of more than 20 antiepileptic drugs, approximately 30 to 36 percent of adults with CPS continue to have uncontrolled seizures[v]. Sabril provides a new and valuable adjunctive 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 adjunctive therapy.

About infantile spasms

Infantile spasms is a difficult-to-treat epilepsy syndrome that usually strikes infants between three to six months old[vi]. An estimated 8,500 infants in the US have been diagnosed with IS[vii]. Each year, approximately 2,500 new cases of IS are reported in the US and until now, no FDA-approved treatments have been available. Sabril may not be appropriate for use in all IS patients given the potential risk of permanent vision loss.

About Sabril® (vigabatrin) Tablets and Oral Solution

Sabril is an oral antiepileptic drug developed in the US by Lundbeck Inc. Sabril is available in two formulations - in 500 mg tablets for use as adjunctive 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 anti-seizure 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 resynthesis rather than on the rate of elimination of the drug from the systemic circulation[viii].

Lundbeck contacts

Investors:

Jacob Tolstrup
Director, IR & Communication
+45 36 43 30 79

Palle Holm Olesen
Head of Investor Relations
+45 36 43 24 26

Magnus Thorstholm Jensen
Investor Relations Officer
+45 36 43 38 16

Media:

Mads Kronborg
Media Relations
+45 36 43 28 51

Kasper Riis
Media Relations
+45 36 43 28 33

About Lundbeck

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 central nervous system (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.

---

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

[ii] Devinsky O. Patients with refractory seizures. New England Journal of Medicine. May 20, 1999; 340:1565-70.

[iii] Epilepsy and Seizure Statistics. Epilepsy Foundation.org. http://www.epilepsyfoundation.org/about/statistics.cfm. Last accessed 03/09/2009.

[iv] Murro, Anthony M. EMedicine.com. Complex Partial Seizures. http://www.emedicine.com/Neuro/topic74.htm Last accessed on February 17, 2009.

[v] Sperling, M. The consequences of uncontrolled epilepsy. CNS Spectr 2004;9(2):98-101,106-109.

[vi] National Institute of Neurological Disorders and Stroke. NINDS Infantile Spasms Information Page. Available at: http://www.ninds.nih.gov/disorders/infantilespasms/infantilespasms.htm?css=print. Last accessed on December 8, 2008.

[vii] Hurst D. The epidemiology of infantile spasms. In: Dulac O, Chugani H. Dalla Bernardina B., eds. Infantile Spasms and West Syndrome. Philadelphia, PA: Saunders; 1994.

[viii] Sabril® (vigabatrin) for Oral Solution full Prescribing Information, including Boxed Warning