FOR IMMEDIATE RELEASE
CONTACT:
Matt Flesch
847-282-1154

FDA Approves ONFI™ (clobazam) for the Adjunctive Treatment of Seizures Associated with Lennox-Gastaut Syndrome in Patients Two Years and Older

Approval based on largest clinical trial to date evaluating pediatric and adult patients with a current or prior diagnosis of LGS1,2

Deerfield, Ill. October 24, 2011 – Lundbeck Inc. (“Lundbeck”), a wholly owned subsidiary of H. Lundbeck A/S in Denmark (LUN: Copenhagen Stock Exchange), announced today that the U.S. Food and Drug Administration (FDA) has approved ONFI™ (clobazam) as adjunctive therapy for seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years and older.1 ONFI (pronounced “ON-fee”) will be available in U.S. pharmacies in early January and is a federally controlled schedule four substance (C-IV).

LGS is a rare and severe form of epilepsy that is typically diagnosed in childhood and often persists into adulthood.3,4 LGS is associated with multiple types of seizures with periods of frequent seizures, and daily seizures are common.5 Some of these seizures, including atonic, tonic and myoclonic seizures, may cause falls, or “drop seizures” (also referred to as “drop attacks”), which may result in injury.3

“As an epileptologist treating patients with a variety of challenging seizure disorders, I’m aware of the need for new add-on therapies to address the severe and frequent seizures associated with LGS,” said Joan A. Conry, MD, professor of neurology at Children’s National Medical Center in Washington, D.C., and a principal investigator of the CONTAIN Trial. “Clobazam, now approved as ONFI, was shown to be effective as adjunctive therapy for reducing seizures associated with LGS,1 and its upcoming availability provides hope for additional seizure management to patients and their physicians, caregivers and families.”

The FDA approval of ONFI was based on two multicenter controlled studies similar in terms of disease characteristics and prior treatment of patients, including a pivotal Phase III study in 238 patients with a current or prior diagnosis of LGS.1 Named the CONTAIN Trial, the study’s primary endpoint was the percent reduction in the weekly frequency of drop seizures (atonic, tonic, or myoclonic), from the 4-week baseline period to the 12-week maintenance period. A Phase II dose-ranging study was also conducted (n=68) that was consistent with results of the CONTAIN Trial.1

The most common adverse reactions in the CONTAIN Trial included sleepiness or tiredness, fever, drooling, acting aggressive, irritability, lack of coordination and constipation. The adverse reactions leading to discontinuation in ≥ 1 percent in the CONTAIN Trial in decreasing order of frequency included tiredness, sleepiness, lack of coordination, acting aggressive, fatigue and difficulty sleeping.1

“The FDA approval of ONFI is a major milestone for Lundbeck as we continue our efforts to develop therapies for people with disorders of the central nervous system, including severe seizure disorders,” said Christopher Silber, M.D., vice president of U.S. clinical research and medical affairs at Lundbeck. “ONFI will be the second therapy for challenging types of epilepsy that Lundbeck has launched in the last two and a half years.”

About ONFI™ (clobazam)
ONFI is an oral antiepileptic drug developed in the United States by Lundbeck Inc, and will be available in 5 mg, 10 mg, and 20 mg tablets. ONFI is a 1,5 benzodiazepine. The exact mechanism of action for ONFI is not fully understood, but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA_A receptor.1

- more -
Important Safety Information

• **ONFI is a prescription medicine used along with other medicines to treat seizures associated with Lennox-Gastaut syndrome in people 2 years of age or older.**

• **ONFI can make you sleepy or dizzy and can slow your thinking and make you clumsy which may get better over time.** Do not drive, operate heavy machinery, or other dangerous activities until you know how ONFI affects you. Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ONFI without first talking to your healthcare provider as your sleepiness or dizziness may get much worse.

• **ONFI can cause withdrawal symptoms.** Do not stop suddenly taking ONFI without first talking to a healthcare provider. Stopping ONFI suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.

• **ONFI can be abused and cause dependence.** Physical dependence is not the same as drug addiction. Talk to your healthcare provider about the differences. **ONFI is a federally controlled substance (C-IV) because it can be abused or lead to dependence.**

• **Like other antiepileptic drugs, ONFI may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.** Call your healthcare provider 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.

• If you are pregnant or plan to become pregnant, ONFI may harm your unborn baby. You and your healthcare provider will have to decide if you should take ONFI while you are pregnant.

• **ONFI can pass into breast milk.** You and your healthcare provider should decide if you should take ONFI or breast feed. You should not do both.

• The most common side effects seen in ONFI patients include: sleepiness; drooling; constipation; cough; pain with urination; fever; acting aggressive, being angry or violent; difficulty sleeping; slurred speech; tiredness and problems with breathing.

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.

For more information, please see the **ONFI Medication Guide** and **Full Prescribing Information**.

About Lundbeck Inc.
Headquartered in Deerfield, Illinois, Lundbeck Inc., a wholly-owned subsidiary of H. Lundbeck A/S, is committed to developing and providing innovative specialty therapies that fulfill unmet medical needs of people with central nervous system (CNS) disorders, including rare diseases. For more information, please visit www.lundbeckinc.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 central nervous system (CNS) 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 CNS 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.

ONFI is a trademark of Lundbeck Inc.

###
Sources

1. **ONFI Full Prescribing Information.** Deerfield, IL: Lundbeck Inc. October 2011.


