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Five Presentations at American Epilepsy Society Annual Meeting Highlight Data on Lundbeck's ONFI™ (clobazam)

Oral presentation provides post-hoc analyses of ONFI in patients across the age spectrum, including adults with a current or previous diagnosis of Lennox-Gastaut syndrome (LGS)¹

Baltimore, Md., Dec. 2, 2011 — Five presentations highlighting ONFI™ (clobazam), including *post-hoc* analyses drawn from the pivotal Phase III Contain Trial, will be presented at the American Epilepsy Society's Annual Meeting in Baltimore, Md., Dec. 2–6, 2011.¹ The CONTAIN Trial supported the U.S. FDA approval of ONFI for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years and older.² Approved on October 21, 2011, ONFI (pronounced "ON-fee") will be available in U.S. pharmacies in early January and is a federally controlled schedule four substance (C-IV).³

"The CONTAIN Trial evaluated 238 patients with a current or prior diagnosis of LGS, and produced an abundance of data that we continue to analyze,"² said Christopher Silber, M.D., vice president of U.S. clinical research and medical affairs at Lundbeck. "Analyses of these data presented at AES increase the depth of information available about ONFI as health care professionals and caregivers anticipate the U.S. availability of ONFI in January."

An oral presentation (AES Platform #: B.04) examined ONFI by age group, sex and ethnicity based on a *post-hoc* subanalysis of the CONTAIN Trial.¹ The CONTAIN Trial'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.¹

"While typically diagnosed in childhood, LGS should not be mistaken as a condition that only affects children — it often persists into adulthood⁴ and continues to be associated with several types of seizures,"⁵ noted Joan A. Conry, M.D., professor of neurology at Children's National Medical Center in Washington, D.C., and a principal investigator of the CONTAIN Trial. "This subanalysis of the CONTAIN Trial provides additional valuable information for physicians treating both adults and pediatric patients older than two years with a history of LGS, and is consistent with the FDA approved label for clobazam, which is now approved as ONFI."

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.

Additional ONFI data presented at AES will be made available at Lundbeck's Scientific Exhibit, Sunday, Dec. 4, 8 a.m. – 11 a.m., Baltimore Convention Center (Room 337).

About ONFI™ (clobazam)

ONFI is an oral antiepileptic drug developed in the United States by Lundbeck, and will be available in 5-mg, 10-mg, and 20-mg tablets.¹ 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

Important Safety Information

- **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 (CIV) 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.
- Tell your healthcare provider about all of your medical conditions including liver or kidney problems, lung problems (respiratory disease), depression, mood problems, or suicidal thoughts or behavior.
- 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.
- Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements as taking ONFI with certain other medicines can cause side effects or affect how well they work. ONFI may make your birth control medicine less effective. Talk to your healthcare provider about the best method to use.
- 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](#).

ONFI is a trademark of Lundbeck Inc.

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 challenging seizure disorders.

With a special commitment to addressing the needs of the epilepsy community, Lundbeck makes several therapies available in the United States 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 an 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, and 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.

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Sources

1. Mitchell, Wendy, et al. "Clobazam is Efficacious for Drop Attacks in Patients with Lennox-Gastaut Syndrome Across the Age Spectrum: Subgroup Analysis of the CONTAIN Trial." Lundbeck Poster and Oral Presentation B.04. December 2011.
2. ONFI [Full Prescribing Information](#). Deerfield, IL: Lundbeck Inc. October 2011.
3. U.S. Food and Drug Administration. "FDA approves Onfi to treat severe type of seizures." FDA News Release. October 24, 2011.
4. Van Rijckevorsel, Kenou et al. Treatment of Lennox-Gastaut syndrome: overview and recent findings. *Neuropsychiatric Disease and Treatment*. 2008; 4(6) 1001-1019.
5. Borggraefe I, Noachtar S. Pharmacotherapy of Seizures Associated with Lennox-Gastaut Syndrome. *Clinical Medicine Insights: Therapeutics*. 2010;2 15-24.