



For Immediate Release

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FDA Accepts Lundbeck Inc. Submission of New Drug Application for Clobazam

Onfi™ (clobazam) proposed as United States trade name

Deerfield, Ill. March 4, 2011 – Lundbeck Inc. today announced the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for the investigational compound clobazam as adjunctive therapy in treating seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years and older. The filing was assigned a standard review and an action letter is anticipated in October 2011. Additionally, Lundbeck announced Onfi™ (pronounced “on-fee”) as the proposed U.S. trade name for clobazam.

The NDA submission is based on a clinical development program that evaluated the safety and efficacy of Onfi as add-on therapy in patients with LGS. Positive results from the largest Phase III trial ever conducted in patients with LGS were presented at the December 2010 annual meeting of the American Epilepsy Society (AES).^{1,2}

LGS is a rare and severe form of epilepsy that is typically diagnosed in childhood and often persists into adulthood.^{3,4,5} Most patients with LGS experience multiple types of seizures with periods of frequent seizures, and daily seizures are common.⁶ Some of these seizures may cause falls, or “drop seizures,” which may result in injury.⁷

“The FDA’s acceptance for review of the Onfi NDA represents a significant milestone for Lundbeck as we work to improve the lives of people living with epilepsy,” said Timothy M. Cunniff, PharmD, vice president of global regulatory affairs at Lundbeck. “We’re pleased to be one step closer to providing a new treatment option for people in the U.S. with LGS, a form of epilepsy that severely impacts the health of the patient, often due to the severity of seizures and frequent injuries.”

About Onfi (clobazam)

Clobazam is a 1,5-benzodiazepine that potentiates the inhibitory action of gamma-aminobutyric acid (GABA) by binding to GABA-A receptors.^{8,9} GABA-A receptors contain a benzodiazepine binding site, also referred to as the omega receptor (ω), of which three subtypes have been identified.⁸ In non-clinical studies, clobazam was shown to have higher affinity for the ω 2 compared to the ω 1 receptor.⁸ The precise mechanism of action by which clobazam exerts its antiepileptic effects is unknown.

Clobazam is marketed outside of the U.S. under various brand names, including Frisium(R) and Urbanyl(R). Brand names listed are property of their owners.

About Lennox-Gastaut Syndrome (LGS)

Lennox-Gastaut syndrome (LGS) is a rare and severe form of epilepsy characterized by multiple types of seizures, mental retardation or regression, and abnormal electroencephalogram (EEG) with generalized slow spike and wave discharges (1.5-2 Hz).^{3,5,10} Responsible for 1-4 percent of all childhood epilepsies,¹⁰ LGS typically occurs between two and eight years of age (peak onset occurs from 3-5 years).³ Eighty percent of those with LGS will have continued seizures throughout childhood and into their adult years.³ LGS is associated with multiple seizure types, including atonic, tonic and myoclonic seizures, which can all cause falls, or “drop seizures”, that are associated with a high rate of recurrent injuries.⁷ Prognosis for individuals with LGS varies, and complete recovery, including freedom from seizures and normal development, is uncommon.⁵

About Lundbeck Inc.

Headquartered in Deerfield, Illinois, Lundbeck Inc., a wholly-owned subsidiary of H. Lundbeck A/S, is committed to providing innovative specialty therapies that fulfill unmet medical needs of people with

central nervous system (CNS) disorders and rare diseases for which few, if any, effective treatments are available. 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 2009, the company's revenue was DKK 13.7 billion (approximately EUR 1.8 billion or USD 2.6 billion). For more information, please visit www.lundbeck.com.

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Sources

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