FOR IMMEDIATE RELEASE

Post-Hoc Analysis of Open-Label Extension Study Assesses the use of ONFI® (clobazam) CIV and the Potential for Tolerance

Deerfield, Ill. September 28, 2016 – Results from a post-hoc analysis of an open-label extension (OLE) study evaluating the potential of developing tolerance to adjunctive ONFI (clobazam) CIV in patients with Lennox-Gastaut syndrome (LGS) were published online in Neurology. Tolerance can occur with repeated administration of a medication – resulting in diminished efficacy and the need for higher doses to maintain clinical effect. ONFI is a benzodiazepine indicated for adjunctive treatment of seizures associated with LGS in patients 2 years of age or older.

The post-hoc analysis was conducted to determine the change in mean dosages over the first two years of the OLE (OV-1004) study based on responder rates and baseline seizure quartiles in the Phase III lead-in Study (OV-1012). A dosage increase of greater than or equal to 40 percent, plus loss of response, was defined as tolerance for individual patients.

“LGS is a severe epilepsy syndrome that can persist over many years, and patients need treatment options that have demonstrated efficacy,” said Barry Gidal, PharmD, University of Wisconsin School of Pharmacy & Dept. of Neurology, and lead investigator of the post-hoc analyses. “One question that many clinicians have is whether antiepileptic drug therapy can lose effectiveness due to the development of pharmacologic tolerance. This study is important because it is the first to examine the potential of developing tolerance to ONFI.”

To read the full study, see the “Ahead of Print” section of the Neurology website. The study will also be published in the upcoming October print issue of Neurology.

Lundbeck initially presented results from this study at the American Epilepsy Society (AES) Annual Meeting in December, 2015.

About ONFI (clobazam) CIV
ONFI is an oral antiepileptic drug developed in the United States by Lundbeck, and is available in 10 and 20 mg tablets, and as a 2.5 mg/mL Oral Suspension. 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 GABAA receptor.¹

About Lennox-Gastaut syndrome
LGS is a rare and severe form of epilepsy that is typically diagnosed in childhood and often persists into adulthood.²,³ LGS is associated with multiple types of seizures, and daily seizures are common.³ 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.²

Use
ONFI (clobazam) CIV 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.

Important Safety Information

- Do not take ONFI if you have a known allergy to ONFI or its ingredients.
- ONFI can make you sleepy or dizzy, slow your thinking, and make you clumsy which may get better over time. Do not drive, operate heavy machinery, or do 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. ONFI may make your sleepiness or dizziness much worse.

- **ONFI can cause withdrawal symptoms.** Do not suddenly stop 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.**

- **Serious skin reactions have been seen with ONFI and may require stopping its use.** A serious skin reaction can happen at any time during your treatment with ONFI. Call your healthcare provider immediately if you have skin blisters, rash, sores in the mouth, hives or any other allergic reaction.

- **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 of depression, 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 over-the-counter medicines, vitamins, and herbal supplements. 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. Do not start or stop ONFI or other medicines without talking to your healthcare provider.

- ONFI oral suspension should be kept in its original bottle in an upright position and used within 90 days of first opening the bottle. After 90 days, safely throw away any unused ONFI oral suspension.

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

For more information, please see the full Prescribing Information, Medication Guide, and Instructions for Use.

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.

ONFI is a registered trademark of Lundbeck.

About Lundbeck
Lundbeck is a global pharmaceutical company specialized in psychiatric and neurological disorders. For more than 70 years, we have been at the forefront of research within neuroscience. Our key areas of research focus are depression, schizophrenia, Parkinson's disease and Alzheimer's disease.

An estimated 700 million people worldwide are living with psychiatric and neurological disorders and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with psychiatric and neurological disorders — we call this Progress in Mind.
Our approximately 5,000 employees in 55 countries are engaged in the entire value chain throughout research, development, manufacturing, marketing and sales. Our pipeline consists of several late-stage development programs and our products are available in more than 100 countries. We have research centers in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 14.6 billion in 2015 (EUR 2 billion; USD 2.2 billion).

In the U.S., Lundbeck employs nearly 1,000 people focused solely on accelerating therapies for brain disorders, including epilepsy. With a special commitment to the lives of patients, families and caregivers, Lundbeck U.S. actively engages in hundreds of initiatives each year that support our patient communities.

For additional information, we encourage you to visit our corporate site www.lundbeckus.com and connect with us on Twitter at @LundbeckUS.

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Sources


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