



FOR IMMEDIATE RELEASE

Lundbeck Announces Availability of NORTHERA™ (droxidopa) Capsules in the U.S. for Symptomatic Neurogenic Orthostatic Hypotension

Neurogenic Orthostatic Hypotension (NOH) is a Disorder Caused by an Underlying Neurologic Disease (e.g., Parkinson's Disease, Multiple System Atrophy or Pure Autonomic Failure)¹

Deerfield, Ill. September 2, 2014 – Lundbeck announced today that NORTHERA™ (droxidopa) capsules for oral use are now available for healthcare providers to prescribe in the United States. NORTHERA, a norepinephrine prodrug, was recently approved by the U.S. Food and Drug Administration, and is now available across the United States through a specialty pharmacy.²

NORTHERA is approved for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson’s disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond two weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically.³

NORTHERA is the only FDA-approved therapy for this condition and carries a boxed warning for supine hypertension. There are other serious risks associated with NORTHERA including hyperpyrexia and confusion, cardiovascular risk and allergic reactions. The most common adverse events in NORTHERA-treated patients in controlled clinical trials were headache, dizziness, nausea, and hypertension. For more information, please refer to the Important Safety Information below.³

“For people living with symptomatic NOH, the availability of NORTHERA may provide a new treatment option to discuss with their healthcare provider,” said Staffan Schüberg, president of Lundbeck in the U.S. “As a company with a long-standing and proven track record of working closely with smaller patient populations facing considerable unmet medical needs, we are passionate about delivering this needed therapy to patients and their families.”

Symptomatic NOH is a rare autonomic nervous system disorder associated with failure to release adequate amounts of norepinephrine upon standing.⁴ NOH is caused by an underlying autonomic neurologic disorder, such as Parkinson’s disease, multiple system atrophy, or pure autonomic failure.¹ Norepinephrine deficiency may result in an inability for a person to maintain adequate blood pressure and blood flow to the brain upon standing, resulting in dizziness, lightheadedness, and the “feeling that you are about to black out.”

“While the exact mechanism of action in the treatment of neurogenic orthostatic hypotension is unknown, NORTHERA is a prodrug that is directly metabolized to norepinephrine, the naturally occurring neurotransmitter of the sympathetic nervous system,”³ said Horacio Kaufmann, M.D., lead investigator of the NORTHERA pivotal trial. “I’m pleased that patients who have symptomatic NOH will now have another treatment option to discuss with their physician.”

“Our entire community of patients rallied to help ensure NORTHERA gained FDA approval, and we’re delighted that it’s now available throughout the U.S.,” said Judy Biedenharn, president of the Multiple System Atrophy (MSA) Coalition.

Commitment to Helping Eligible Patients Access NORTHERA

NORTHERA is available across the United States through a specialty pharmacy that is experienced in supporting people with rare disorders. Lundbeck has implemented comprehensive patient support programs to help ensure that all eligible patients, especially those with demonstrated economic need, have access to NORTHERA. To learn more about how to access NORTHERA, please contact Lundbeck’s NORTHERA Support Center services toll-free at 844-601-0101 (Monday through Friday from 8 AM to 8 PM ET) or visit www.NORTHERA.com.

Important Safety Information

WARNING: SUPINE HYPERTENSION

Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue NORTHERA.

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

- **Supine Hypertension:** NORTHERA therapy may cause or exacerbate supine hypertension in patients with NOH, which may increase cardiovascular risk if not well-managed.
- **Hyperpyrexia and Confusion:** Postmarketing cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported in Japan with NORTHERA use. Observe patients carefully when the dosage of NORTHERA is changed or when concomitant levodopa is reduced abruptly or discontinued, especially if the patient is receiving neuroleptics. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia,

muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.

- **Ischemic Heart Disease, Arrhythmias, and Congestive Heart Failure:** NORTHERA therapy may exacerbate symptoms in patients with existing ischemic heart disease, arrhythmias, and congestive heart failure.
- **Allergic Reactions:** This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

- The most common adverse reactions (greater than 5%) were headache, dizziness, nausea, hypertension, and fatigue.

DRUG INTERACTIONS

- Administering NORTHERA in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension. Dopa-decarboxylase inhibitors may require dose adjustments for NORTHERA.

USE IN SPECIFIC POPULATIONS

- Clinical experience with NORTHERA in patients with severe renal function impairment (GFR less than 30 mL/min) is limited. There are no adequate and well-controlled trials of NORTHERA in pregnant women. Women who are nursing should choose nursing or NORTHERA. The safety and effectiveness of NORTHERA in pediatric patients have not been established. No overall differences in safety or effectiveness were observed between subjects aged 75 years and older and younger subjects in clinical trials, but greater sensitivity of some older individuals cannot be ruled out.

For more information, please see the accompanying full [Prescribing Information](#), including Boxed Warning, visit www.NORTHERA.com, or call toll-free at 844-601-0101.

About NORTHERA

NORTHERA is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic NOH caused by primary autonomic failure (Parkinson’s disease, multiple system atrophy and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond two weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically.³

Lundbeck is committed to the further study of NORTHERA including a long-term, phase IV, multi-center, placebo-controlled, randomized study. Lundbeck acquired NORTHERA as part of its acquisition of Chelsea Therapeutics, which was completed on June 23, 2014. Droxidopa was initially developed by Dianippon Sumitomo Pharma Co., Ltd. (DSP) and first commercialized in Japan in 1989.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to helping people living with brain diseases. 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, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of DKK 15.3 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site www.lundbeck.com.

About Lundbeck in the U.S.

Lundbeck in the U.S., headquartered in Deerfield, Illinois, is a wholly-owned subsidiary of H. Lundbeck A/S in Denmark. Globally, our mission is to help people suffering from psychiatric and neurologic disorders. To drive this mission in the U.S., nearly 800 employees are engaged in the research, development, production, marketing and sale of innovative specialty therapies that fulfill unmet medical needs. We see the person behind the disease and how it affects the lives of patients, families and caregivers. Lundbeck is actively involved with hundreds of local and national U.S. events each year that support our patient communities. To learn more, visit us at www.LundbeckUS.com and connect with us on Twitter at @LundbeckUS.

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Sources

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2. United States Food and Drug Administration. Press Release. FDA approves Northera to treat neurogenic orthostatic hypotension. February 18, 2014.
3. NORTHERA Full Prescribing Information. Deerfield, IL: Lundbeck. August 2014.
4. Freeman R, Wieling W, Axelrod FB, et al. Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome. *Clin Auton Res.* 2011;21:69-72.

NORTHERA is a trademark of Lundbeck NA Ltd.

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