ADDITIONAL RESOURCES

FOR THOSE WITH NEUROGENIC OH AND PARKINSON'S DISEASE, MULTIPLE SYSTEM ATROPHY, OR PURE AUTONOMIC FAILURE:

LUNDBECK
lundbeckus.com

MICHAEL J. FOX TRIAL FINDER
foxtrialfinder.michaeljfox.org

CLINICALTRIALS.GOV
clinicaltrials.gov

PARKINSON'S DISEASE TRIALS
pdtrials.org

NATIONAL PARKINSON'S FOUNDATION
parkinson.org

THE MULTIPLE SYSTEM ATROPHY COALITION®
multiplesystematrophy.org

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS & STROKE
ninds.nih.gov

RESTORE
STUDY NOH402

WHY ENROLL

IN THIS NEUROGENIC OH CLINICAL TRIAL?

Clinical trials are a part of research and are at the heart of all medical advances. Although NORTHERA® has been approved by the FDA, more information about the long term effectiveness of this treatment is needed. By participating in this clinical trial you will play an important role in the discovery of additional information about this medication, which will be helpful to the treatment of patients with neurogenic OH in the future.

RESTORE
STUDY NOH402

April 2017

ATTENTION PATIENTS WITH:

PARKINSON'S DISEASE, MULTIPLE SYSTEM ATROPHY, OR PURE AUTONOMIC FAILURE

Do You Often Feel Dizzy, Lightheaded, Feel Like You Might Faint or "Black Out"?

Do Your Symptoms Appear When You Stand Up or Have Been Standing For Some Time, and Improve When You Sit down or Lie Down?

RESTORE
STUDY NOH402

YOU MAY BE ELIGIBLE FOR AN IMPORTANT CLINICAL TRIAL TO STUDY THE LONG-TERM EFFECTIVENESS OF AN FDA APPROVED DRUG!

WHAT IS **NEUROGENIC ORTHOSTATIC HYPOTENSION?**

Neurogenic orthostatic hypotension (or NOH) is low blood pressure (hypotension) that occurs upon standing (orthostatic). This can affect people with certain neurologic conditions, including:

- Parkinson's disease (PD)
- Multiple system atrophy (MSA)
- Pure autonomic failure (PAF)
- Dopamine Beta Hydroxylase (DBH) Deficiency
- Non-Diabetic Autonomic Neuropathy (NDAN)

THOSE SUFFERING FROM NOH MAY EXPERIENCE SYMPTOMS SUCH AS:

- Dizziness, lightheadedness, feeling faint or feeling as though the individual might black out
- Problems with vision (blurring, seeing spots, tunnel vision, etc.)
- Weakness
- Fatigue
- Trouble concentrating
- Head/neck discomfort (often described as coat-hanger pain)

For many with NOH, these symptoms are persistent and are often disabling because they interfere with everyday activities like standing and walking.

WHO CAN PARTICIPATE **IN THIS CLINICAL TRIAL?**

To participate in this clinical trial you must meet certain criteria, including:

- At least 18 years of age
- Have NOH associated with PD, MSA, PAF, DBH Deficiency or NDAN
- Do not have a diagnosis of hypertension (high blood pressure) that requires treatment with medications to lower your blood pressure
- Do not have a history of myocardial infarction (heart attack) or stroke within the past two years
- Do not have a history of cancer in the last two years
- Do not have congestive heart failure

Individuals currently taking NORTHERA® prescribed by their doctor are eligible to participate.

QUALIFIED STUDY PARTICIPANTS WILL:

- Attend up to 15 visits at the trial site and participate in 3 visits via telephone. The study will last up to a maximum of 36 weeks
- Receive study-related medical exams and study drug throughout the study at no cost.
- Complete questionnaires about their nOH symptoms during site visits
- Provide blood draws and urine samples for laboratory tests

WHAT DRUG IS BEING STUDIED **IN THIS CLINICAL TRIAL?**

In 2014, the U.S. Food and Drug Administration (FDA) approved the study drug (NORTHERA® also known as droxidopa) for, "the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic OH caused by...Parkinson's disease, multiple system atrophy, pure autonomic failure, dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of NORTHERA should be assessed periodically." The purpose of the current trial is to assess the effectiveness of the study drug to treat symptoms of NOH over a longer period of time.

All participants will receive the study drug for up to 16 weeks during the "open-label" portions of the study. This will help your study doctor determine your optimal dose of study drug. Participants will then receive either the study drug or a matching placebo during the 12-week, "double-blind" portion of the trial (a placebo is a pill that contains no active drug;"double-blind" means that neither you nor the study doctor will know if you are taking the study drug or placebo).