



Chelsea Therapeutics to Discuss NORTHERA(TM) (droxidopa) NDA for the Treatment of Symptomatic Neurogenic OH at FDA Advisory Committee Meeting on February 23

Chelsea and FDA Briefing Materials Now Available Online

CHARLOTTE, N.C., Feb. 21, 2012 (GLOBE NEWSWIRE) -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) will meet with the Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) on Thursday, February 23, 2012 to review clinical data in support of the New Drug Application (NDA) for NORTHERA™ (droxidopa). Chelsea is seeking approval of NORTHERA for the treatment of symptomatic neurogenic orthostatic hypotension (known as Neurogenic OH) in patients with primary autonomic failure (Parkinson's disease, multiple system atrophy and pure autonomic failure), dopamine beta hydroxylase deficiency and non-diabetic autonomic neuropathy.

Chelsea and FDA briefing materials are now available online at www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm285415.htm.

"We have closely reviewed the materials prepared by the FDA, and look forward to presenting our clinical data to the Advisory Committee, which we believe will address the questions raised by the FDA," commented Dr. Simon Pedder, President and CEO of Chelsea Therapeutics. "We believe that our clinical program has established robust safety and efficacy data for NORTHERA in this patient population."

Chelsea will host a conference call following the conclusion of the CRDAC meeting to discuss the outcome with shareholders and members of the investment community. Details will be available on the Chelsea Therapeutics website.

The NDA for NORTHERA was submitted on September 28, 2011 and a Prescription Drug User Fee Act (PDUFA) action date has been scheduled for March 28, 2012. NORTHERA was previously granted Orphan Drug Designation, which is granted by the FDA to treatments for rare diseases.

About Neurogenic Orthostatic Hypotension

Neurogenic OH is a chronic neurogenic disorder resulting from deficient release of norepinephrine, the neurotransmitter used by sympathetic autonomic nerves to send signals to the blood vessels and the heart to regulate blood pressure. This deficiency results in lightheadedness, dizziness, blurred vision, fatigue, poor concentration and fainting episodes when a person assumes a standing position. Symptoms of chronic Neurogenic OH can be incapacitating, not only putting patients at high risk for falls and associated injuries, but also severely affecting the quality of life of patients.

About NORTHERA™ (droxidopa)

NORTHERA™ (droxidopa), the lead investigational agent in Chelsea Therapeutics' pipeline, has been studied in two Phase III clinical trials for the treatment of symptomatic neurogenic orthostatic hypotension in patients with primary autonomic failure -- a group of diseases that includes Parkinson's disease, multiple system atrophy (MSA) and pure autonomic failure (PAF). Droxidopa is a synthetic catecholamine that is directly converted to norepinephrine (NE) via decarboxylation, resulting in increased levels of NE in the nervous system, both centrally and peripherally. Droxidopa previously demonstrated clinical benefits in treating both intradialytic hypotension and adult attention deficit hyperactivity disorder in Phase II trials and is currently being evaluated in an ongoing Phase II trial for the treatment of fibromyalgia.

About Chelsea Therapeutics

Chelsea Therapeutics is a biopharmaceutical development company that acquires and develops innovative products for the treatment of a variety of human diseases. Chelsea's most advanced drug candidate, NORTHERA™ (droxidopa), is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. In addition to Droxidopa, Chelsea is also developing a portfolio of metabolically inert oral antifolate molecules engineered to have potent anti-inflammatory and anti-tumor activity to treat a range of immunological disorders, including two clinical stage product candidates: CH-1504 and CH-4051. Preclinical and clinical data suggest superior safety and tolerability, as well as increased potency versus methotrexate (MTX).

This press release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include risks and costs of drug development, risk of regulatory approvals, our reliance on our lead drug candidates droxidopa and CH-4051, reliance on collaborations and licenses, intellectual property risks, our need to raise additional operating capital in the future, our history of losses, competition, market acceptance for our products if any are approved for marketing, and reliance on key personnel including specifically Dr. Pedder.

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