



Chelsea Therapeutics Achieves Target Enrollment in Phase III Trial of Northera in Neurogenic Orthostatic Hypotension

- **Top-line Data Expected in Q3 10**

CHARLOTTE, N.C., June 30, 2010 -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) has successfully reached its target enrollment of 150 patients in its Northera™ (Droxidopa) pivotal Phase III Study 301 for the treatment of symptomatic, neurogenic orthostatic hypotension (NOH). Results from the trial are expected in September 2010 and the full registration program is on track to initiate a new drug application (NDA) in the first half of 2011.

NOH is a disorder of the nervous system resulting from a deficient release of norepinephrine, the neurotransmitter used by sympathetic autonomic nerves to send signals to the blood vessels and the heart. This deficiency results in lightheadedness, dizziness, blurred vision and fainting episodes when a person assumes a standing position. Northera, an oral compound which the body converts directly to norepinephrine, is the only therapeutic treatment to specifically target the underlying cause of NOH: norepinephrine deficiency.

"We are delighted to have reached our target enrollment in Study 301 and are confident the trial will capture the full therapeutic benefit of Northera in symptomatic NOH," commented Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. "We are grateful to all the clinicians and patients for their continued strong support and participation in this trial. We look forward to seeing the top-line results from this trial in September and continuing to work with the clinical investigators and their staff throughout the year to complete our other on-going Phase III trial and file a new drug application next year."

Study 301 was reviewed by the U.S. Food and Drug Administration (FDA) and awarded a Special Protocol Assessment (SPA) in February 2008. The FDA subsequently confirmed that the SPA remained in effect following the protocol amendments approved by the FDA late last year. An SPA provides a binding agreement that the study design, including trial size, clinical endpoints and/or data analyses is acceptable to support regulatory approval.

In addition to the SPA, the FDA has awarded Chelsea Fast Track designation for its pivotal program in NOH. Fast Track designation is designed to facilitate the review of products that address serious or potentially life-threatening conditions for which there is an unmet medical need and provides the option to file a New Drug Application (NDA) on a rolling basis. This permits the FDA to review the filing as it is received, expediting the review process.

About Neurogenic Orthostatic Hypotension

NOH is a 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 decreased blood pressure when a person assumes a standing position and is characterized by lightheadedness, dizziness, and fainting episodes. Symptoms of chronic NOH can be incapacitating -- not only putting patients at high risk for falls and associated injuries and generating significant health care costs -- but also severely affecting the quality of life of patients and their loved ones. The only FDA-approved treatment for orthostatic hypotension has a black box warning indicating that the drug has not been shown to be effective in alleviating the symptoms of the condition and is associated with a pronounced side-effect profile including significant supine hypertension.

About Northera™

Northera (Droxidopa), the lead investigational agent in Chelsea Therapeutics' broad pipeline, is currently in Phase III clinical trials for the treatment of symptomatic neurogenic orthostatic hypotension (NOH) 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 is also being studied for the treatment of fibromyalgia in an ongoing phase II trial and completed a phase II trial in intradialytic hypotension (IDH) study with positive results.

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 Northera, 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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