



Chelsea Therapeutics Completes Enrollment in Phase II Trial of Droxidopa in Intradialytic Hypotension

Top Line Data Expected in First Quarter 2009

CHARLOTTE, N.C., Nov. 19, 2008 -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) has completed patient enrollment in its Phase II trial of Droxidopa, an orally active synthetic precursor of norepinephrine, in patients with intradialytic hypotension (IDH).

The multi-center, double-blind, placebo controlled trial is a dose response study comparing 400mg and 600mg of Droxidopa to placebo in a total of 75 patients. Following a two-week run-in period to establish baseline, patients in this 3-arm study will receive a single oral dose of Droxidopa or placebo 1 hour prior to each dialysis treatment over a four-week period (approximately 12 dialysis sessions). The study will compare the change in mean blood pressure and symptomatic improvement during the final two weeks of treatment to baseline established prior to drug treatment.

"We believe that by alleviating not only the serious adverse events and complications associated with intradialytic hypotension, but also potentially decreasing the repetition of dialysis sessions experienced by these patients, Droxidopa could become a valuable part of the treatment paradigm for the growing number of patients undergoing dialysis each year," commented Dr. Simon Pedder, Chelsea's President and Chief Executive Officer. "We are very pleased to have now completed enrollment in this Phase II study and look forward to the final results which should provide not only confirmation of the efficacy demonstrated in prior Japanese trials, but provide the specific data from which to determine the optimal dose for future development. We expect that treatment of patients will still be ongoing in this Phase II trial through December, and therefore data from all treated patients will be available during the first quarter of 2009."

Droxidopa is the Company's most advanced investigational product and is currently in development for the treatment of neurogenic orthostatic hypotension (NOH) as its lead indication. Chelsea plans to seek its first marketing approval for Droxidopa in NOH following the completion of its pivotal Phase III program in mid 2009.

About Droxidopa and Intradialytic Hypotension (IDH)

Intradialytic hypotension, or IDH, is the most common adverse event during routine hemodialysis. IDH is characterized by an abrupt decline in blood pressure (BP) greater than or equal to 30 mm Hg (normal or hypertensive patients predialysis) or predialysis systolic BP less than 100 mm Hg with a decrease during dialysis of less than 30mm HG. Symptoms may include visual complaints, cramping, and nausea. Vascular complications include cerebral infarction, cardiac ischemia, vascular access thrombosis, nonocclusive mesenteric ischemia and arrhythmias. IDH has been reported in approximately 15 - 25% of all hemodialysis patients, with elderly patients reporting higher incidences. These complications can interrupt dialysis sessions, resulting in insufficient uremia toxin removal and necessitating repetition of the procedure. Interruptions due to IDH increase the costs of both the dialysis treatment sessions and the long-term care of less healthy hemodialysis patients.

Pivotal clinical studies conducted by Dainippon Sumitomo Pharmaceuticals (DSP) have demonstrated the efficacy of Droxidopa in the treatment of vertigo, dizziness and weakness associated with hypotension in hemodialysis patients. Subsequently, in 2000, after showing benefit in clinical trials, DSP received expanded marketing approval in Japan for this indication.

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. The Company is currently developing a library of metabolically inert antifolate compounds engineered to have potent anti-inflammatory and anti-tumor activity to treat a range of immunological disorders. Early clinical data suggests that Chelsea's lead antifolate compound, CH-1504, is a safe and effective treatment alternative to methotrexate for RA and may have further applications for psoriasis, IBD and certain cancers. Chelsea's antifolate program is complemented by the development of the I-3D portfolio of therapeutics targeting immune-mediated inflammatory disorders and transplantation. In addition to its autoimmune pipeline, Chelsea is developing Droxidopa, an orally active synthetic precursor of norepinephrine, for the treatment of neurogenic orthostatic hypotension. Currently approved and marketed in Japan, Droxidopa has accumulated over 15 years of proven safety and efficacy, historically generating annual revenues of approximately \$50 million in Japan.

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 reliance on collaborations and licenses, risks and costs of drug development, regulatory approvals, intellectual property risks, our reliance on our lead drug candidate, our history of losses and need to raise more money, competition, market acceptance for our products if any are approved for marketing, reliance on key personnel including specifically Dr. Pedder, management of rapid growth, and the need to acquire or develop additional products.

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