



Chelsea Therapeutics Receives Notice of Allowance of Key U.S. Patent for Novel, Controlled Release Formulation of Northera(TM)

Patent Offers Protection of Once-A-Day Formulation Until at Least 2026

CHARLOTTE, N.C., Dec. 15, 2011 (GLOBE NEWSWIRE) -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) received a notice of allowance from the U.S. Patent & Trademark Office (USPTO) for its patent application "Threo-DOPS Controlled Release Formulation," U.S. Patent Application Number 11/698,974. Upon issuance, the patent will expire no earlier than 2026.

The newly allowed claims relate to certain oral, controlled release formulations of Northera™ (droxidopa) that include an extended release component and an immediate release component. The patent will establish protection for a once-a-day Northera beyond the seven-year marketing exclusivity afforded by its orphan designation in the U.S., enabling Chelsea to pursue the therapeutic development of Northera in indications expected to benefit from a controlled release formulation.

"This patent allowance notice from the USPTO provides key support for the intellectual property protection we are building for Northera," said Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. "This latest patent could provide significant growth opportunities for Chelsea, as we investigate additional, potential therapeutic applications of Northera which is currently under review at the FDA for the treatment of symptomatic, neurogenic orthostatic hypotension and has a PDUFA date of March 28, 2012."

This notice of allowance marks the second major milestone for the Company's intellectual property pursuits this year. In August 2011, the United States Patent and Trademark Office issued U.S. Patent No. 8,008,285 entitled "Droxidopa and pharmaceutical composition thereof for the treatment of fibromyalgia." The claims of the patent are related to methods of reducing pain associated with fibromyalgia by administering droxidopa alone, or in combination with other specified medications, to patients diagnosed with fibromyalgia.

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 (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 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 risk of regulatory approvals; risks and costs of drug development, including the uncertainty of cost, timing and outcome of clinical trials; our need to raise operating capital; our reliance on our lead drug candidates droxidopa and CH-4051; our history of losses; reliance on collaborations and licenses; intellectual property risks; 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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