



Chelsea Therapeutics Announces Update on Antifolate Clinical Program

CHARLOTTE, N.C., June 9, 2010 -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) announced that during a teleconference yesterday, the U.S. Food and Drug Administration (FDA) requested that the company delay the initiation of its proposed Phase II clinical study of CH-4051 in rheumatoid arthritis and indicated that the agency is requesting additional detail from the preclinical studies previously submitted as part of the company's investigational new drug (IND) application. Chelsea anticipates specific written comments from the FDA in the next few weeks, but expects the data requested should be readily available, should not require additional studies and could be provided to the agency shortly after receiving the written response.

"The FDA has provided us with verbal feedback regarding our protocol submission and asked for additional detail from our previously conducted preclinical studies to more fully characterize the safety of our proposed Phase II doses of CH-4051," commented Dr. Simon Pedder, president and CEO of Chelsea Therapeutics. "Having conducted comprehensive preclinical and Phase I evaluations of CH-4051 that support the safety and tolerability of CH-4051 at the proposed doses, we believe we will be able to provide the necessary supportive data to the FDA in a timely fashion."

As previously reported, results from Chelsea's Phase I single and multiple ascending dose studies demonstrated that CH-4051 was well tolerated at doses up to and including 7.5mg, a dose range likely to be effective for multiple autoimmune disorders. The 5mg dose was as well tolerated as placebo. High doses of CH-4051 demonstrated mostly mild toxicities, with the 10mg and 20mg doses groups reporting both gastrointestinal side-effects and reversible liver enzyme elevations. No serious adverse events occurred during the study. Chelsea's proposed Phase II trial of CH-4051 is intended to evaluate up to 3.0 mg daily oral doses of CH-4051 in a 12-week, head-to-head study against 20.0 mg weekly oral doses of methotrexate in rheumatoid arthritis patients that have previously demonstrated an inadequate response to methotrexate treatment.

Chelsea's program evaluating Northera™ (droxidopa) in neurogenic orthostatic hypotension remains on track with Phase III data from Study 301 expected in the 3rd Quarter. The company also plans to begin dosing in its confirmatory Phase III Northera Study 306 this month.

About CH-4051

CH-4051 is the L-isomer of CH-1504 and second drug candidate from Chelsea's portfolio of orally bioavailable, non-metabolized antifolates. Both are orally available molecules with anti-inflammatory, autoimmune and anti-tumor properties that potently inhibit dihydrofolate reductase, an enzyme required for cell proliferation. Preclinical and clinical data to date suggests superior safety and tolerability, as well as increased potency versus methotrexate, or MTX, currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases. Diseases that may potentially be treated with these compounds include rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis, uveitis, psoriatic arthritis and several different kinds of cancer.

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, 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, our need to raise operating capital, 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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