



NeoPharm Presents the Phase II Data of Liposome-Entrapped Paclitaxel (LEP) in Patients with Metastatic Breast Cancer

LAKE BLUFF, Ill., Jan 06, 2010 (BUSINESS WIRE) -- NeoPharm, Inc. (Other OTC: NEOL.PK) today announced the results of a Phase II clinical trial of Liposome-Entrapped Paclitaxel (LEP) an active component of Taxol(R). This multicenter, open-label trial of LEP was conducted at 5 centers in India.

Thirty-five subjects were enrolled and received LEP doses of 275 mg/m² administered over 90 minutes every 21 days without routine prophylactic pre-medication for infusion-related reactions. Subjects received a median of 6 cycles (range 2 to 10) with 22 subjects receiving greater-than or equal to 6 cycles. Overall tumor responses with fully audited data were as follows: 16 subjects (46%) with tumor response including 15 partial responses and one complete response; 10 subjects (29%) with stable disease (mean duration, 6 cycles; range, 2-10 cycles); 9 subjects (25%) with progressive disease. LEP was well tolerated with sensory polyneuropathy greater-than or equal to grade 3 in only one subject (3%) and neutropenia greater-than or equal to grade 3 in 2 subjects (6%), two common toxicities of Taxol(R) and Abraxane(R). No significant infusion-related reactions were observed as indicated by adverse events or prophylactic pre-medication use.

Dr. Aquilur Rahman, President and Chief Executive Officer of NeoPharm commented, "We are very pleased with the high radiographic tumor response rate of LEP in this population of metastatic breast cancer patients as well as the safety profile of LEP. A response rate of 46% (partial and complete responses) is quite noteworthy in this heavily pretreated patient population with advanced breast cancer. In addition, if responses and stable disease are considered together the potential clinical benefit may extend to 75% of patients. Although LEP response rate needs to be replicated in randomized controlled studies it compares quite favorably to Taxol(R) and Abraxane(R) study results in metastatic breast cancer patients with response rates of 11% and 21% respectively. We continue to evaluate whether to extend Phase II trials of LEP or to start a Phase III randomized trial with free Taxol(R) as a comparator arm in metastatic breast cancer patients. Our goal is to be able to embark on the path of regulatory approval of LEP as an effective modality for the treatment of cancer patients as early as possible"

About NeoPharm, Inc.

NeoPharm, Inc., based in Lake Bluff, Illinois, is a publicly traded biopharmaceutical company dedicated to the research, development and commercialization of new and innovative cancer and other drugs for therapeutic applications. Additional information, including ongoing clinical trials, can be obtained by visiting NeoPharm's Web site at www.NeoPharm.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "projects," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to, any statements relating to the Company's drug development programs, the initiation, progress, and outcomes of clinical trials of the Company's drug product candidates including, but not limited to LEP, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, risks and uncertainties relating to difficulties or delays that may arise in the development, testing, regulatory approval, production, and marketing of the Company's drug and non-drug compounds, including, but not limited to, LEP, the Company's possible need to reduce its funding of certain of its development projects in order to conserve its cash resources, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug product candidates, including, but not limited to, LEP, that could slow or prevent products coming to market, uncertainty regarding the Company's ability to commercialize any of its drug product candidates, including, but not limited to, LEP, and other risks of the type previously detailed from time to time in filings the Company formerly made with the Securities and Exchange Commission ("SEC"). Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release. At the Company's request, the Company's obligation to file reports with the SEC was suspended effective February 12, 2009. For the foregoing reasons, you should not rely on these forward-looking statements or our previously filed SEC reports as a prediction of actual future results.

SOURCE: NeoPharm, Inc.

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