

EntreMed's MKC-1 Meets Primary Efficacy Endpoint in Non-Small Cell Lung Cancer Clinical Trial

Phase 2 Randomized Study Under Consideration

ROCKVILLE, Md., November 10, 2008 - EntreMed, Inc. (Nasdaq: ENMD), a clinical-stage pharmaceutical company developing therapeutics for the treatment of cancer and inflammatory diseases, today announced that it has met the primary endpoint for the efficacy portion of the open label Phase 1/2 study of MKC-1 in combination with pemetrexed (Alimta(R)) in non-small cell lung cancer patients.

The Phase 1/2 study was designed to first evaluate a dose of MKC-1 to be used safely in combination with Alimta(R) to treat patients with advanced NSCLC. Patients were subsequently enrolled into the Phase 2 portion where the primary endpoint was tumor response. The primary endpoint has been met and EntreMed is considering options for further studies in NSCLC patients. Options include the continuation of the current single arm study or a randomized Phase 2 study in the same patient population.

MKC-1 is a novel, orally-active cell cycle inhibitor with in vitro and in vivo efficacy against a broad range of human solid tumor cell lines, including multi-drug resistant cell lines. Data from previous studies with MKC-1 demonstrate broad-acting antitumor effects, showing tumor growth inhibition or regression in multiple preclinical models, including paclitaxel-resistant models.

MKC-1 has been shown to inhibit mitotic spindle formation, prevent chromosome segregation in the M-phase (mitosis) of the cell cycle, and induce apoptosis. Furthermore, MKC-1 inhibits the Akt-mTOR signaling pathways, which may occur through inhibition of the mTOR/ricin pathway. The Akt-mTOR pathway is the most frequently mutated pathway in human tumors and mutations have been shown to promote tumor progression and decrease survival in cancer patients. EntreMed Vice President and Chief Medical Officer, Carolyn F. Sidor, M.D., M.B.A., commented on the study, "We are pleased to have met the primary efficacy endpoint in the first stage of this study. We are now considering whether to continue the current study or pursue additional options such as a randomized Phase 2 study in patients with non-small cell lung cancer. We will continue to collect data over the next few months from patients participating in this trial to determine the most efficient path forward in this indication."

Alimta(R) is a registered trademark of its owner and is not a registered trademark of EntreMed, Inc.

About EntreMed

EntreMed, Inc. is a clinical-stage pharmaceutical company developing therapeutic candidates primarily for the treatment of cancer and inflammation. MKC-1, an oral cell-cycle regulator with activity against the mTOR pathway, is currently in multiple Phase 2 clinical trials for cancer. ENMD-2076, a selective angiogenic kinase inhibitor, and ENMD-1198, a novel antimetabolic agent are in Phase 1 studies in advanced cancers. The Company also has an approved IND application for Panzem(R) in rheumatoid arthritis. EntreMed's goal is to develop and commercialize new compounds based on the Company's expertise in angiogenesis, cell cycle regulation, cell signaling and inflammation — processes vital to the treatment of cancer and other diseases, such as rheumatoid arthritis. Additional information about EntreMed is available on the Company's web site at www.entremed.com and in various filings with the Securities and Exchange Commission.

Forward Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act with respect to the outlook for expectations for future financial or business performance (including the timing of royalty revenues and future R&D expenditures), strategies, expectations and goals. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and no duty to update forward-looking statements is assumed. Actual results could differ materially from those currently anticipated due to a number of factors,

including those set forth in Securities and Exchange Commission filings under "Risk Factors," including risks relating to the need for additional capital and the uncertainty of additional funding; variations in actual sales of Thalomid(R), risks associated with the Company's product candidates; the early-stage products under development; results in preclinical models are not necessarily indicative of clinical results, uncertainties relating to preclinical and clinical trials; success in the clinical development of any products; dependence on third parties; future capital needs; and risks relating to the commercialization, if any, of the Company's proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks).

Article printed from EntreMed, Inc.: <http://www.entremed.com>

URL to article: <http://www.entremed.com/news/entremeds-mkc-1-meets-primary-efficacy-endpoint-in-non-small-cell-lung-cancer-clinical-trial/>