



## **EpiCept Announces Ceplene(R) Included in Swedish AML Medical Guidelines**

### ***First Official Endorsement by Medical Community***

TARRYTOWN, N.Y., Jan 26, 2010 (BUSINESS WIRE) -- Regulatory News:

EpiCept Corporation (Nasdaq and OMX Stockholm Exchange: EPCT) announced today that the Swedish AML Group which comprises the leading hematology experts in Sweden has included Ceplene<sup>(R)</sup> (histamine dihydrochloride) in its Guidelines entitled "National Guidelines for Diagnosis and Treatment of Acute Myeloid Leukemia in Adults." These guidelines, which were issued earlier this month, recommend for the first time the inclusion of Ceplene for AML remission maintenance therapy. Ceplene plus low-dose interleukin (IL-2) is indicated for remission maintenance and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML) in first remission by the European Medicines Evaluation Agency (EMA).

Earlier this month, EpiCept entered into an exclusive commercialization agreement for Ceplene with Meda AB, (OMX Stockholm Exchange: MEDA-A-ST) a leading international specialty pharmaceutical company based in Stockholm. Meda is expected to launch Ceplene this year.

"The issuance of these medical guidelines is a significant step forward in recognizing the importance of Ceplene plus IL-2 as a remission maintenance therapy for patients suffering from AML in Europe, as it raises the awareness among physicians for this life-saving medicine," remarked Jack Talley, President and CEO of EpiCept. "Ceplene will be able to be utilized without restrictions upon its commercial launch by Meda, while in the meantime it is available through the Named Patient Program at Idis. The guidelines also make reference to our ongoing Phase IV study, a post-approval clinical study. This study is intended to further demonstrate the clinical pharmacology of Ceplene by assessing certain immunologic biomarkers in AML patients in first remission, and to measure the effect of Ceplene/IL-2 on minimal residual disease in the same patient population. Secondary objectives will assess leukemia-free survival after a follow-up period of up to two years," Mr. Talley added. EpiCept intends to work with the European Leukemia Net (ELN) and other national authorities in Europe along with Meda to incorporate Ceplene into AML practice guidelines consistent with the approved labeling.

### **About Ceplene**

Ceplene is indicated for remission maintenance therapy and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML). Ceplene is used together with low dose Interleukin-2. AML is one of four major types of leukemia. The prevalence for AML in the EU is about 41,000 patients and over 16,000 new cases are diagnosed every year. While current induction and consolidation treatments are successful in inducing complete remission for the majority of AML patients, this remission is generally short-lived. After achieving complete remission most patients will suffer a relapse within one year. In an international, multicenter, open-label, randomized phase III study, Ceplene met its primary endpoint of prolonging leukemia-free survival for AML patients in remission. The difference between the treated and control group was highly statistically significant ( $p < 0.008$ ).

### **About EpiCept Corporation**

EpiCept is focused on the development and commercialization of pharmaceutical products for the treatment of cancer and pain. The Company's lead product is Ceplene, which has been granted full marketing authorization by the European Commission for remission maintenance and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML) in first remission. The Company has two oncology drug candidates currently in clinical development that were discovered using in-house technology and have been shown to act as vascular disruption agents in a variety of solid tumors. The Company's pain portfolio includes EpiCept(TM) NP-1, a prescription topical analgesic cream in late-stage clinical development designed to provide effective long-term relief of pain associated with peripheral neuropathies.

### **Forward-Looking Statements**

This news release and any oral statements made with respect to the information contained in this news release contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements which express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Factors that may cause actual results or

developments to differ materially include: the risk that Ceplene will not receive regulatory approval or marketing authorization in the United States or Canada, the risk that Ceplene will not be launched or achieve significant commercial success, the risk that any required post-approval clinical study for Ceplene will not be successful, the risk that we will not be able to maintain our final regulatory approval or marketing authorization for Ceplene, the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern, the risks associated with our ability to continue to meet our obligations under our existing debt agreements, the risk that our securities may be delisted by The Nasdaq Capital Market and that any appeal of the delisting determination may not be successful, the risk that Myriad's development of Azixa(TM) will not be successful, the risk that Azixa(TM) will not receive regulatory approval or achieve significant commercial success, the risk that we will not receive any significant payments under our agreement with Myriad, the risk that the development of our other apoptosis product candidates will not be successful, the risk that we will not be able to find a buyer for our ASAP technology, the risk that clinical trials for EpiCept™ NP-1 or crinobulin will not be successful, the risk that EpiCept(TM) NP-1 or crinobulin will not receive regulatory approval or achieve significant commercial success, the risk that we will not be able to find a partner to help conduct the Phase III trials for EpiCept(TM) NP-1 on attractive terms, a timely basis or at all, the risk that our other product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later stage clinical trials, the risk that we will not obtain approval to market any of our product candidates, the risks associated with dependence upon key personnel, the risks associated with reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates; the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process; our history of operating losses since our inception; the highly competitive nature of our business; risks associated with litigation; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in our periodic reports, including our reports on Forms 8-K, 10-Q and 10-K and other filings with the U.S. Securities and Exchange Commission. You are urged to carefully review and consider the disclosures found in our filings which are available at [www.sec.gov](http://www.sec.gov) or at [www.epicept.com](http://www.epicept.com). You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors.

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