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## **EPICEPT IDENTIFIES CEPLENE<sup>®</sup> SURVIVAL BENEFIT IN KEY AML SUBGROUP FILES NEW PATENT APPLICATIONS FOR CEPLENE<sup>®</sup> IN AML OF MONOCYTE ORIGIN**

**TARRYTOWN, N.Y. (March 3, 2011)** – EpiCept Corporation (Nasdaq and Nasdaq OMX Stockholm Exchange: EPCT) today announced the Company has identified a statistically significant survival benefit in a subgroup of Acute Myeloid Leukemia (AML) patients in its previous Phase III trial with Ceplene<sup>®</sup> (histamine dihydrochloride) administered with low-dose interleukin-2 (IL-2). The identification of this subgroup is expected to influence the design of the protocol for a new Phase III trial to support resubmission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA). Ceplene<sup>®</sup> is approved in the European Union and Israel for the remission maintenance and prevention of relapse in adult patients with AML in first remission.

In October 2010 EpiCept reached an agreement with the FDA on a regulatory path for a resubmission of the Ceplene<sup>®</sup> NDA. Under the agreement, EpiCept intends to undertake a new confirmatory clinical trial to demonstrate Ceplene<sup>®</sup>'s benefit with overall survival as the primary endpoint.

As part of its clinical trial protocol preparations for the Ceplene<sup>®</sup> pivotal study, EpiCept conducted an additional analysis of AML subgroups from its previous Phase III study of Ceplene<sup>®</sup>. While that study was not powered to determine overall survival, EpiCept's analysis has identified that patients with AML of monocyte origin achieved a statistically significant increase in overall survival after treatment with Ceplene<sup>®</sup> plus low-dose IL-2. Furthermore, this analysis identified a strong correlation between the administration of high-intensity consolidation treatment, and improvements in overall survival.

EpiCept has applied these findings in the development of the clinical trial protocol and is currently reviewing the protocol with key opinion leaders in hematology. The Company expects

to submit this protocol to the FDA in the second quarter of 2011, following which the FDA, via the Special Protocol Assessment procedure, will provide guidance on specific sections of the protocol. Based on this anticipated schedule, EpiCept expects to initiate the trial in the second half of 2011.

EpiCept also announced that it has submitted additional U.S. and global patent applications based on the discoveries of the efficacy of Ceplene<sup>®</sup> plus IL-2 in AML of monocyte origin. The Company believes that these provisional patents, if granted, would provide an additional 20 years of market exclusivity for Ceplene<sup>®</sup> from the date of patent filing.

### **About Ceplene<sup>®</sup>**

Ceplene<sup>®</sup> is approved in the European Union and Israel and is indicated for remission maintenance therapy and prevention of relapse in adult patients with AML, one of four types of leukemia. Ceplene<sup>®</sup> is used together with low-dose Interleukin-2. The prevalence for AML in the EU is about 41,000 patients and more than 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<sup>®</sup> met its primary endpoint of prolonging leukemia-free survival for AML patients in first remission. The difference between the treated and control group was highly statistically significant ( $p < 0.008$ ). Recently completed subset analyses of patients in the Phase III trial determined that patients with AML of monocyte origin achieved a statistically significant increase in overall survival after treatment with Ceplene<sup>®</sup> plus low-dose IL-2 and identified a strong correlation between the administration of high-intensity consolidation treatment and improvements in overall survival, suggesting that statistically significant improved overall survival could be achieved in a well designed and adequately powered clinical trial.

### **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<sup>®</sup>, approved in the EU and Israel for the remission maintenance and prevention of relapse in adult patients with AML in first remission. In the United States, a pivotal trial is scheduled to commence in 2011. The Company has two other 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<sup>™</sup> 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 that 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, the risk that Ceplene® will not 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 risk that future financing will not successfully close or that the proceeds thereof will be materially less than anticipated, 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 Azixa™ will not receive regulatory approval or achieve significant commercial success, the risk that we will not receive any significant payments under our agreement with Myrexix, the risk that the development of our other apoptosis product candidates will not be successful, the risk that clinical trials for EpiCept™ NP-1 or crolibulin™ will not be successful, the risk that EpiCept™ NP-1 or crolibulin™ 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™ 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 risk that our securities may be delisted from Nasdaq; 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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*\*Azixa is a registered trademark of Myrexix, Inc.*

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