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# CEPLENE® RECEIVES POSITIVE EUROPEAN OPINION FOR APPROVAL FROM CHMP

Marketing Authorization Normally Anticipated within 67 Days in the EU Conference Call to be Held July 28 at 9:00 a.m. Eastern Time

**TARRYTOWN, N.Y.** (July 25, 2008) – EpiCept Corporation (Nasdaq and OMX Nordic Exchange: EPCT) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion regarding the marketing authorization for Ceplene® (histamine dihydrochloride), for the remission maintenance and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML) in first remission. Ceplene is to be administered in conjunction with low-dose interleukin-2 (IL-2). This positive opinion was issued following a request made by EpiCept to have the initial negative opinion of March 2008 re-examined by the CHMP. Ceplene has been designated as an orphan medicinal product, and as such is entitled to 10 years of marketing exclusivity in the EU.

EpiCept attended an oral explanation hearing at the CHMP's plenary meeting on July 22, 2008. Following this oral explanation, the CHMP recommended that Ceplene be granted a full marketing authorization under the provision of Exceptional Circumstances.

As part of granting of the marketing authorization under Exceptional Circumstances, EpiCept has agreed to perform two post-approval clinical studies. One of the studies seeks to further elucidate the clinical pharmacology of Ceplene by assessing certain biomarkers in AML patients in first remission. The other study will assess the effect of Ceplene/IL-2 on the development of minimal residual disease in the same patient population. EpiCept is entitled to seek further guidance on the design of such studies from the EMEA through the protocol assistance procedure.

"We are thrilled with the positive opinion reached by the CHMP and are pleased by the overwhelming support for Ceplene we received from key opinion leaders in hematology across Europe during this successful re-examination effort," stated Jack Talley, President and CEO of EpiCept. "Ceplene, in conjunction with IL-2, is the first therapy shown to significantly prolong leukemia-free survival and prevent relapse in AML patients in first remission."

The CHMP's recommendation will now be forwarded to the European Commission for issuing a marketing authorization in the form of a Commission Decision, which normally occurs within 67 days. The marketing authorization with unified clinical usage for Ceplene granted under the Centralized Procedure will be valid for the entire European Union as well as in Iceland, Liechtenstein and Norway.

"We are highly optimistic about the commercial prospects for Ceplene and we intend to pursue its commercial introduction as expeditiously as possible," continued Mr. Talley. "We are evaluating all of our strategic options for the marketing of Ceplene, and will continue to work towards realizing the drug's potential to fulfill an important unmet medical need for AML patients in Europe."

#### **Conference Call**

EpiCept announced that it will host a conference call to discuss this opinion and the Ceplene program on Monday, July 28, 2008 at 9:00 a.m. Eastern Daylight Time.

To listen to the conference call, please dial:

(877) 494-5472 (United States and Canada) (706) 758-9407 (International) The access code for the call is 57724791

A web cast of the conference can be accessed at <a href="www.epicept.com">www.epicept.com</a>. The webcast will be archived for 90 days.

A playback of the call will be available for one week and may be accessed by dialing: (800) 642-1687 (United States and Canada) (706) 645-9291 (International)
Please reference reservation number 57724791

## About Acute Myeloid Leukemia (AML)

AML is the most common type of leukemia in adults. There are approximately 40,000 AML patients in the EU, with 16,000 new cases occurring each year. Once diagnosed with AML, patients are typically treated with induction chemotherapy and consolidation therapy, with the majority achieving complete remission. However, about 75-80% of patients who achieve first remission will relapse, with the median time in remission before relapse being only 12 months with current treatments. Less than 5% of relapsed patients survive long term.

### **About Ceplene**

Ceplene is EpiCept's compound for the treatment of AML. Ceplene is designed to protect lymphocytes responsible for immune-mediated destruction of residual leukemic cells. Laboratory research has demonstrated that Ceplene reduces formation of oxygen radicals from phagocytes, inhibiting NADPH oxidase and protecting IL-2-activated NK-cells and T-cells.

#### **About EpiCept Corporation**

EpiCept is focused on unmet needs in the treatment of cancer and pain. The Company's broad portfolio of pharmaceutical product candidates includes several pain therapies in clinical development and a lead oncology compound for AML. In addition, EpiCept's ASAP technology, a proprietary live cell high-throughput caspase-3 screening technology, can efficiently identify new cancer drug candidates and molecular targets that selectively induce apoptosis in cancer cells. Two oncology drug candidates currently in clinical development that were discovered using this technology have also been shown to act as vascular disruption agents in a variety of solid tumors.

## **Forward-Looking Statements**

This news release and any oral statements made with respect to the information contained in this news release, contains 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 EpiCept's 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 risks that Ceplene(R) will not receive final regulatory approval or marketing authorization in the EU, the risk that Ceplene(R), if approved, will not achieve significant commercial success, the risk that any post-approval clinical study will not be successful, the risk that EpiCept will not be able to maintain its final regulatory approval or marketing authorization if received, the risks associated with the adequacy of our existing cash resources and our need to raise additional financing to continue to meet our capital needs 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 or that we may default on our loans or that our lenders may declare the Company in default or that our secured lender would seek to sell our assets, the risk that the Company's securities may be delisted by The Nasdaq Capital Market or the OMX Nordic Exchange 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 our ASAP technology will not yield any successful product candidates, the risk that clinical trials for NP-1 or EPC2407 will not be successful, the risk that NP-1 or EPC2407 will not receive regulatory approval or achieve significant commercial success, 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; risks associated with prior material weaknesses in our internal controls; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in EpiCept's periodic reports, including its 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 EpiCept's filings, which are available at <a href="www.sec.gov">www.sec.gov</a> or at <a href=

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#### **EPCT-GEN**

\*Azixa is a registered trademark of Myriad Genetics, Inc.