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# EPICEPT RECEIVES INITIAL FDA COMMENTS ON APPLICATION FOR CEPLENE® SPECIAL PROTOCOL ASSESSMENT

**TARRYTOWN, N.Y. (June 27, 2011)** – EpiCept Corporation (Nasdaq and Nasdaq OMX Stockholm Exchange: EPCT) today announced that it has received initial written responses from the U.S. Food and Drug Administration (FDA) regarding the Company's application for a Special Protocol Assessment (SPA) of the Ceplene® (histamine dihydrochloride) Phase III protocol. Ceplene, which is administered in conjunction with low-dose interleukin-2 (IL-2), is EpiCept's maintenance therapy for patients with acute myeloid leukemia (AML) in first remission. Among those responses, the FDA noted that in contrast to its earlier position it is now proposing that the trial attempt to isolate Ceplene's effect by including an IL-2 monotherapy arm in the trial protocol. The FDA has invited the Company to request a meeting to discuss its responses to the Company's application.

In its initial protocol submission, EpiCept proposed a two-arm trial comparing the efficacy of maintenance therapy with Ceplene in conjunction with IL-2 to investigator's choice, which is often no treatment.

EpiCept intends to meet with the FDA as soon as possible to reconcile this response with the position taken at its meeting with the Company in October 2010 in which an IL-2 monotherapy arm was not part of the agreed-upon trial design, and to discuss other responses to the SPA application. The Company retains the right to appeal any decision by the FDA's Office of Oncology Drug Products.

## **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. The Company has two other oncology drug candidates 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 AmiKet<sup>TM</sup>, 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 risks associated with our ability to continue to meet our obligations under our existing debt agreements, the risk that our application to change our listing status on the Nasdaq OMX Stockholm Exchange may not be approved, the risk that our securities may be delisted from The Nasdaq Capital Market, the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern, the risk that Ceplene<sup>®</sup> will not receive regulatory approval or marketing authorization in the United States or Canada, the risk that Ceplene<sup>®</sup> will not achieve significant commercial success, the risk that any required post-approval clinical study for Ceplene<sup>®</sup> will not be successful, the risk that we will not be able to maintain our final regulatory approval or marketing authorization for Ceplene<sup>®</sup>, the risk that Azixa<sup>TM</sup> will not receive regulatory approval or achieve significant commercial success, the risk that we will not receive any significant payments under our agreement with Myrexis, the risk that the development of our other apoptosis product candidates will not be successful, the risk that clinical trials for AmiKet<sup>TM</sup> or crolibulin<sup>TM</sup> will not be successful, the risk that AmiKet<sup>TM</sup> or crolibulin<sup>TM</sup> 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 AmiKet<sup>TM</sup> 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-O 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 or at 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.

\*Azixa is a registered trademark of Myrexis, Inc.

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