



EpiCept Announces Fulfillment of Ceplene's Third European Post-Approval Commitment

EMA Agrees Confirmatory Trial Not Needed or Feasible

TARRYTOWN, N.Y., Jun 01, 2010 (BUSINESS WIRE) -- Regulatory News:

EpiCept Corporation (Nasdaq and Nasdaq OMX Stockholm Exchange: EPCT) today provided an update on the post-approval commitments requested by the European Medicines Agency (EMA) as part of its marketing authorization for Ceplene(R) (histamine dihydrochloride). Ceplene is approved in the EU for remission maintenance and prevention of relapse in adults with Acute Myeloid Leukemia (AML) in first complete remission. The EMA has notified EpiCept that it has accepted the conclusion of a panel of prominent hematologists convened by the Company that it is not feasible to conduct, in conjunction with cooperative groups in Europe and/or the United States, a confirmatory Phase III study to evaluate the safety and efficacy of Ceplene with low-dose interleukin-2 (IL-2) versus a comparator arm of either no treatment or IL-2 alone. As a result, the EMA now considers this post-approval commitment fulfilled.

In reaching its decision, the EMA accepted the consensus opinion of the panel, which concluded, in part, that robust data on the safety and efficacy of Ceplene in conjunction with low-dose IL-2 have already been collected. A new clinical study of Ceplene/IL-2 in remission maintenance for AML versus a comparator without demonstrated efficacy would raise ethical and practical issues in obtaining required study approvals from institutional ethics committees and institutional review boards.

EpiCept is continuing enrollment in its post-approval clinical trial studying the effects of remission maintenance therapy with Ceplene/IL-2 on minimal residual disease (MRD) in adult patients with AML in first complete remission. This open-label, multicenter study is also assessing the quantitative and qualitative pharmacodynamic effects of Ceplene/IL-2 by monitoring T-cell and natural killer cell phenotypes and their functionality after the first and third treatment cycles. The study will enroll up to 150 patients at approximately 30 centers across Europe with sites in Sweden, Belgium, France, the U.K., Spain and Italy.

Commenting on the EMA's decision, Jack Talley, President and Chief Executive Officer of EpiCept, said, "We are pleased that EMA officials have agreed that obtaining data from a new confirmatory study versus a comparator with unproven efficacy was not feasible. We intend to inform other regulatory authorities, including Health Canada and the FDA, of the EMA's conclusion during their respective reviews of the Ceplene application for marketing approval. We expect to complete the post-approval trial with Ceplene in 2011 and remain on track with our plans to submit a New Drug Application to the U.S. Food and Drug Administration during the current quarter."

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. Approximately 16,000 new cases of AML are diagnosed in Europe 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 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 the 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 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 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 clinical trials for EpiCept NP-1 or crolibulinTM 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 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 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 Myriad Genetics, Inc.*

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