



## Delcath Submits CE Mark Technical File for Hepatic ChemoSAT(TM) Delivery System

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NEW YORK, Dec. 6, 2010 /PRNewswire via COMTEX/ --

Delcath Systems, Inc. (Nasdaq: DCTH) today announced that the Company has submitted its CE Mark Technical File to its European Notified Body to obtain CE Mark approval for its proprietary chemosaturation system, which the Company intends to market in the European Union (EU) as the Delcath Hepatic ChemoSAT(TM) Delivery System. CE Marking is an indication that a medical device complies with the essential requirements of applicable medical device directives, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark will allow Delcath to market and sell the product in countries in the EU.

"The EU represents an attractive opportunity for this product," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "Our filing in the EU is seeking an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. With the EU's aging population and liver cancer rates on the rise we believe the Hepatic ChemoSAT Delivery System will fulfill an unmet clinical need for many liver cancer patients in this region. With the submission of our Technical File, and successful completion of the audits of our quality system and manufacturing facility, we expect potential CE Mark approval in mid-2011."

"With respect to U.S. regulatory status, we continue to expect to submit the remaining modules of our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2010, and will make additional announcements as we progress," added Mr. Hobbs.

### **About Delcath Systems**

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath concluded a Phase III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company has not yet received FDA or any foreign regulatory approval for commercial sale of its system. For more information, please visit the Company's website at [www.delcath.com](http://www.delcath.com).

*The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to the acceptability of the Phase III clinical trial data by the FDA, our ability to successfully complete an FDA new drug application(NDA), acceptance of the Company's NDA by the FDA, acceptance of the Company's CE Mark Technical File by its Notified Body, receipt of CE Mark approval, adoption, use and resulting sales in the EU, if any, approval of the Company's NDA by the FDA or other regulatory authorities of the current or future drug delivery system for the treatment of metastatic melanoma, the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver, actions by the FDA or other regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, and uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.*

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