Delcath Achieves ISO 13485 Certification

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NEW YORK, Feb. 17, 2011 /PRNewswire via COMTEX/ --

Delcath Systems, Inc. (Nasdaq: DCTH) today announced that the Company has achieved ISO 13485:2003 Certification--an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union (EU). ISO 13485 Certification is a regulatory requirement of the EU's Medical Device Directive, and represents an important step toward attaining European CE Mark approval for the Company's proprietary Hepatic ChemoSAT(TM) Delivery System.

Commenting on the announcement, Eamonn P. Hobbs, CEO & President of Delcath Systems, said, "ISO 13485 Certification confirms that our manufacturing and quality systems meet the high standards required of medical device companies selling into Europe, and we are pleased to have achieved this important milestone toward the receipt of CE Mark approval. Our technical file for CE Mark is pending, and we continue to expect CE Mark approval for our product in mid-2011."

About Delcath Systems

Delcath Systems, Inc. is a 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, Delcathconcluded a Phase III metastatic melanoma study, and the Company recentlycompleted a multi-arm Phase II trial to treat other liver cancers. The Company has not yet received FDA approval for commercial sale of its system. For more information, please visit the Company's website at 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, 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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