Delcath's Ireland Operations Achieves ISO 13485 Certification

December 28, 2011

NEW YORK, Dec. 28, 2011 /PRNewswire/ --Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the Company's Galway, Ireland location has achieved ISO 13485:2003 Certification—an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive quality 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 commercialization of the Delcath Hepatic CHEMOSAT® Delivery System following its European CE Mark approval in April 2011.

"ISO 13485 Certification of our Galway facility confirms that our manufacturing and quality systems meet the high standards required of medical device companies selling into Europe," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "This achievement represents one more important milestone toward commercialization of CHEMOSAT in the EU, and we are looking forward to a successful initial launch of the product early next year."

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 chemotherapeutic 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 obtained authorization to affix a CE Mark for the Hepatic CHEMOSAT Delivery System in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States. For more information, please visit the Company's website at 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 future initial launch and distribution of the CHEMOSAT system Europe, CE Marking for the Generation Two system and the timing of our commercial launch in Europe, the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future chemosaturation system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the results of research and development projects and future clinical trials, 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.

Contact Information:

Investor Contact:	Media Contact:
Doug Sherk/Gregory Gin	Janine McCargo
EVC Group	EVC Group
415-568-4887/646-445-4801	646-688-0425

SOURCE Delcath Systems, Inc.