Delcath Receives Notice of European Regulatory Approval for Hepatic CHEMOSAT(TM) Delivery System

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NEW YORK, April 13, 2011 /PRNewswire via COMTEX/ --

Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the Company has been notified of CE Mark approval for its proprietary Hepatic CHEMOSAT(TM) Delivery System. The product has been approved with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver.

CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark allows Delcath to market and sell the product in countries in the European Economic Area.

"Receipt of our CE Mark represents the first regulatory approval for this product, and marks the beginning of the Company's transition into a fully commercial enterprise," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "With its rising liver cancer rates, Europe represents a large opportunity for this product. We believe the Hepatic CHEMOSAT Delivery System may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in this region. With the CE Mark in hand, we will now begin to build inventory and establish the commercialization infrastructure in Europe, including assembling a direct sales organization to cover countries in Northern Europe and establishing a network of third party distributors in Southern Europe. We will also begin establishing and training initial sites in select European countries as Centers of Clinical Excellence for the chemosaturation procedure."

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 time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales for the Hepatic CHEMOSAT delivery system in the EEA, if any, 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 in the United States, if any, approval of the current or future chemosaturation system for other indications, actions by the FDA or other foreign 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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