



Delcath Completes New Drug Application Submission to the FDA for the Chemosaturation Delivery System

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NEW YORK, Dec. 22, 2010 /PRNewswire via COMTEX/ --

Delcath Systems, Inc. (Nasdaq: DCTH) today announced that the Company has submitted the remaining modules of its 505(b)(2) New Drug Application (NDA) for its proprietary chemosaturation system to the U.S. Food & Drug Administration (FDA). The Company had previously submitted Module 4, consisting of literature based non-clinical data, to the FDA in late April 2010. The Company is seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver.

"Our team has achieved a significant milestone with the filing of our NDA," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "We believe that our application is comprehensive and complete, and we are optimistic that it will be accepted for review by the FDA. Considering the limitations of current treatment options, we believe the chemosaturation system can offer hope to patients with metastatic melanoma in the liver. We have requested priority review of our NDA by the FDA, which if granted could result in a 6-month review of the application. Priority review is granted by the FDA to those products that address significant unmet medical needs or have the potential to provide significant improvement compared to marketed products. With the strength of our Phase III data, we believe that our application meets the FDA's criteria for priority review."

The FDA normally requires 60 days to perform a cursory review and assess whether the NDA is sufficiently complete to warrant a substantive review and issue a Prescription Drug User Fee Act (PDUFA) action date. Delcath intends to make further announcements as the review proceeds, including the FDA's response to the application and potential determination of a PDUFA action date.

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.

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, FDA's acceptance of the Company's request for and granting of priority review to the Company's NDA, approval of the Company's NDA by the FDA of the chemosaturation system for the treatment of metastatic melanoma, adoption, use and resulting sales, if any, of the chemosaturation system in the United States, 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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