Delcath to Initiate Expanded Access Treatment Program for PHP System With Melphalan

February 16, 2010

Company Updates Phase III Trial Data Analysis Timetable

NEW YORK, Feb. 16 -- Delcath Systems, Inc. (Nasdaq: DCTH), which is testing its proprietary treatment system for metastatic cancers to the liver, announced today that the U.S. Food and Drug Administration ("FDA") will allow the Company to initiate an Expanded Use – Intermediate Size Population protocol for the hepatic arterial infusion of melphalan with venous filtration via the Delcath PHP System™ for patients with ocular and cutaneous melanoma metastatic to the liver.

Expanded access programs make certain treatments still being evaluated in late-stage trials available to patients for whom no satisfactory alternatives are available. To grant expanded access, the FDA generally must be satisfied that the potential benefit for the patient justifies the potential risk.

Delcath recently announced that sufficient patient events had occurred in its randomized, multi-center Phase III trial of melphalan for data analysis to begin. Under the Expanded Access Program, the five centers treating the highest number of patients during the Phase III trial may continue to treat patients with metastatic melanoma to the liver while the data is being evaluated. The Expanded Access Program allows patients to be enrolled into the non-randomized study, materially identical to the melphalan arm of the randomized Phase III trial that will be submitted to FDA for a New Drug Application ("NDA") review. Patients treated under the Expanded Access Program will not be included in the data analysis currently underway. Delcath is currently in the final stages of negotiating research contracts with the individual institutions and achieving Institutional Review Board ("IRB") approvals at these five centers. The Company may in the future petition the FDA to add additional centers.

"The Expanded Access Program is terrific news," said Eamonn P. Hobbs, President and CEO of Delcath. "It allows us to offer help to patients with metastatic melanoma to the liver who have no other options at this stage of their disease. And as it is based on available evidence, this development underscores our confidence in the efficacy of high-dose melphalan combined with the Delcath PHP System for this unmet medical need."

Delcath's Phase III trial completed enrollment of 93 patients in October 2009 and the 73rd event required under the study's Special Protocol Assessment prior to the initiation of patient data analysis, was reported on February 4, 2010. The trial's data analysis has begun and involves the initial review by the trial's principal clinical investigators at each of the enrolling centers, additional review by the Company's retained Clinical Research Organization, and then a final review by an independent core lab for verification of results before final statistical results can be attained. Given recently updated schedules by the external reviewers, the completion of this comprehensive review process is now expected to be in April and the Company plans to promptly release key elements as they become available. Submission of the NDA package to the FDA for marketing approval will be made as soon as practically possible, once the data analysis process is completed.

"Our goal is to make sure that all data from the trial is thoroughly reviewed before any release and we fully support the comprehensive process underway. We remain highly confident that the trial's data will meet the trial's primary endpoint, and our confidence has been further buoyed by the FDA's acknowledgement of an expanded access program," Mr. Hobbs concluded.

About Delcath Systems, Inc.

Delcath Systems, Inc. is a medical technology company specializing in cancer treatment. The Company is testing a proprietary, patented drug delivery system for the treatment of primary and metastatic liver cancers. Delcath's novel drug delivery platform is testing the delivery of ultra-high doses of anti-cancer agents to the liver while controlling the systemic exposure of those agents. In addition to the Phase III metastatic melanoma study, the Company is currently conducting trials to treat other forms of tumor metastases to the liver. The Company maintains a broad intellectual property portfolio on a worldwide basis including the U.S., Europe, Asia and Canada. 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 our ability to successfully complete Phase III clinical trials and secure regulatory approval of our current or future drug-delivery system 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.

This Site contains information and press releases about us. This information should be considered accurate only as of the date prepared. You acknowledge that this information may change over time and you should not assume that the information is accurate at a later date. Delcath Systems, Inc. is not obligated to update the press releases and information contained in this section of the Site.