Data Safety Monitoring Board Unanimously Recommends Continuation of Delcath's Phase III Clinical Trial

September 11, 2009
Enrollment Reaches 95% Accrual --

NEW YORK, Sept. 11 -- Delcath Systems, Inc. (Nasdaq: DCTH), a medical technology company testing its proprietary treatment method for primary and metastatic cancers to the liver, announced that the Data and Safety Monitoring Board ("DSMB") reviewed clinical data on 77 patients enrolled in its pivotal Phase III clinical trial and unanimously recommended that the trial continue to enroll patients with the goal of reaching the 92 patients required to complete the study. In addition, the Company announced it now expects enrollment to be completed by mid-October.

Eamonn Hobbs, President and CEO of Delcath Systems stated, "We are pleased by the successful review of our safety data and the recent, accelerated pace of enrollment, which has put us in the trial's home stretch. This is an exciting time for the Company. With current enrollment trends, we now expect to complete enrollment by the middle of October and are still on track for an FDA submission by mid-2010."

The DSMB is an independent group of experts with the responsibility for reviewing and evaluating the safety and response data generated from the Company's Phase III trial. The primary responsibilities of the DSMB are to ensure the safety of all patients enrolled in the trial, the quality of the data collected and the continued scientific validity of the trial design. The DSMB reviews data periodically in order to make an informed risk versus benefit recommendation concerning the continuation, modification, or termination of the trial due to safety concerns. This DSMB review was triggered upon randomization of the 77th patient which marks the 75% enrollment point for the trial.

About the Phase III Study
This clinical study is testing the Delcath PHP System(TM) for the regional delivery of melphalan to the liver to treat patients with metastatic cutaneous and ocular melanoma who have unresectable tumors in the liver. The Delcath PHP System(TM) is designed to deliver significantly higher doses of anti-cancer drugs to a patient's liver while minimizing entry of the drugs into the rest of the patient's circulation. This isolation limits toxicities which result from systemic chemotherapy treatments.

Patients in the Phase III trial are randomized into one of two treatment arms, including immediate treatment with melphalan via the Delcath PHP System(TM) or treatment with best alternative care. The study is designed to evaluate the duration of tumor response in each of the two study arms. Following guidelines established by U.S. Food and Drug Administration under a Special Protocol Assessment (SPA), patients are permitted to "cross-over" from the best alternative care arm to receive treatment with the Delcath System at the time of disease progression.

About Delcath Systems, Inc.
Delcath Systems, Inc. is a medical device company specializing in cancer treatment. The Company is testing a proprietary, patented drug delivery system for the treatment of liver cancers. Delcath's novel drug delivery platform is testing the delivery of ultra-high doses of anti-cancer drugs to the liver while preventing these high doses of drug from entering the patient's bloodstream. The Company is currently enrolling patients in Phase III and Phase II clinical studies for the treatment of liver cancers using high doses of melphalan. The Company's intellectual property portfolio consists of twenty-seven patents 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.

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