



Delcath Systems, Inc. Announces Patient Recruitment Exceeds 90%

August 25, 2009

NEW YORK, Aug. 25- -- Delcath Systems, Inc. (Nasdaq: DCTH), a medical technology company testing its proprietary treatment method for primary and metastatic cancers to the liver, announced today that it has exceeded 90% enrollment reaching 85 patients for its pivotal Phase III Metastatic Melanoma Trial. Based on trial specifications, the Company needs 92 for enrollment achievement.

"We are pleased to report this important patient enrollment milestone. Our success validates the need for a drug delivery platform that is unique in the interventional oncology arena. With approximately 250,000 cases of primary or secondary cancer of the liver diagnosed each year in the U.S. and 2.6 million cases globally, we believe our Percutaneous Hepatic Perfusion (PHP(TM)) technology is a compelling proposition," said Eamonn Hobbs, President and CEO of Delcath Systems. "Our next milestone will be a successful review of safety data in early September in preparation for a FDA submission by mid-2010, as well as CE Mark approval, which would allow for marketing outside the U.S.A. by June 2010."

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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