



Delcath Phase III Trial Results Exceed Primary Endpoint Expectations

April 21, 2010

Treatment Arm Shows More Than 3x Median hPFS Compared to Control Arm

Conference Call Today at 5:15 p.m. ET

New York, NY -- April 21, 2010 -- Delcath Systems, Inc. (NASDAQ: DCTH), a development stage, oncology-focused, specialty pharmaceutical and medical device company, announced that its Phase III National Cancer Institute (NCI)-led multi-center clinical trial has successfully met the study's primary endpoint of extended hepatic progression-free survival (hPFS) in patients with melanoma metastases to the liver based on an independently corroborated intent-to-treat analysis. Comparing treatment with the Delcath PHP System™ with melphalan to Best Alternative Care (BAC), based on independent core lab review of patient scans, the statistical analysis revealed that the PHP patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the BAC arm ($p=0.001$). This reflects a 144-day prolongation of hPFS over that of BAC control arm, with less than half the risk of progression and/or death in the PHP group compared to the BAC group (Hazard Ratio = 0.46).

James F. Pingpank, MD, FACS, Associate Professor of Surgery at the University of Pittsburgh School of Medicine and a lead Principal Investigator of the Phase III trial, will present full trial data on June 5th at the American Society of Clinical Oncology's (ASCO) 2010 Annual Meeting. The endpoints announced today are results of the independent core lab analysis, which will be submitted to support Delcath's New Drug Application (NDA) for its drug and proprietary treatment system to the U.S. Food and Drug Administration (FDA). Delcath expects to initiate its rolling NDA submission to the FDA within the next 30 days.

"We believe that these data support that the Delcath PHP System may provide a significantly better treatment option for patients suffering from melanoma metastases in the liver," said Eamonn P. Hobbs, President and CEO of Delcath. "With the treatment arm having a median hPFS of more than three-fold that of the control arm, we easily exceeded our expectations of clinical trial success. This is a major step forward in our plan to introduce what we believe is an effective treatment for patients who currently have very few viable options."

About the Trial

This clinical study tested the Delcath PHP System for the regional delivery of melphalan to the liver to treat patients with metastatic ocular and cutaneous melanoma with unresectable tumors in the liver. Patients in the Phase III trial were randomized into one of two treatment arms, including immediate treatment with melphalan via the Delcath PHP System or treatment with BAC. The study was designed to evaluate the hPFS in each of the two study arms. Following guidelines established by FDA under a Special Protocol Assessment (SPA), patients were permitted to "cross-over" from the BAC arm to receive treatment with the Delcath PHP System at the time of disease progression.

About the Delcath PHP System

The Delcath PHP System is an investigational system which is comprised of the chemotherapeutic agent melphalan combined

with a proprietary administration system. The System is designed to provide a regionalized approach for the treatment of unresectable hepatic malignancies in which an ultra-high dose of anti-cancer drug is administered to the liver via the hepatic artery, and venous effluent from the liver is collected and filtered using a percutaneously placed catheter and an extracorporeal filtration system. Significantly higher doses of anti-cancer drugs can therefore be delivered 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 and allows for infusion of doses exceeding those of systemic or intra-arterial administration. The Delcath PHP System is not currently approved for marketing by the FDA, or determined to be safe and effective for this intended use.

Conference Call Details

The Company will host a conference call today to discuss these results at 5:15 p.m. ET. Eamonn Hobbs, CEO, Dave McDonald, CFO, Dr. Kris Kandarpa, CMO, and Jason Rifkin, SVP of Clinical Affairs, will host the call.

To participate in the live call by telephone, please dial 877-941-8609 for domestic participants and 480-629-9031 for international participants. Participants are asked to call the above numbers 5-10 minutes prior to the starting time. The call will also be webcast live at www.delcath.com. An audio replay of the call will be available for 7 days following the call. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4287086#. An archived webcast will also be available at www.delcath.com.

About Delcath Systems, Inc.

Delcath Systems, Inc. is a development stage, oncology focused, specialty pharmaceutical and medical device company. The Company is investigating 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 its fully enrolled Phase III metastatic melanoma study, the Company is currently conducting trials to treat other liver cancers. 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 the acceptability of the Phase III clinical trial data by the FDA, our ability to successfully complete the new drug application and submit to the FDA within the next 30 days, acceptance of the new drug application by the FDA, approval by the FDA or other regulatory authorities of the current or future drug delivery system for the treatment of metastatic melanoma, our ability to successfully complete other clinical trials and secure regulatory approval of our current or future drug-delivery system for the treatment of other liver cancers and other organs 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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