# Delcath Announces Updated Efficacy Results From Phase 3 Trial of Chemosaturation for Melanoma Metastases in the Liver Presented at European Multidisciplinary Cancer Congress

September 23, 2011

NEW YORK and STOCKHOLM, September 23, 2011 /PRNewswire via COMTEX/ -- March 2011 Data Confirm Strong Treatment Effect of Chemosaturation

Delcath Systems (NASDAQ: DCTH) announced today that James F. Pingpank, MD, FACS, Associate Professor of Surgery at the University of Pittsburgh School of Medicine, will present updated investigator results from the Phase 3 randomized trial of Delcath's chemosaturation system with melphalan in patients with hepatic metastases from ocular or cutaneous melanoma.

Dr. Pingpank, a lead principal investigator of the Phase 3 trial, will present the abstract (9304), "Percutaneous Hepatic Perfusion (PHP) vs. Best Alternative Care (BAC) for Patients with Melanoma Liver Metastases - Efficacy Update of the Phase 3 Trial," in the plenary session today at 11:15am CEST at the European Multidisciplinary Cancer Congress in Stockholm. These updated results include follow-up data from patients through March 2011, an additional 12 months of data maturation from when Dr. Pingpank first presented investigator data from this Phase 3 trial in June 2010, at the American Society of Clinical Oncology's Annual Meeting.

With respect to the study's primary endpoint of hepatic progression free survival ("hPFS"), the updated investigator-assessed results showed that patients in the chemosaturation arm demonstrated median hPFS of 8.0 months compared to 1.6 months in the BAC arm, a significant 6.4 month extension of hPFS (hazard ratio 0.35, $p<0.0001$). Median overall PFS in the chemosaturation arm was 6.7 months compared to 1.6 months in the BAC arm, an increase of 5.1 months (hazard ratio 0.36, $p<0.0001$).

As reported previously, the hepatic response rate in the chemosaturation arm was 34% compared to 2% for the BAC arm. In addition, 52% of patients in the chemosaturation arm achieved stable disease, compared with 27% in the BAC group, giving a tumor growth control rate of 86% for the chemosaturation group versus 29% for the BAC group ($p<0.001$). Patients who crossed from the BAC arm to chemosaturation treatment after progression of liver disease showed consistent efficacy with patients treated on the chemosaturation arm. As expected, there was no difference in overall survival in the randomized study due to the crossover trial design. An analysis of survival trends by patient cohorts indicated that patients treated with chemosaturation, including crossover patients, had a median survival of 11.4 months compared to 4.1 months for BAC patients who did not receive chemosaturation. As of June 30th, 11 patients treated with chemosaturation were still alive compared to two patients in the BAC arm who did not receive chemosaturation.

"The additional 12 months of data and extended survival for a significant percentage of the treated patients confirm our belief that chemosaturation may provide a significantly better option than the few treatments presently available for patients with melanoma metastases in the liver," said Eamonn P. Hobbs, President and CEO of Delcath. "The hepatic PFS, overall PFS and response rate are consistent with past investigator assessments and highly statistically significant. We are encouraged by the data presented in Stockholm today."

***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 3 metastatic melanoma study, and the Company recently completed a multi-arm Phase 2 trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Hepatic CHEMOSAT delivery system in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States. For more information, please visit the Company's website at http://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 time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver including metastatic melanoma to the liver, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future chemosaturation system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the results of research and development projects and future clinical trials, 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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