



Delcath Announces Further Results From Neuroendocrine Tumor Cohort Presented at European Multidisciplinary Cancer Congress

September 25, 2011

NEW YORK and STOCKHOLM, Sept. 25, 2011 /PRNewswire via COMTEX/ -- Delcath Systems (NASDAQ: DCTH) announced that James F. Pingpank, MD, FACS, Associate Professor of Surgery at the University of Pittsburgh School of Medicine, will present a poster today that includes additional data from the metastatic neuroendocrine tumor (mNET) cohort of Delcath's recently completed Phase 2 clinical trial of its chemosaturation system. The poster being presented at the European Multidisciplinary Cancer Congress in Stockholm includes the data previously presented in Dr. Pingpank's late-breaking abstract at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) congress on September 12, 2011, as well as an additional secondary endpoint of median hepatic progression-free survival (hPFS) of 15.5 months. The mNET cohort is only one of four cohorts in this Phase 2 trial.

In this mNET cohort, 24 patients with unresectable mNET in the liver underwent an average of three chemosaturation procedures with concentrated melphalan and subsequent extra-corporeal venous hemofiltration. Dr. Pingpank will also present the updated hepatic response rate of 70% in 20 evaluable patients, and median overall survival of 30.4 months in all 24 patients on an intent-to-treat basis, as presented at CIRSE. The safety profile of the chemosaturation system remains consistent with that previously reported for the Company's Phase 3 melanoma trial.

"Currently available treatment options for patients with unresectable neuroendocrine liver metastases have response rates around 5%. The anti-tumor activity, disease control and duration of response seen in the mNET arm of this Phase 2 study is very positive, and suggest a potential role for chemosaturation in this difficult to treat population," said Eamonn P. Hobbs, President & CEO of Delcath. "The data presented today add to those presented at CIRSE, and we believe these data affirm the treatment effect of chemosaturation on liver metastases of NET as seen in the Phase 2 study as well as provide a solid efficacy signal in a tumor type other than melanoma."

Conducted at the National Cancer Institute (NCI), this Phase 2 clinical trial included four patient cohorts: 1) primary hepatobiliary cancers and metastatic cancers of 2) neuroendocrine, 3) ocular or cutaneous melanoma, and 4) colorectal (adenocarcinoma) origins. Top-line results from the trial's [hepatobiliary cohort](#) were announced on August 22, 2011, and from the [metastatic colorectal cohort](#) on September 1, 2011. The primary objectives were to determine the hepatic response rate and duration of response to intrahepatic infusion of melphalan with subsequent venous hemofiltration. Secondary objective measures included hepatic PFS, overall survival, safety and tolerability.

Delcath has previously described Phase 1/2 NCI-led trial results on 23 patients with mNET that were presented at the 2008 American Hepato-Pancreato-Biliary Association annual meeting. These results included patients from a Phase 1 trial with patients that had been enrolled in the Phase 2 trial up to that time. The neuroendocrine cohort of the current, completed Phase 2 trial consisted of 24 patients, all of whom were enrolled in the Phase 2 trial.

About mNET

Neuroendocrine tumors (NETs) are a group of malignant tumors that originate from intersections of the nervous system and endocrine (glandular) system throughout the body and are found in various locations, such as the pancreas, thyroid, lungs, gastrointestinal tract and biliary system. An estimated 9,000 patients in Europe are diagnosed annually with neuroendocrine tumor metastases in the liver, which is the most common site for neuroendocrine tumors to metastasize. Surgery is an accepted treatment for mNETs, but the type and extent of surgery for liver metastasis is contingent upon tumor size and distribution, disease progression, site of origin and other factors including the age and health of the patient. Recently published data from the control arms of randomized controlled trials in pancreatic NET show that progression-free survival is of the order of 6 months without treatment.

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 III metastatic melanoma study, and the Company recently completed a multi-arm Phase II 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 mNET, 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.

Contact Information:

Investor Contact:	Media Contact:
Doug Sherk/Gregory Gin	Janine McCargo
EVC Group	EVC Group
415-568-4887/646-445-4801	646-688-0425

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