



Delcath Announces Encouraging Top-Line Results From Hepatobiliary Cohort in Phase II Trial of Chemosaturation System

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Delcath Systems, Inc. (NASDAQ: DCTH) reported encouraging top-line results from the hepatobiliary cohort of the Phase II clinical trial of the Delcath chemosaturation system with melphalan in the treatment of patients with unresectable liver cancer. This study, conducted at the National Cancer Institute (USA), included four patient cohorts: hepatobiliary cancers, and metastatic cancers of neuroendocrine, ocular or cutaneous melanoma, and colorectal (adenocarcinoma) origins.

There were nine patients with tumors of hepatobiliary origin: five hepatocellular carcinomas (HCC) and four cholangiocarcinomas. HCC is the most common primary cancer of the liver, with approximately 500,000 new cases diagnosed worldwide annually. Both groups had positive efficacy signals. The responses were especially encouraging in the HCC cohort and consisted of confirmed partial response or durable stable disease. The safety profile of the chemosaturation system was consistent with that previously reported for the Company's Phase 3 melanoma trial.

"The disease control and anti-tumor activity seen in the HCC arm of this Phase II study is very encouraging for primary liver cancer patients who currently face limited treatment options," said Eamonn P. Hobbs, President and CEO of Delcath System, Inc. "We believe these results show a strong signal of efficacy, and support our plan to initiate Phase III and Phase IV trials for HCC in the second half of 2012."

Mr. Hobbs added, "We expect to announce additional data from this Phase II trial in the near future, and look forward to presenting detailed results from the metastatic neuroendocrine arm of this trial at the Cardiovascular and Interventional Radiological Society of Europe and European Society for Medical Oncology scientific meetings in September."

The trial's primary objectives were to determine the response rate and duration of response to intrahepatic infusion of melphalan with subsequent venous hemofiltration. Secondary objective measures included patterns of recurrence, progression-free survival and overall survival. Additional secondary objectives were to evaluate safety and tolerability in this patient population, and assess filter characteristics including melphalan pharmacokinetics and filtration of cytokines and clotting factors.

About Hepatocellular Carcinomas

Hepatocellular carcinoma (HCC) is a primary cancer of the liver and one of the most deadly forms of cancer. HCC ranks as the fifth most common solid tumor cancer, with an annual incidence of approximately 20,000 cases per year in the United States, approximately 40,000 cases per year in Europe and approximately 500,000 cases per year worldwide, due to the high prevalence of Hepatitis B and C in developing countries. Usually seen in people aged 50 - 60, this type of cancer occurs more often in men than women. Treatment options of HCC and prognosis are dependent on many factors including tumor size and location, the underlying functional capacity of the liver, and the stage of the disease. High-grade tumors will have a poor prognosis, while low-grade tumors may go unnoticed for many years. Hepatocellular carcinoma is potentially curable by surgical resection, but surgery is the treatment of choice for only the small fraction of patients with localized disease. The usual outcome is poor, because only 10-20% of HCC can be removed completely using surgery. If the cancer cannot be completely removed, the disease is usually deadly within 6 months.

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, 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 future clinical trials including HCC trials, uncertainties relating to the results of research and development projects, 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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