



DELCATH ANNOUNCES TREATMENT OF FIRST PATIENT IN PHASE 2 TRIAL OF MELPHALAN HEPATIC DELIVERY SYSTEM IN PRIMARY LIVER CANCER

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(Thomson Reuters ONE via COMTEX) --Goethe University Hospital Frankfurt Performs First Treatment

New York, NY - November 10, 2014 - Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the first treatment has been performed in the Company's Global Phase 2 Clinical Program for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC), or primary liver cancer. A team led by Prof. Dr. med. Thomas J. Vogl, Director of the Institute for Diagnostic and Interventional Radiology at Goethe University Hospital Frankfurt, Germany, treated its first case on November 5, 2014. The treating physicians reported that the patient was treated successfully.

HCC is the most common primary cancer of the liver, with approximately 700,000 new cases diagnosed worldwide annually. Surgical removal is not possible for an estimated 80-90 percent of primary liver cancer patients. In Europe, the Company's Phase 2 trial program will investigate the safety and efficacy of Melphalan/HDS treatment without sorafenib in patients with unresectable liver cancer confined to the liver, evaluate tumor response (objective response rate) as measured by modified Response Evaluation Criteria in Solid Tumor (mRECIST), and assess progression-free survival and safety. Additional analyses will be conducted to characterize the systemic exposure of melphalan administered by Melphalan/HDS, as well as assess patient-reported clinical outcomes, or quality-of-life. The Company's Phase 2 trial program is expected to include four to seven centers in Europe and the United States, and will seek to enroll approximately 30 patients.

"Our team at Goethe University Hospital Frankfurt has been using percutaneous hepatic perfusion with the Melphalan/HDS to treat patients in a non-clinical trial setting since February 2012," said Prof. Vogl. "In our experience, we believe that the Melphalan/HDS has an important role to play in the treatment of a variety of cancers in the liver, including HCC. We are pleased to be participating in this trial to assess the efficacy and safety of Melphalan/HDS in this difficult disease state."

"With treatments now underway and two centers open for enrollment, we believe our Phase 2 HCC Clinical Program is on track," said Dr. Jennifer Simpson, Ph.D., Interim President and CEO of Delcath Systems. We expect to add additional centers to the program in the coming weeks, and subject to timely enrollment of suitable patients, we anticipate having interim data from this trial in the first half of 2015."

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary product-Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS)-is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic liver cancers. In the United States, the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States. In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company has commenced a global phase 2 clinical trial in Europe to investigate Melphalan/HDS system for primary liver cancer and is initiating plans to evaluate intrahepatic cholangiocarcinoma.

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: timely enrollment and treatment of patients in the Phase 2 HCC trial, IRB or ethics committee clearance of the Phase II HCC protocol from additional participating sites and the timing of site activation and subject enrollment in the HCC Phase II trial program, the timing and results of clinical trials including without limitation the HCC clinical trial program, the ability of hospitals in Germany to successfully negotiate and receive reimbursement for the CHEMOSAT procedure in their region under Value 4 status and the amount of reimbursement, if any, to be provided under Value 4 status in 2014, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact of Value 4 status on potential CHEMOSAT product use and sales in Germany, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK, the Company's ability to successfully commercialize the Melphalan HDS/ CHEMOSAT system and the potential of the Melphalan HDS/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver, our ability to obtain reimbursement for the CHEMOSAT system in various markets, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, approval of the current or future Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects, our ability to maintain NASDAQ listing, and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials 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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