



## **DEL CATH COMMENCES U.S. PHASE 2 STUDY OF MELPHALAN HEPATIC DELIVERY SYSTEM IN PRIMARY LIVER CANCER**

October 2, 2014

### ***Moffitt Cancer Center In Tampa, Florida Opens For Enrollment***

**New York, NY - October 2, 2014** - Delcath Systems, Inc. (NASDAQ: DCTH) today announced the opening of its United States (U.S.) Clinical Development Program for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC) or primary liver cancer. Moffitt Cancer Center in Tampa, Florida is the first U.S. center to open for patient enrollment. Johann Wolfgang Goethe University Hospital (JWG) in Frankfurt, Germany opened for enrollment in the European HCC Phase 2 trial in July. The Company's Clinical Development Program is expected to include four to seven centers in Europe and United States and will seek to enroll approximately 30 patients.

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 the U.S., the Phase 2 program will investigate the safety and efficacy of Melphalan/HDS treatment followed by 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), assess progression-free survival, safety, and the safety of sorafenib following treatment with Melphalan HDS. Additional analyses will be conducted to characterize the systemic exposure of melphalan administered by Melphalan HDS, as well as an assessment of patient-reported clinical outcomes, or quality-of-life.

"Moffitt Cancer Center is an early pioneer in the clinical trial use of the Melphalan/HDS to treat patients with liver cancers. We are pleased that Moffitt will play a leading role in our HCC Phase 2 program," said Dr. Jennifer Simpson, Delcath's Interim President and CEO. "We now have two centers one in each of the U.S. and Europe participating in our HCC Phase 2 program, and we expect to add additional sites in both regions in the coming months. Subject to timely enrollment of eligible patients, we anticipate having interim data from this trial available 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: the ability of Moffitt and JWG to timely enroll and treat 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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