ICC Cohort Of Delcath's Global Phase 2 Trial Of Melphalan/HDS In Hepatocellular Carcinoma Now Open For Enrollment

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Ethics Boards at Three Hospitals in Germany Approve Trial Expansion

NEW YORK, May 21, 2015 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH) announces that the intrahepatic cholangiocarcinoma (ICC) study cohort of its expanded Global Phase 2 Clinical Trial Program of Melphalan/HDS for use in the treatment of patients with unresectable hepatocellular carcinoma (primary liver cancer, or HCC) has opened for patient enrollment. The ICC study will be conducted at the same hospitals in Europe participating in the Company's Phase 2 HCC trial, and ICC enrollment is now open at Goethe University Hospital in Frankfurt, the Medical School Hannover and Jena University Hospital. Additional centers in Germany as well as centers in the United Kingdom are expected to open for enrollment in the coming weeks.

ICC is a tumor in the bile duct that arises within the liver. It is the second most common primary liver tumor and represents approximately 15% of new HCC cases diagnosed annually. Surgical resection, the standard of care, is not possible for an estimated 80% to 90% of patients diagnosed with ICC.

The ICC cohort of the Phase 2 trial will investigate the safety and efficacy of Melphalan/HDS treatment in patients with unresectable ICC confined to the liver. This cohort will evaluate tumor response (objective response rate) as measured by modified Response Evaluation Criteria in Solid Tumor (mRECIST), and will 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 to assess patient-reported clinical outcomes, or quality-of-life.

"We believe our Melphalan/HDS treatment may offer significant clinical benefit for ICC patients who face limited treatment options," said Jennifer Simpson, Ph.D., Interim President and CEO of Delcath Systems. "A positive efficacy signal may provide a regulatory pathway to a U.S. registration trial, and consolidated safety data from the HCC and ICC cohorts of this global Phase 2 trial will offer valuable information for us to provide to the FDA."

About Delcath Systems
Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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 systemic exposure. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced a global Phase 2 clinical trial in Europe and the U.S. to investigate Melphalan/HDS for the treatment of primary liver cancer (hepatocellular carcinoma or HCC), and we are initiating a cohort within the global phase 2 clinical trial to evaluate patients with intrahepatic cholangiocarcinoma (ICC). We are also advancing plans to conduct a global Phase 3 trial in ocular melanoma that has metastasized to the liver.

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 timing and results of the Company's clinical trials including without limitation the HCC, ICC and OM clinical trial programs timely enrollment and treatment of patients in the global Phase 2 HCC and ICC clinical trial, FDA and European Health Authority approval of the global Phase 3 OM clinical trial protocol, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM protocols from participating sites and the timing of site activation and subject enrollment in each trial, acceptance of the Phase 3 manuscript at a leading peer reviewed medical journal and the impact of publication to support the Company's business, the impact of the presentations at ESSO and SSO and future clinical results consistent with the data presented, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact, if any 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 U.S. 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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