Data Supporting Delcath's Chemosat System Presented At The Cardiovascular and Interventional Radiology Society Annual Meeting

September 30, 2015

Poster presentations present results of filter efficiency and safety and efficacy of CHEMOSAT treatment in patients with unresectable liver metastases

NEW YORK, Sept. 30, 2015 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces that results of two European investigator-sponsored studies with the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) for the treatment of liver metastases were presented as posters at the Cardiovascular and Interventional Radiology Society (CIRSE) annual meeting being held in Lisbon, Portugal, September 26-30, 2015. Details of the CIRSE scientific program can be found here.

An investigator-sponsored study entitled "*Safety and Efficiency of The Delcath 2nd Generation Filter in Percutaneous Hepatic Perfusion (PHP) with Melphalan for Unresectable Hepatic Metastases of Colorectal Cancer and Uveal Melanoma"* conducted at the Leiden University Medical Center (LUMC) by M.C. Burgmans, N. de Leede, et al. analyzed safety and pharmacokinetics of CHEMOSAT. Investigators examined pharmacokinetic blood samples taken at baseline and set intervals during 15 PHP procedures performed with CHEMOSAT on 10 patients. The PHP procedures were performed with a melphalan dose of 3.0 mg/kg. Results showed grade 3 complications (mostly asymptomatic leukocytopenia and thrombocytopenia) in seven patients, and febrile neutropenia with bacterial pharyngitis in one patient. Febrile neutropenia was not seen again in the study after growth factors were instituted in a study protocol amendment. First blood sample showed filter efficiency of 93%. Investigators concluded that the efficiency of the Delcath 2nd Generation Filter was very high, and that PHP with the filter was associated with no mortality and acceptable morbidity consistent with commercial use in Europe.

Another study, entitled "*Lessons and Early Results from the Largest Single Centre Experience in Europe of Treating Ocular Melanoma Liver Metastases with Chemosaturation via Percutaneous Hepatic Perfusion"* and conducted at Southampton University in the United Kingdom by G. Hickson, I. Wilson, B. Steadman, et al., reported results from a retrospective analysis of mortality, morbidity, intra-procedural imaging and complication data on 22 consecutive patients who were planned for PHP treatment over a 30-month period. Of the 20 patients who were able to receive treatment, 11 patients remained alive after a median of 280 days, with one complete response ongoing at more than one year post-treatment. Nine deaths from disease progression occurred after a median of 264 days from the first procedure. A complete imaging response in the liver was observed in two patients (10%), 13 patients (65%) had a partial liver response and two patients (10%) had stable disease for more than three months. Investigators concluded that "PHP is an effective palliative treatment in a bleak disease with an acceptable side-effect profile."

"The study by investigators from LUMC in the Netherlands represents the first independent assessment of melphalan pharmacokinetics with our CHEMOSAT system, and we are pleased to see the 93% filter efficiency performance they reported," noted Jennifer Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "We are especially pleased with the consistent safety data presented in both of these studies. We believe that these efficacy and safety profiles can be validated in the ongoing and planned studies in our Clinical Development Program."

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with an emphasis 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. the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). The Melphalan/HDS system 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 the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC), and expect to initiate a global Phase 3 trial in ocular

melanoma (OM) 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: future patient outcomes and clinical trial results consistent with the data contained in the SSO abstract, acceptance and publication of the Phase 3 trial manuscript and the impact of publication to support the Company's efforts, 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 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, the impact of the presentations at ESSO 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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