Data Supporting Delcath's CHEMOSAT System Presented At The European Association Of Dermato Oncology Annual Congress

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Three European Studies Report on Use of CHEMOSAT for Liver Metastases from Ocular/Uveal Melanoma

NEW YORK, Nov. 2, 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 data from three studies supporting treatment for liver metastases with the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) were presented at the European Association of Dermato Oncology (EADO) annual congress, which was held in Marseille, France, October 28-31, 2015.

Details of the presentations are as follows:

Liver Directed Treatment Of Metastatic Uveal Melanoma By Chemosaturation Via Percutaneous Hepatic Perfusion – A Single Centre Experience, Southampton University (United Kingdom), presented by lead author Dr. Ioannis Karydis. Researchers conducted a retrospective evaluation of 20 patients treated with CHEMOSAT over 3 years, analyzing survival, tumor response, time to progression and treatment related adverse events. Eighteen patients were able to receive treatment, and 17 of these were evaluable for study purposes. Results showed that ten patients remained alive after median 256 days, with one complete response (6%), four partial responses (24%), and eleven (65%) patients with stable disease for greater than 90 days. Progression free survival for patients who had progressed was 181 days at the time of data cut off, and six patients were alive for greater than one year following their first treatment. Eight deaths from disease progression occurred at a median of 241 days following first treatment, and there were no treatment related deaths. Treatment overall was well tolerated, and non-hematological adverse events were rare (3). Most common adverse events were transient, mild ≤grade 2 and included transaminitis (56%) and thrombocytopenia (89%); grade 3 anemia was seen in 4 patients and grade 2-4 neutropenia was seen in 4 patients. Researchers concluded that "PHP can be used safely by an experienced team to deliver liver-directed therapy in selected uveal melanoma patients with high progression free and excellent overall survival."

Treating Unresectable Liver Metastases Of Uveal Melanoma With Percutaneous Hepatic Perfusion With Melphalan, Leiden University Medical Center, Erasmus Cancer Institute (the Netherlands) presented by Dr. Mark Burgmans (Leiden). This is an active two-center Investigator Initiated Phase 2 study that aims to evaluate 20 patients with uveal, or ocular melanoma treated with PHP (CHEMOSAT). Data from the first 11 patients with a maximum follow up period of 16 months were presented. Primary endpoints for the study are response rate (as measured by RECIST criteria) following two treatments at 6-week intervals and the percentage of patients with stable disease. Secondary endpoints are safety, overall survival, hepatic progression free survival, and quality of life. Eighteen treatments have been performed on eleven patients and the maximum follow up is currently sixteen months. Current results are that ten patients remain in follow up, and four are without progression of disease. Four patients experienced grade 3 or 4 toxicities that were managed with blood or platelet transfusions. The researchers concluded that PHP with CHEMOSAT "appears to be an effective and safe procedure in selected patients with unresectable liver metastases of uveal melanoma and can be repeated."

Chemosaturation with Percutaneous Hepatic Perfusion of Melphalan for Hepatic Metastases from Uveal Melanoma: Multiinstitutional Evaluation. This study was presented as a poster by lead author Prof. Thomas Vogl, Frankfurt University Hospital and was a retrospective evaluation of non-resectable hepatic metastases from uveal melanoma in 14 patients treated with CHEMOSAT between 2012 and 2014. Eleven patients who received one to three treatments were evaluated by RECIST criteria; survival time analysis was conducted and complications were recorded. Results showed 4 patients (36%) with a partial response, five (46%) with stable disease, and two (18%) with progressive disease. Survival time ranged between 1.5 months to 23 months, with median overall survival of 6.5 months. Time to progression for the two patients who had progressed was 6.2 months for one patient and 1.6 months for a patient who died after evaluation. Treatment was well tolerated by all 14 patients, with seven experiencing leukopenia, six had thrombocytopenia, and two had neutropenia. Researchers concluded that PHP with CHEMOSAT "has been manifested as a potential treatment for patients with non-resectable hepatic metastases of uveal melanoma."

"These studies complement others presented at major medical conferences this fall in examining the potential for treatment with CHEMOSAT for unresectable liver metastases," said Dr. Jennifer K. Simpson, President & CEO of Delcath Systems. "We are pleased with the quality and pace of research being presented and published recently, and look forward to building on this momentum to further advance the commercial and clinical adoption of CHEMOSAT in Europe."

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: the impact, if any, of publication of the Phase 3 trial manuscript 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 major medical conferences 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 ZE reimbursement 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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