Positive Results From a Multi-Center Analysis of Delcath PHP Therapy Published in Journal of Surgical Oncology

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NEW YORK, Jan. 09, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that results of a multi-center retrospective analysis of Delcath's PHP ® Therapy have been published in the peer-reviewed Journal of Surgical Oncology. The study, Percutaneous Hepatic Perfusion with Melphalan in Uveal Melanoma: A Safe and Effective Treatment Modality in an Orphan Disease, was conducted by researchers from Moffitt Cancer Center (Moffitt) in Tampa, FL and the University Hospital Southampton (UHS) in the United Kingdom. The retrospective analysis of outcomes in 51 patients with liver metastases from ocular melanoma represents the largest data set compilation on the use of PHP Therapy in this tumor type outside of a clinical trial setting.

Patients in the study were treated at the two centers between December 2008 and October 2016. Patients received up to four PHP treatments at UHS and up to six PHP treatments at Moffitt. All patients received at least one PHP treatment, the median number of treatments per patient was two, and a total of 134 PHP treatments had been administered.

Results showed that of the 51 treated patients, 22 (43.1%) showed a partial response, 3 (5.9%) showed a complete response, and 17 (33.3%) had stable disease. The six-month overall and hepatic disease control rates were 64.7% and 70.6% respectively. Survival analysis showed median overall survival of 15.3 months at the time of data cut off. One year overall survival was 64.6%.

Safety analysis showed that 19 patients (37.5%) had Grade 3 or 4 non-hematologic toxicity. Cardiovascular toxicity was seen in 17.6% of patients, a rate comparable to the company's prior Phase 3 study. Further to implementation of the Gen 2 filter along with prophylactic use of growth factors, severe neutropenia was seen in 16 (31.3%) patients as opposed to 60 (85.7%) patients in the prior Phase 3 trial. Most significantly, as compared to the prior Phase 3, there were no treatment related deaths. Researchers stated that PHP Therapy "can be safely employed in appropriately selected ocular melanoma patients in institutions with appropriate expertise."

The study authors further concluded that "results clearly demonstrate that PHP Therapy appears to be an effective means of obtaining rapid intrahepatic disease control, and is a sensible option in patients with predominant liver disease." Researchers said their results support the use of PHP Therapy in an integrated approach to the management of metastatic ocular melanoma, and looked to the company's Phase 3 FOCUS Trial to further quantify the benefit and optimize treatment strategies for these patients.

Commenting on the announcement, Jennifer K. Simpson, Ph.D., President and CEO of Delcath Systems, said, "gathered over a period of 8 years, this retrospective two-center study represents the most robust data demonstrating a durable response, manageable side effects and a trend toward prolonged survival in this patient population since our prior Phase 3 trial. These data provide confidence that our Phase 3 FOCUS Trial can confirm these findings and produce the evidence necessary to support an application for a labeled indication in this tumor type."

PHP Therapy with Melphalan/HDS was developed by Delcath Systems as a targeted, whole organ therapy for the liver. It is commercially available as a device in Europe, where it is marketed as CHEMOSAT®. The system has not been approved by the U.S. Food and Drug Administration, and is undergoing Phase 3 clinical testing in the U.S. as an investigational product**.**

About Delcath Systems

Delcath Systems, Inc. is an interventional oncology Company focused on the treatment of primary and metastatic liver cancers. Our investigational 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 systemic exposure and associated side effects. We have commenced a global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and plan to initiate a Registration trial for intrahepatic cholangiocarcinoma (ICC) in the fall of 2017. Melphalan/HDS has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system has been commercially available since 2012 under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Forward Looking Statements

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 OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM clinical trial, IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial 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,, 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 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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Source: Delcath Systems, Inc.