Data from Prospective Phase 2 Study Investigating Delcath's PHP Therapy presented at CIRSE 2018

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Positive Results Observed in Study Endpoints Comparable to Endpoints in Delcath Registration Trial

NEW YORK, Sept. 26, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that results from a prospective study conducted by Leiden University Medical Center (LUMC) in The Netherlands of the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with metastatic ocular melanoma with liver metastases, were presented as a poster at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) annual meeting this week.

The study—*Percutaneous Hepatic Perfusion in Patients with Unresectable Liver Metastases from Ocular Melanoma using Delcath Systems' Second Generation (GEN 2) Hemofiltration System: A Prospective Phase 2 Study* —was conducted by researchers at LUMC reported by T.S. Meijer, MD. The study prospectively evaluated tumor response rate, safety, overall survival (OS), overall progression-free survival (PFS) and hepatic progression-free survival (hPFS) in 35 patients with ocular melanoma liver metastases treated at LUMC from February 2014 to June 2017. In accordance with the study's protocol, patients were treated with a maximum of two cycles of PHP Therapy and a total 67 PHP treatments were administered to the 35 patients in the study.

Post-treatment assessments were possible in 32 patients. Results of the study, according to RECIST 1.1, showed that a complete response was observed in one patient (3.1%) and a partial response was observed in 21 patients (65.6%), resulting in an objective response rate of 68.7%. Stable disease was observed in four patients (12.5%), for a total disease control rate of 81.2%. Median OS was 15.6 months, median PFS was 8.6 months, and median hPFS was 10.8 months.

In their safety analysis, the researchers reported a total of 14 serious adverse events, including one case of cardiac ischemia, five cases of prolonged hospital admission to treat peri-procedure complications, and eight patients re-hospitalized for a variety of post-procedure symptoms. No deaths occurred on the study. No severe bleeding complications, myocardial or cerebral infarctions were observed. Hematologic toxicities of Grade 3/4 were observed in most patients, with 18 (54.5%) patients experiencing thrombocytopenia and 22 patients (66.7%) experiencing neutropenia. The researchers stated that hematologic events were manageable or self-limiting. Additionally, no grade 3 or 4 hepatic serious adverse events were observed by the researchers. The LUMC investigators concluded that, in their institution's study, PHP Therapy was shown to have a manageable adverse event profile and to be a potentially valuable treatment for certain patients with ocular melanoma liver metastases.

Commenting on the study, Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Delcath Systems, said, "The results from the LUMC study are very encouraging since they are from a prospective trial with endpoints very similar to those in our amended Registration Trial in this same patient population. The LUMC team intends to submit a more extensive analysis of their data for publication, and we look forward to the publication of those more detailed results."

The CIRSE 2018 annual meeting was held in Lisbon, Portugal September 22-25, 2018.

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 Registration clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) called The FOCUS Trial and have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called The ALIGN Trial. 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: successful completion of the Company's Rights Offering and related transactions and the amount of gross proceeds, if any; 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 Registration OM clinical trial, IRB or ethics committee clearance of the Registration trial for OM and the Phase 3 ICC 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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