Multi-center Analysis of Outcomes Data on Use of Delcath CHEMOSAT in the Treatment of ICC Published in European Radiology

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PHP Therapy in ICC Treatment Shows Promise in Retrospective Analysis

NEW YORK, Oct. 04, 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 of a multicenter analysis of outcomes in patients with intrahepatic cholangiocarcinoma (ICC) treated with CHEMOSAT has been published in the journal *European Radiology*. The study is the first analysis on the use of Delcath's PHP ® Therapy for the treatment of ICC.

The retrospective analysis—Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival —was conducted by investigators in Germany, Italy, Netherlands, Spain and France with Dr. Steffen Marquardt of Hannover Medical School serving as lead author. The study evaluated 15 patients with ICC who were selected for PHP treatment after failing prior therapies. The patients were treated at nine hospitals throughout Europe between 2012 and 2016. Treatment outcomes were assessed by imaging every three months following PHP treatment.

Results of the study showed that after the first PHP treatment, one patient (7%) has a complete response (CR), two patients (13%) had a partial response (PR), and stable disease (SD) was observed in eight patients (53%). This equates to a control rate (CR+PR+SD) of 73%. The complete response patient was not retreated and is still alive. Three patients (20%) progressed after the first treatment and one patient died prior to post-procedure imaging. Five of the patients with SD received a second PHP treatment, resulting in one PR (20%), three SD (60%), and one PD (20%). During the follow-up phase two of the SD patients received additional PHP treatments.

Median overall survival (OS) was 26.9 months from initial diagnosis and 7.6 months from first PHP treatment. One-year OS from first PHP was 40%. Median progression free survival (PFS) was 122 days, and median hepatic progression free survival (hPFS) was 131 days.

In this retrospective data collection, side-effects were potentially under-reported but were considered by the investigators to be tolerable and comparable to other systemic and local therapies. Nevertheless, in the context of the patient selection, baseline characteristics and number of PHP treatments provided in this retrospective study, practitioners observed no adverse events of grades 3 or 4 severity during the PHP procedure. Post-procedurally, significant hematological toxicity was observed in the form of anemia and thrombocytopenia 5-7 days after the PHP procedure. Management with Granulocyte Colony Stimulating Factor (GCSF) was employed in some patients. These toxicities were considered consistent with those toxicities reported in the ABC 02 trial of systemic chemotherapy in this patient population.

Investigators concluded that PHP Therapy provides "promising response rates in patients with ICC," and that side-effects were tolerable and comparable to other treatment strategies.

Commenting on the study, Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Delcath Systems, said, "Results of this study are very encouraging when you consider that PHP Therapy was used for these patients after failing prior therapy(ies) and that all patients had been heavily pre-treated. Additionally, many of the patients included in this retrospective analysis were treated before certain aspects of the PHP procedure had become standard, such as the prophylactic use of GCSF growth factors to mitigate certain side-effects. These data have been previously used to inform the trial design for our Phase 3 trial in ICC, and we look forward to further investigating the use of PHP Therapy in a disease that has particularly challenging patient outcomes."

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

The 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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