



Data on Delcath's PHP Therapy presented at CIRSE 2018

September 24, 2018

NEW YORK, Sept. 24, 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 data from a study conducted in Germany of the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with metastatic ocular melanoma with liver metastases, was presented as a poster at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) annual meeting.

The study entitled *Survival and Response of Patients with Metastatic Ocular Melanoma after Chemosaturation Percutaneous Hepatic Perfusion* was conducted by M. Zeile, and A. Stang, et al of the Asklepios Barmbek Clinic in Hamburg, Germany. The study retrospectively evaluated response rates and overall survival in 12 patients with ocular melanoma liver metastases after treatment with Delcath's PHP® Therapy. Five patients had metastases confined to the liver, and seven had additional extra-hepatic metastases. A total of 30 PHP procedures were performed in the sample, and patients received an average of 2.5 treatments.

Results of the study showed the objective response rate (ORR) was 58.3%, and the disease control rate was 91.7% (1 complete response, 6 partial responses, 4 stable disease, and 1 progressive disease). Following the first PHP treatment, progression free survival was 11.7 months and hepatic progression free survival (hPFS) was 18.6 months. Median overall survival (OS) was 30.6 months following the treatment. Of the cohort of 12 patients, three patients were judged to be candidates for surgery following treatment with PHP. Median OS among these patients was 76.8 months, though investigators cautioned that statistical conclusions cannot be drawn from the small sample size.

Commenting on the study, Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Delcath Systems, said, "Though the cohort in this study was small, the results are consistent with the positive signals provided by other studies published or presented over the last year. The high ORR and disease control rate observed in this study is particularly encouraging, as these data points are now the primary and secondary endpoints, respectively, for our amended Registration trial in ocular melanoma liver metastases. As the study authors note, the role of secondary surgery following PHP treatment is currently unclear given the small sample size, but we believe points to the promise this therapy may have for appropriately selected patients."

The CIRSE 2018 annual meeting is being 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.

Contact:

Delcath Investor Relations

Email: investorrelations@delcath.com

Delcath Systems, Inc.