Delcath Announces Initiation of Registrational Trial of Melphalan/HDS in Intrahepatic Cholangiocarcinoma

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Duke Medical Center Opens for Patient Enrollment

NEW YORK, May 07, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTHD), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the Company has initiated its pivotal trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with intrahepatic cholangiocarcinoma (ICC). Duke Medical Center in Durham, North Carolina is the first cancer center to open for patient enrollment. Dr. Sabino Zani, a surgical oncologist with Duke Medical Center, is serving as the principal investigator for the trial in the United States.

The trial, entitled *A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma*, (the ALIGN Trial) will seek to enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The trial is being conducted under a Special Protocol Assessment (SPA) agreement reached with the U.S. Food and Drug Administration (FDA) in March 2017. Under the terms of the SPA, the primary endpoint is overall survival (OS) and secondary and exploratory endpoints include safety, progression-free survival (PFS), overall response rate (ORR) and quality-of-life measures. The SPA agreement indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS.

"The ALIGN Trial is based on a strong efficacy signal observed in the ICC tumor type through our commercial experience with CHEMOSAT in Europe," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "The sequential design of the therapies under investigation in the trial will allow us to minimize capital investment requirements in 2018. We are also leveraging our existing network of trial sites from our FOCUS Phase 3 trial to rollout the trial protocol as efficiently as possible, and intend to conduct the trial in a financially prudent manner. In this orphan population where there exists a huge unmet need, this trial provides us with a second pathway to commercial drug approval in the United States, and if successful we believe will be an important value driver for the Company."

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 have initiated a Registration trial for intrahepatic cholangiocarcinoma (The ALIGN Trial.) Melphalan/HDS has not been approved by the 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 and ICC clinical trials, 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.

Contact:
Delcath Investor Relations
Email: investorrelations@delcath.com

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