



## Delcath Announces Enrollment of First Patient in ALIGN Trial

October 18, 2018

*The University of Tennessee Health Science Center, Methodist University Hospital, and West Cancer Center Begin Treatments in New Registration Trial for Intrahepatic Cholangiocarcinoma*

NEW YORK, Oct. 18, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that patient treatments have begun in the Company's second global US registration trial investigating Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) in the treatment of patients with intrahepatic cholangiocarcinoma (ICC).

The University of Tennessee Health Science Center (UTHSC) in collaboration with Methodist University Hospital (MUH) and West Cancer Center (WCC) in Memphis, Tennessee have enrolled the trial's first patient and treatments have begun by a team led by Dr. Evan S. Glazer. Dr. Glazer, a board certified surgical oncologist, is the principal investigator for the trial at the UTHSC/MUH/WCC location.

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.

"ICC is a deadly form of liver cancer, and the current treatment options have only shown very limited benefit," said Dr. Evan Glazer, "Our team is encouraged by the initial data available for Melphalan/HDS and are pleased to participate in this trial to explore this therapy's potential as a new treatment option for these patients. We are most excited by the multi-disciplinary approach that this trial takes to help our patients."

"We are delighted to be working with Dr. Glazer and the team in Memphis to initiate The ALIGN Trial," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "In this orphan population where there exists a large unmet need, this trial provides us with a potential second pathway to commercial drug approval in the United States, and if successful we believe will be an important value driver for Delcath."

### 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 been enrolling 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: 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.*

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