## Delcath Announces Beginning of Enrollment of Amended Metastatic Ocular Melanoma Registration Trial

Stanford University Medical Center First Location to Begin Enrollment Under Single Arm Protocol

NEW YORK, Aug. 20, 2018 — Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that patient enrollment has begun under the amended protocol for its registration trial in ocular melanoma liver metastases. Stanford University Medical Center is the first trial site to obtain Institutional Review Board (IRB) approval for the amended protocol and the center is open to patient enrollment.

"Our team at Stanford are encouraged by the previous research into the use of Melphalan/HDS to treat ocular melanoma liver metastases, and we look forward to further exploring its potential for appropriately selected patients," said Dr. Sunil A. Reddy, Assistant Professor at Stanford. "We believe the new single arm protocol, which allows all patients to receive the Melphalan/HDS, will allow the trial to enroll patients expeditiously, while providing a basis for evaluating the safety and efficacy of treatment with Melphalan/HDS in this patient population."

"Results published earlier this year by researchers at the University of Southampton and Moffitt Cancer Center provide us with confidence that our amended trial can provide evidence in support of an NDA submission," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "We are very pleased that the team at Stanford were able to complete the IRB review so quickly, and we look forward to rolling out the amended protocol to other centers in both the United States and Europe in the coming months."

The trial, A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma (The FOCUS Trial), will enroll a minimum of 80 patients with ocular melanoma metastatic to the liver. Patients previously enrolled in the Melphalan/HDS arm of the trial under the prior randomized protocol will continue to be treated and evaluated as part of the amended trial. With this amendment, the Company anticipates completing trial enrollment by the end of the first half of 2019.

## **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 has initiated a Registration trial for intrahepatic cholangiocarcinoma (ICC). 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 forwardlooking 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 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: <u>investorrelations@delcath.com</u>