# Delcath Announces 3rd Independent Safety Review of Randomized Trial Data for Metastatic Ocular Melanoma; Recommended Continuation with no Trial Modification

Trial Continues on Scheduled Path with Expected Completion of Enrollment by June 2019

NEW YORK, Aug. 23, 2018 — Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that the independent Data Safety Monitoring Board (DSMB) of the Phase 3 clinical trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial) completed another pre-specified review of safety data for treated patients in the trial. This review was conducted on data collected from the prior randomized protocol for the FOCUS Trial. The DSMB again recommended that no safety related modifications to the treatment protocol be made.

In July, the Company announced that it has amended the protocol for the FOCUS trial, which will now enroll as a single-arm, multi-center open label study. Safety data to be collected were not modified as a result of the amendment, and safety data from both the randomized and single-arm protocols will be pooled in any analyses submitted to the Food & Drug Administration as part of a New Drug Application. The FOCUS trial, now entitled *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 under the prior randomized protocol will continue to be treated and evaluated as part of the amended trial, and periodic DSMB reviews will continue to be conducted.

“The safety data in the Melphalan/HDS arm of the prior randomized protocol of the FOCUS trial has been consistent with that observed in recent research in a non-clinical setting,” said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. “Given that safety concerns with the prior generation product and procedure were the primary issue in the FDA’s previous assessment, we are pleased with the safety profile observed by our therapy in the trial thus far.”

**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 trial (The FOCUS Trial) for Patients with Hepatic Dominant Ocular Melanoma (OM) and have initiated a global Phase 3 trial (The ALIGN Trial) for patients with 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 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 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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