Delcath's CHEMOSAT Included in German Treatment Guidelines for Melanoma Liver Metastases

NEW YORK, May 16, 2018 — Delcath Systems, Inc. (OTCQB:DCTHD), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the German Guidelines Program in Oncology (GGPO) has included treatment

with Delcath's CHEMOSAT[®] in the German national treatment guidelines for liver metastases from melanoma. This inclusion of treatment with CHEMOSAT is in the S3 Guidelines, which represents the highest level within the classification of the guidelines indicating that it is based on evidence and consensus within the German clinical community.

The GGPO's update was based on its evaluation of published data on treatment with CHEMOSAT as a loco-regional treatment for melanoma liver metastases. Following this evaluation, and after soliciting additional feedback from the oncology community in Germany, treatment with CHEMOSAT was classified with Evidence Level 1B, indicating the second highest level of evidence. Treatment with CHEMOSAT is the sole therapy classified with this top designation. Other loco-regional therapies previously included in the guidelines have been designated with Evidence Level 4, indicating an absence of clinical trial supporting evidence.

"Inclusion in the GGPO treatment guidelines reflects the steady accumulation of both clinical data and experience built with our therapy in Germany over the last several years," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "Importantly, the guidelines established that treatment with CHEMOSAT is the best supported option for patients with melanoma liver metastases based on current evidence. Through our Clinical Development Program and our commercialization efforts in Germany and other European markets, we are working toward establishing treatment with CHEMOSAT as a first line treatment option for appropriately selected patients."

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 called The ALIGN 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: 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 clinical trial, 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>