# Data on Delcath's CHEMOSAT System Presented at CIRSE Annual Meeting

NEW YORK, Sept. 19, 2017 — Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the results of a single institution study were presented at the Cardiology and Interventional Radiology of Europe (CIRSE) annual meeting, held in Copenhagen, Denmark on September 16-20, 2017.

The study, Prospective Clinical and Pharmacological Evaluation of the Delcath System's Second Generation (GEN2) Hemofiltration System in Patients Undergoing Percutaneous Hepatic Perfusion (PHP) with Melphalan, was conducted by a team at the Leiden University Medical Center (LUMC) in Leiden, The Netherlands and presented by T.S. Meijer, MD. The study prospectively evaluated filtration efficiency and hematologic side effects in seven patients who received a total of ten PHP procedures with the GEN2 CHEMOSAT system. Pharmacokinetic sampling was conducted at several points during the PHP procedure, and filtration efficiency was calculated at several discrete points. Blood tests were conducted following each procedure to determine hematologic side effect Grade Levels until the blood values normalized.

Results of the study showed the GEN2 CHEMOSAT system had an overall efficiency of 86%, with efficiency highest at the time of highest concentration of melphalan in the blood and declining as melphalan blood concentration declined. Peak efficiency was 95.4% in samples taken after 10 minutes of filtration, 85.9% at the end of the drug infusion period, and 77.5% at the end of the saline washout period. Researchers noted these results were superior to and more consistent than prior experience published with the first generation CHEMOSAT system. Hematologic side effects were mainly Grade 1 and 2 with some Grade 3 and 4 side effects emerging post-procedure, including 40% of treatment cycles showing Grade 4 thrombocytopenia, 80% showing Grade 3 or 4 leucopenia, and 70% showing lymphocytopenia. All patients were asymptomatic and all lab results normalized in three weeks. Other adverse events were managed, and there was no mortality, no severe bleeding complications, and no hypotensive cardiac or cerebral events. Researchers concluded that the GEN2 CHEMOSAT system appears to have higher melphalan filter efficiency, more consistent performance, and appears safe but needs further validation.

Commenting on the study, Dr. Jennifer K. Simpson, President & CEO of Delcath Systems, said, "This study provides good external confirmation of the filtration efficiency capability and consistent performance seen with the GEN2 CHEMOSAT, and is consistent with what we are seeing in the commercial setting. This study also indicates that the hematologic side effects of treatment with CHEMOAT are manageable. We look forward to validating these observations in our registration trials, which include robust evaluation of the pharmacokinetic characteristics of the PHP procedure."

### **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 plans to initiate a global 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: 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, an orderly transition to the OTCQB market , 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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