## Results of Single Center Study on Delcath's PHP Therapy Published in Cancer Imaging

Retrospective Study by University Hospital of Tubingen Shows Median Overall Survival of 27.4 Months in Patients with Ocular Melanoma Liver Metastases

NEW YORK, July 22, 2019 — Delcath Systems, Inc. (OTCPK: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that results from a single-institution retrospective study conducted by University Hospital of Tubingen (UHT) in Germany on the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with metastatic ocular melanoma with liver metastases were published in the journal *Cancer Imaging*.

The study, <u>Chemosaturation with percutaneous hepatic perfusion of melphalan for liver dominant metastatic uveal melanoma: a single center experience</u>, by Dr. Christoph Artzner, et al, evaluated the safety and efficacy of PHP® Therapy in 16 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between June 2015 and December 2018. Tumor response was evaluated following each PHP treatment using Response Evaluation Criteria in Solid Tumors (RECIST), and serious adverse events (SAEs) were evaluated using Common Criteria for Adverse Events (CTCAE).

The 16 patients underwent a total of 28 PHP treatments. Results of the study in the 15 evaluable patients showed that after the first PHP treatment, nine patients (60%) had a partial response (PR), five patients (33%) stable disease, and one patient (7%) had progressive disease for an initial disease control rate of 93%. Median progression free survival (PFS) after the first treatment was 11.1 months. Six patients received a second PHP treatment, three patients received three treatments, and a single patient received six treatments. Median overall survival (OS) was 27.4 months.

Safety analysis showed that grade three SAEs were observed in 14% of treatments, and these were anemia, leukopenia and thrombocytopenia. The sole grade four SAE observed was in one patient who suffered a cardiac arrest during the first PHP treatment and was removed from the study. Subsequent evaluation discovered this patient had coronary artery occlusion which was successfully treated. Retrospective evaluation of this patient's preprocedure imaging reveal signs of coronary artery disease, and investigators subsequently modified their screening procedures for cardiovascular risk factors. Investigators stated that most SAEs were grade one or two and that 5% of the reported grade three and four SAEs required additional intervention.

Investigators concluded that for patients with liver-dominant metastatic uveal melanoma, treatment with PHP Therapy had "observed rates for OS and PFS that exceeded the reported outcomes for traditional systemic treatment." Investigators stated that SAEs were frequent,

but most did not require additional intervention, and that care should be taken in patients with suspected coronary heart disease.

## **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 is marketed under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT) and has been used at major medical centers to treat a wide range of cancers of the liver. Since January 2019 CHEMOSAT is marketed under an exclusive licensing agreement with medac, a privately held multinational pharmaceutical company headquartered in Germany which specializes in the diagnosis and treatment of oncological, urological and autoimmune diseases.

## **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 and ICC Registration 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, 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 impact of the Company's exclusive licensing agreement with medac on commercial adoption in Europe and resulting revenue, if any, the Company's ability to successfully enter into other strategic partnerships 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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