

## **Results of Single Center Prospective Study on Delcath's PHP Therapy Presented at ECIO 2019**

Study by LUMC Shows Overall Survival of 20.3 Months in Patients with Ocular Melanoma Liver Metastases

NEW YORK, April 16, 2019 — Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that results from a prospective phase 2 study conducted by Leiden University Medical Center (LUMC) in the Netherlands on the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with metastatic ocular melanoma with liver metastases were presented at the European Conference on Interventional Oncology (ECIO) annual meeting.

The LUMC study, *Percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from ocular melanoma using the Delcath System's second-generation hemofiltration system: a prospective phase II study*, was conducted by a team led and presented by Dr. Mark Burgmans. The study evaluated 35 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between February 2014 and June 2017. The 35 patients underwent a total of 72 PHP treatments, and tumor response was evaluable in 32 patients. Primary endpoints were overall response, overall survival, and progression free survival. Secondary measures included safety measures and hematologic toxicity.

Results of the study showed that one patient had a complete response and 22 had partial response, for a combined overall response rate of 74.1%. Overall survival was 20.3 months and mean progression free survival was 8.1 months.

Safety analysis showed a total of 14 serious adverse events were recorded. The hematologic toxicities were in a majority of the cases self-limiting and manageable. Investigators concluded that "PHP Therapy with the Generation Two version of CHEMOSAT is an effective and safe treatment for patients with hepatic metastases from ocular melanoma."

The ECIO 2019 conference was held April 8-11 in Amsterdam, the Netherlands.

### **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 and specializing in the treatment and diagnosis 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 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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