Delcath Announces Preliminary Safety Analysis for Phase 3 Focus Trial

NEW YORK, Dec. 19, 2017 — Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the independent Data Safety Monitoring Board (DSMB) of the Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma has completed its pre-specified review of safety data for treated patients in the trial. The DSMB has recommended that the study continue without modification.

The FOCUS Trial is evaluating the efficacy, safety and pharmacokinetics of Melphalan/HDS versus best alternative standard of care in 240 patients with metastatic ocular melanoma (OM). The primary objective of the study is a comparison of overall survival between the Melphalan/HDS treatment arm and best alternative care arm comprised of selected therapies; secondary objectives include overall progression-free survival and objective response rate, each as determined by the Investigator, while exploratory objectives include progression-free survival, objective response rate, hepatic progression free survival and hepatic objective response rate all as determined by blinded Independent Central Review, and quality of life measures. The FOCUS Trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) to support marketing approval in the U.S.

“The DSMB’s recommendation to proceed without modification with the FOCUS Trial as planned confirms our own observations of the safety profile of PHP therapy based on prior research and our commercial experience with CHEMOSAT in Europe,” said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. “Importantly, this initial independent evaluation of the safety profile of melphalan/HDS used the Generation Two filter configuration of the device and the current version of the procedure protocol, and so provides confidence in both our product and procedure. Given that safety concerns with the previous generation product and procedure were the primary issue in the FDA’s previous assessment, we are pleased to have successfully passed this important milestone.

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 plan to initiate a 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 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: 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.

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