Review of Delcath Melphalan/HDS System Published in “Cardiovascular & Interventional Radiology”

First Review of Current Product and Procedure to be used in the Planned Global Phase 3 Trial

NEW YORK, Jan. 11, 2016 — Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces that a review of the Delcath Hepatic Delivery System (Melphalan/HDS) for the treatment of patients with liver cancers has been published in *Cardiovascular & Interventional Radiology (CVIR*), a leading peer-reviewed medical journal.

The review is entitled, “*Percutaneous Isolated Hepatic Perfusion for the Treatment of Unresectable Liver Malignancies,”* by Dr. Mark C. Burgmans, et al. from Leiden University Medical Center (LUMC), in the Netherlands, and includes the first published overview of the enhanced version of the Melphalan/HDS device and procedure. This version of the Melphalan/HDS device and procedure has been used commercially in Europe since 2012 and is being used in the current trials that comprise the Company’s clinical development plan. In their update of current literature on percutaneous hepatic perfusion, the LUMC team noted that the current version of the Delcath product and procedure “appear to have reduced the rate and severity of bone marrow suppression” over the previous version of the system. The authors concluded that treatment with Melphalan/HDS “holds promise as a locoregional therapy for patients with hepatic malignancies” and “is a novel, minimally invasive and repeatable alternative for isolated hepatic perfusion.”

“The review provides a useful overview of the refinements to both our product and procedure that have been made since the 2010 completion of our prior U.S. Phase 3 trial,” said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. “We look forward to initiating our new Global Phase 3 trial in hepatic dominant ocular melanoma, and are confident that the improvements in the reduction of toxicities noted by the LUMC team can be formally validated in this pivotal study. We look forward to working further with LUMC and others to realize the potential identified in this review.”

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. the Melphalan/HDS system is considered a combination drug and device product, and is

regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC), and expect to initiate a global Phase 3 trial in ocular melanoma (OM) that has metastasized to the liver.

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 impact, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, the timing and results of the Company's clinical trials including without limitation the HCC, ICC and OM clinical trial programs timely enrollment and treatment of patients in the global Phase 2 HCC and ICC clinical trial, FDA approval of the global Phase 3 OM clinical trial protocol, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM 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, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, 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, our ability to maintain NASDAQ listing, 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/review-of-delcath-melphalanhds-system-published-in-cardiovascular–interventional-radiology-300201875.html

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