Leading U.S. Cancer Centers Join Delcath's Focus Phase 3 Trial For Patients With Hepatic Dominant Ocular Melanoma

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NEW YORK, May 3, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on the treatment of primary and metastatic liver cancers, announces that John Wayne Cancer Institute in Los Angeles, California and Duke Cancer Institute in Durham, North Carolina have been activated as clinical trial sites in the Company's *FOCUS Phase 3 Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma* (the FOCUS Trial). The prestigious centers join Moffitt Cancer Center in Tampa, Florida as active participants in the FOCUS Trial. Delcath plans to include approximately 30 cancer centers in the United States and Europe in the FOCUS Trial.

"We are pleased to add these highly-respected cancer centers to our FOCUS Phase 3 trial," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and CEO of Delcath Systems. "Interest in participating in the FOCUS trial is high among other major cancer centers in both the United States and Europe, and we expect to announce further trial site activations in the coming months."

About the FOCUS Trial

The FOCUS Trial is evaluating the safety, efficacy and pharmacokinetic profile of the Company's Melphalan/HDS system versus best alternative care in 240 patients with ocular melanoma liver metastases. The FOCUS Trial's primary endpoint is a comparison of overall survival between the two study arms; secondary and exploratory endpoints include progression-free survival, overall response rate and quality-of-life measures. The FOCUS Trial is being conducted under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS.

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 our global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and 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).

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, HCC ,and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma and the global Phase 2 HCC and ICC clinical trials, 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, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, 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, 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 remaining 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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