Delcath Announces Initiation Of Phase 3 Trial Of Melphalan/HDS System For Treatment Of Hepatic Dominant Ocular Melanoma

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Moffitt Cancer Center Begins Patient Enrollment in FOCUS Trial; Study Results to Support U.S. New Drug Application

NEW YORK, Jan. 20, 2016 /PRNewswire/ -- 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 the initiation of a Phase 3 clinical trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) for the treatment of patients with hepatic dominant ocular melanoma (OM).

The *FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma* (the FOCUS Trial) will evaluate the safety, efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with OM. The 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), and per the SPA is the only Phase 3 trial required for submission of a New Drug Application.

In the trial's treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years. The FOCUS Trial will be conducted at leading cancer centers in the United States and Europe.

Under the terms of the SPA, at least 50% of patients will be treated in the U.S. The Moffitt Cancer Center in Tampa, Fla. has been activated as a participating center and Jonathan Zager, M.D., FACS, Professor of Surgery in the Cutaneous Oncology and Sarcoma Departments and a Senior Member at Moffitt Cancer Center, is serving as the trial's principal investigator.

"I am particularly pleased to serve as principal investigator in this very promising study as I have treated patients with Melphalan/HDS through both formal clinical research and compassionate use since 2007," said Dr. Zager. "Our experience at Moffitt with Melphalan/HDS in patients with hepatic dominant ocular melanoma has shown significant potential. We are pleased to be taking a leadership role in the FOCUS Trial, and look forward to verifying the potential for Melphalan/HDS in this life-threatening cancer with no effective treatment options."

"We believe the FOCUS Trial puts us on the fastest path to a regulatory submission in the U.S. and initiation of this trial is a landmark event for Delcath," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "We are delighted to be working with the Moffitt Cancer Center and look forward to activating a number of other premier cancer centers as clinical sites in the coming months. Our goal is to have an interim analysis, which we expect to occur in the second half of 2017. We look forward to bringing this potentially life-saving therapy to patients suffering with hepatic ocular melanoma."

"The FOCUS Trial will utilize an improved Melphalan/HDS product/procedure that addresses safety issues raised in our previous Phase 3 study. Based on our commercial experience in Europe, and the bolus of clinical data recently presented and published, we are optimistic that the FOCUS Trial will demonstrate a compelling benefit/risk profile and that the study's objectives will be met," added Dr. Simpson.

About Moffitt Cancer Center
Located in Tampa, Moffitt is one of only 45 National Cancer Institute-designated Comprehensive Cancer Centers, a distinction that recognizes Moffitt's excellence in research, its contributions to clinical trials, prevention and cancer control. Moffitt is the top-ranked cancer hospital in Florida and has been listed in U.S. News & World Report as one of the "Best Hospitals" for cancer care since 1999. With more than 5,000 team members, Moffitt has an economic impact in the state of $1.9 billion. For more information, visit MOFFITT.org, and follow the Moffitt momentum on Facebook, Twitter and YouTube.

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 a global Phase 3 trial in hepatic dominant ocular melanoma (OM). We also plan to evaluate intrahepatic cholangiocarcinoma (ICC) in a Phase 2 clinical study.

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 FOCUS Trial, Phase 2 HCC and ICC clinical trial, 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 remaining requirements of the FDA's 2013 Complete Response Letter, 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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