Delcath Announces First European Clinical Sites For FOCUS Phase 3 Trial For Ocular Melanoma Liver Metastases

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NEW YORK, Oct. 12, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces that five clinical sites in Europe have been activated and are open for patient enrollment in the Company's FOCUS Phase 3 clinical trial for patients with hepatic dominant ocular melanoma (the FOCUS Trial). The sites are the first centers in Europe to begin enrolling patients in the FOCUS Trial. One center, Charité University Hospital in Berlin, Germany, has treated its first patient. Delcath now has 13 centers in the U.S. and Europe open for patient recruitment, and expects up to 30 centers will participate in the FOCUS Trial.

The following highly-accredited European centers are now open for patient enrollment:

Austria

- University Hospital, Graz

Germany

- Charité University Hospital, Berlin
- University Hospital, Marburg
- University Hospital, Regensburg

United Kingdom

- University Hospital Southampton

"We are pleased to add these highly respected European cancer centers to our FOCUS Trial," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and CEO of Delcath. "This expansion allows Delcath to work with the some of Europe's top universities and institutes while providing some of Europe's leading clinicians with first-hand knowledge of our therapy, which will continue to be of great value as we expand our commercial footprint for CHEMOSAT as a treatment for ocular melanoma in Europe."

About the FOCUS Trial

The FOCUS Trial is a global Phase 3 clinical study 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 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 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). 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.

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: our ability to repay and comply with the obligations under our senior secured convertible notes, 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, 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 CHEMOSAT/Melphalan HDS system and the potential of the CHEMOSAT/Melphalan HDS 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 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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