



Researchers at Leiden University Medical Center receive outstanding service award for Publication on Delcath's Melphalan/HDS

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NEW YORK, Sept. 12, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces that a research team led by Dr. Mark C. Burgmans at Leiden University Medical Center (LUMC) in the Netherlands has received the prestigious *Outstanding Service Award* from *Cardiovascular & Interventional Radiology (CVIR)*, a leading peer-reviewed medical journal. The LUMC team were recognized for their review of the Delcath Hepatic Delivery System (Melphalan/HDS), entitled, "[Percutaneous Isolated Hepatic Perfusion for the Treatment of Unresectable Liver Malignancies](#)," which was published by CVIR in January 2016. The award was presented to Dr. Burgmans and his team at a ceremony during the *Cardiovascular & Interventional Radiology Society of Europe (CIRSE)* annual conference, held in Barcelona, Spain, September 10-14, 2016.

The LUMC's research review was the first published overview of the current version of the Melphalan/HDS device and procedure, which includes upgrade filters and further developed procedural techniques. 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."

"We are very pleased to see the team at LUMC recognized for their contribution to the growing body of research into the potential of Melphalan/HDS for patients with cancers of the liver," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "Research presented or published since this review was conducted have added support to the LUMC teams' conclusions, and we are confident that the improvements in the reduction of toxicities and the overall potential noted by the LUMC team can be formally validated in trials that comprise our clinical development plan. 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 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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