Delcath Announces CHEMOSAT Treatment Milestones In Europe

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250th Treatment Performed Since Introduction of Second Generation CHEMOSAT in Europe; Prestigious Harley Street Clinic Activated in the United Kingdom

NEW YORK, Dec. 2, 2015 /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 that physicians in Europe have completed over 250 treatments with Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) since the second generation of CHEMOSAT was launched. Physicians in Europe have used CHEMOSAT in both commercial and clinical settings to treat patients for a wide variety of cancers in the liver, including ocular melanoma liver metastases, hepatocellular carcinoma and intrahepatic cholangiocarcinoma, and liver metastases from colorectal cancer, breast cancer and others.

Concurrently, Delcath announces the activation of the prestigious Harley Street Clinic (HSC) in London, United Kingdom as a CHEMOSAT treatment site. HSC is a specialist private hospital that provides complex cardiac, cancer and neurosciences care. HSC is supported by HCA International and owned by HCA Inc., the largest provider of private healthcare in the world. Julian Hague, M.D., an interventional radiologist with HSC, performed the clinic's first CHEMOSAT treatment on a patient with breast cancer liver metastases in November.

"I believe the future of interventional oncology lies in tailoring the treatment to the individual patient," said Dr. Hague. "I believe having CHEMOSAT in our treatment armamentarium represents major progress in our ability to provide liver directed therapies to patients."

"The completion of our 250th CHEMOSAT treatment and the activation of the Harley Street Clinic highlight the steady progress our team has made in expanding the clinical adoption of this therapy," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "Over the past two years our team has built a strong commercial and clinical footprint for CHEMOSAT in Europe. We look forward to continuing to build on this momentum in the New Year in order to increase revenue and, importantly, to enhance the lives of patients suffering with these life-limiting conditions."

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with an emphasis 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). The Melphalan/HDS system 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.

Contact Information:
Investor Contact:
LHA
Anne Marie Fields, afields@lhai.com
212-838-3777