# Delcath Announces National Reimbursement Coverage For CHEMOSAT Procedures In Germany

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**German Authority Establishes Procedure Code for CHEMOSAT; ZE Code is First National Reimbursement Mechanism for CHEMOSAT in Europe**

NEW YORK, Oct. 8, 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 the establishment of a national reimbursement code for procedures performed with the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) in Germany. The German Institute for the Hospital Remuneration System (InEK) issued a ZE diagnostic-related group (DRG) code, which permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures beginning in 2016. This new nationwide code replaces the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually for reimbursement of their CHEMOSAT treatment. The decision represents the first national reimbursement mechanism for CHEMOSAT procedures in Europe.

"The receipt of ZE reimbursement represents an important step towards increased commercialization of CHEMOSAT and highlights the role our therapy has been playing in Germany for the treatment of patients with cancers in the liver," said Jennifer K. Simpson, Ph.D., MSN, CRNP, CEO & President of Delcath Systems, Inc. "The application for coverage under the ZE scheme was made by the German Radiology Society and has been widely supported by major German cancer hospitals, which also speaks to the confidence the German clinical community has in the therapy. With a ZE DRG code established, an application under the annual NUB process is no longer required. We look forward to supporting participating hospitals in their negotiations with insurers in the coming year and are pleased that this new reimbursement will make CHEMOSAT treatment more easily accessible to patients in Germany suffering with cancers in the liver."

ZE is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany. The establishment of ZE coverage by InEK was made in response to an application made by the German Radiology Society for CHEMOSAT in March 2015.

**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: future patient outcomes and clinical trial results consistent with the data contained in the SSO abstract, acceptance and publication of the Phase 3 trial manuscript and the impact of publication 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 ESSO*

*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.*

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