



## **DEL CATH ANNOUNCES REIMBURSEMENT FOR CHEMOSAT IN GERMANY**

**NEW YORK, February 4, 2013** – Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the Institut für das Entgeltsystem im Krankenhaus (InEK), the German federal reimbursement agency, has established a reimbursement pathway for the treatment of patients with liver metastases with the Delcath Hepatic CHEMOSAT<sup>®</sup> Delivery System for melphalan hydrochloride. The decision by the InEK followed an endorsement by the German Radiology Association, which prompted 47 cancer centers throughout Germany to submit applications under the Neue Untersuchungs- und Behandlungsmethoden (NUB) scheme for new technology reimbursement at specific hospitals. The Value 4 status given to the CHEMOSAT procedure, while not mandating reimbursement, allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Under the NUB scheme, reimbursement pathways will potentially be available for treatment with CHEMOSAT regardless of primary cancer origin.

Eamonn P. Hobbs, President & CEO of Delcath said, “This is excellent news for both patients in Germany and Delcath, as it represents a significant positive step in our efforts to fully commercialize CHEMOSAT in Europe. This is the first reimbursement mechanism for our procedure in Germany, the biggest market for CHEMOSAT in the European Union. It is important to note that the application for coverage was supported by 47 cancer centers across the country, which we believe speaks to the medical need physicians in Germany see for CHEMOSAT. We will continue to work closely with the participating hospitals to achieve reimbursement with the insurers. With a direct sales force in place and training of the additional centers in Germany on the way, we are now in a good position to begin growing this market for CHEMOSAT.”

### **About Delcath Systems**

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase 2 trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT<sup>®</sup> delivery system for melphalan hydrochloride in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system for melphalan hydrochloride in Europe. In October 2012, the Company satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal

filtration of doxorubicin hydrochloride injection, providing a regulatory pathway for the CHEMOSAT Delivery System to deliver and filter doxorubicin for countries in Asia that accept the CE Marking as part of their national regulatory requirements. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company's NDA has been accepted for filing and substantive review by the FDA. For more information, please visit the Company's website at [www.delcath.com](http://www.delcath.com).

*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: whether each of the 47 cancer centers in Germany will successfully negotiate and receive reimbursement for the CHEMOSAT procedure in their region and the amount of reimbursement to be provided, patient outcomes using the CHEMOSAT system in the EU, patient outcomes using the chemosaturation system under the EAP, timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information or data and our ability to provide the same in a timely manner, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of ocular metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with primary and metastatic disease in the liver, market acceptance of the Gen Two CHEMOSAT system and patient outcomes using the same, approval of the current or future chemosaturation system for delivery and filtration of melphalan, doxorubicin or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and timing an revenue, if any, of the same, the approval of the Hepatic CHEMOSAT Delivery System device to deliver and filter doxorubicin in key Asian markets and patient outcomes using the same, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the timing and results of research and development projects, uncertainties relating to the timing and results of future clinical trials, and uncertainties regarding our ability to obtain financial and other resources for any research, development 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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