



DEL CATH RECEIVES REGULATORY APPROVAL FOR THE GENERATION TWO HEPATIC CHEMOSAT[®] DELIVERY SYSTEM IN AUSTRALIA

NEW YORK, NY – November 5, 2012 – Delcath Systems, Inc. (NASDAQ: DCTH) today announced the Therapeutic Goods Administration (TGA) division of the Australian government has approved the Generation Two Hepatic CHEMOSAT[®] Delivery system for melphalan hydrochloride for listing on the Australian Register of Therapeutic Goods (ARTG). The TGA’s approval allows Delcath to market and sell the system in Australia.

“Australian regulatory approval of our Generation Two CHEMOSAT system with melphalan for injection represents our first approval of the new system in the Pacific Rim,” said Eamonn P. Hobbs, President and CEO of Delcath. “This approval is another significant milestone for Delcath, since it enhances our opportunity to address a potential market of \$50-70 million as we seek an exclusive distributor in this region.”

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 for the Generation Two CHEMOSAT[®] Delivery System for melphalan hydrochloride in April 2012. The right to affix the CE mark allows the Company to market and sell CHEMOSAT system for melphalan hydrochloride in Europe. 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. The Company is seeking approval for its proprietary chemosaturation system with melphalan hydrochloride as a treatment for patients with unresectable metastatic melanoma in the liver.

For more information, please visit the Company's website at 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: market acceptance of the Gen Two CHEMOSAT system in Australia and our ability to commercialize the CHEMOSAT system in Australia, patient outcomes using the Gen Two system, our ability to address the contents of the 74 Day Letter from the FDA, 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 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 in the EEA, our ability to successfully commercialize the chemosaturaton system and the potential of the chemosaturaton system as a treatment for patients with primary and metastatic disease in the liver, approval of the current or future chemosaturaton system for other indications, 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 of the same, the initiation of clinical trials in key Asian markets with the CHEMOSAT system with doxorubicin and timing and results of the same, approval of the CHEMOSAT system with doxorubicin in key Asian markets, patient outcomes using the CHEMOSAT system with doxorubicin, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the timing and results of research and development projects and 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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