



## **DEL CATH PROVIDES UPDATE ON FDA ADVISORY COMMITTEE MEETING ON MELBLEZ™ KIT**

**Queensbury, NY – May 2, 2013** – Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the U.S. Food and Drug Administration’s (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 16 to 0 with no abstentions that benefits of treatment with Delcath’s Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) for the treatment of patients with unresectable ocular melanoma metastatic to the liver do not outweigh the risks associated with the procedure.

The FDA is not bound by the recommendation of its advisory committee, but will consider the committee’s guidance as it evaluates the Melblez Kit New Drug Application (NDA). The Prescription Drug User Fee Act (PDUFA) goal date for completion of the FDA’s review and decision regarding approval of the Melblez Kit NDA is September 13, 2013.

“As we conveyed during the presentation to the ODAC, we believe our clinical trial data support Melblez Kit as an effective treatment option offering clinical benefits to patients with unresectable metastatic ocular melanoma in the liver” said Eamonn P. Hobbs, President and CEO of Delcath Systems. “While we were disappointed in today’s outcome, we will continue to work closely with the FDA throughout its ongoing evaluation of Melblez Kit. We remain committed to providing access to this promising new treatment for patients who have few choices with regard to treatments.”

### **About Oncologic Drugs Advisory Committee Meetings**

The FDA’s Oncologic Drugs Advisory Committee (ODAC) consists of a panel of independent experts who advise the FDA on the safety and efficacy of proposed new cancer therapies. The panel addresses specific questions raised by the FDA as the agency considers regulatory decisions. The FDA is not bound by the committee’s recommendation, but the agency takes its advice into consideration when reviewing new drug applications.

### **About Delcath Systems**

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System, 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. Outside of the United States, our proprietary product to deliver and filter melphalan hydrochloride is marketed under the trade name Delcath Hepatic CHEMOSAT<sup>®</sup> Delivery System (CHEMOSAT Delivery System for Melphalan.) The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT Delivery System for Melphalan 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 (CHEMOSAT Delivery System for Doxorubicin). 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: the impact of the negative advisory vote by the ODAC panel on the FDA's decision regarding the Company's new drug application (NDA), 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, additional extensions to the PDUFA date by the FDA, , 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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