



DELCATH, SKY RIDGE MEDICAL CENTER INITIATE U.S. EXPANDED ACCESS PROGRAM

EAP Provides U.S. Patients Access to Second-Generation Hemofiltration Cartridge Currently Under Active FDA Review

NEW YORK, Jan. 9, 2013 -- Delcath Systems, Inc. (NASDAQ: DCTH) today announced that Sky Ridge Medical Center in Lone Tree, Colo., has become the first U.S. center to initiate the Expanded Access Program (EAP), which will provide eligible patients access to treatment with the Company's second-generation hemofiltration cartridge of its proprietary chemosaturation system. The Company's New Drug Application (NDA) is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of patients with unresectable metastatic ocular melanoma in the liver with a PDUFA goal date of June 15, 2013.

Under certain circumstances, the FDA allows companies to offer early access programs to patients who have serious or immediately life-threatening illnesses for which there are no comparable alternative therapies. Sky Ridge Medical Center, an American College of Surgeons (ACoS) accredited cancer center, is the first of several prestigious U.S. medical centers expected to offer eligible patients access to the treatment option under the Delcath EAP program.

"Patients with unresectable metastatic ocular melanoma in the liver often have few choices with regard to treatments," said Dr. Charles W. Nutting, an interventional radiologist with Sky Ridge Medical Center. "Liver involvement is a life-limiting factor for these patients. We believe the expanded access program provides patients an important access to treatment that could potentially be beneficial."

"As an investigator in our Phase 3 clinical trial, Dr. Nutting has been a pioneer in the development of chemosaturation therapy, and we are pleased that Sky Ridge Medical Center is participating in our EAP under his leadership" said Eamonn P. Hobbs, President & CEO of Delcath Systems. "The EAP is a beneficial program offered by the FDA that provides patients with limited treatment options the opportunity to access drugs that are still in investigational stages. We felt it was important to pursue EAP approval for our chemosaturation system with the Generation Two filter because many of the patients with metastatic melanoma cannot wait while our New Drug Application is under review by the FDA."

"Dr. Nutting and his Interventional Radiology team at Sky Ridge have led the way in advancing this and other life enhancing treatments for patients," said Maureen Tarrant, CEO of Sky Ridge Medical Center. "As a destination center for high quality, compassionate care, we are proud of Dr. Nutting's leadership, innovation and commitment to our oncology program."

About Sky Ridge Medical Center

As Douglas County, Colorado's first hospital, Sky Ridge Medical Center opened on August 20, 2003 and has since become a destination center for healthcare, providing a depth and breadth of quality services and advanced treatment options to the region. Sky Ridge has earned not only quality designations from the Joint Commission and other governing bodies but has earned high marks for patient satisfaction. Sky Ridge Medical Center is a member of the HealthONE system of excellence, which includes seven hospitals; three surgery centers; more than 30 occupational medicine/rehabilitation, specialty clinics; and AirLife, which provides critical care air and ground transportation for the HealthONE system. More information can be found online at www.skyridgemedcenter.com.

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® 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.

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: patient outcomes using the chemosaturation system in 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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