Delcath Receives European Regulatory Approval for Second Generation Hemofiltration Cartridge

The Associated Press

Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the Company has received CE Mark approval for the second generation hemofiltration cartridge of the Company's proprietary Hepatic CHEMOSAT@ Delivery System. With the new hemofiltration cartridge, the CHEMOSAT system carries the same broad indication as the previous generation system, permitting physicians to use the product for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver to any patient who in their opinion may benefit.

"With receipt of CE Mark for our second generation CHEMOSAT system, we will now be able to supply centers in Europe with a product that we believe offers improved filtration efficiency compared to the previous generation filter used in our clinical trials," said Eamonn P. Hobbs, President & CEO of Delcath Systems. "The new hemofiltration cartridge has demonstrated melphalan removal of greater than 98% during drug infusion in an in vivo study. Additionally the new filter removed significantly fewer blood platelets in the same study.

"With the new hemofiltration cartridge, we believe that CHEMOSAT may help to improve the management of side effects on treated patients and potentially complement other systemic cancer therapies, leading to greater system utilization. We look forward to the first European commercial procedure using the new filter, which is scheduled for next week," Mr. Hobbs added.

CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark allows Delcath to market and sell its Class III medical device in countries in the European Economic Area (EEA). Delcath's new hemofiltration cartridge's design and technology is patent pending.

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 III 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 II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT@ delivery system in April 2011. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in

Europe. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company continues with the preparation of its NDA submission and intends to seek FDA approval for commercial sale of its chemosaturation system with melphalan. For more information, please visit the Company's website at www.delcath.com.

The 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 benefits of the new Chemofilter cartridge for the CHEMOSAT system and market acceptance of the same, the timing of the supply and distribution of the CHEMOSAT system including the new Chemofilter cartridge to early launch centers Europe, the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the 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, approval of the current or future chemosaturation system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the 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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