Delcath Announces Completion of Regulatory Notification Process in New Zealand

October 19, 2011

NEW YORK, Oct. 19, 2011 /PRNewswire via COMTEX/ -- Delcath Systems (NASDAQ: DCTH) announced today that the Company has, through its designated sponsor, completed the product notification process for the Delcath Hepatic CHEMOSAT® Delivery system with the Medicines and Medical Device Safety Authority (MEDSAFE) in New Zealand. Completion of this process permits Delcath to legally supply and distribute CHEMOSAT to the New Zealand market. The Company expects to begin supplying the system through an authorized distributor in 2012.

Commenting on the announcement, Eamonn P. Hobbs, President and CEO of Delcath, said, "Completion of the notification process in New Zealand is part of our plans to expand our addressable markets by leveraging our CE Mark for CHEMOSAT. New Zealand is just one of several markets that require CE Mark as a prerequisite that we expect to open over the next few years. We have also completed our filing with the Australian Therapeutic Goods Administration, and expect approval by year-end. We also intend to seek regulatory acceptance in other markets in Asia, Latin America and the Middle East. With market access in New Zealand and anticipated acceptance in Australia by the end of the year, our plans for introducing chemosaturation therapy into the Pacific region have begun."

About Delcath Systems

Delcath Systems, Inc. is a development stage 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 concluded a Phase 3 metastatic melanoma study, and the Company recently completed a multi-arm Phase 2 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 Company has not yet received FDA approval for commercial sale of its system in the United States. For more information, please visit the Company's website at http://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 our ability to commercialize the CHEMOSAT system in New Zealand including adoption, use and resulting sales, if any, regulatory approval of the CHEMOSAT system in Australia and other countries in the Pacific region, 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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