Delcath Signs Agreement With Synerx and Mylan's Bioniche Teoranta for Melphalan Supply

October 14, 2010

NEW YORK, Oct 14, 2010 /PRNewswire via COMTEX/ --

Delcath Systems, Inc. (Nasdaq: DCTH) announced today that it has executed a multi-year supply agreement with Synerx Pharma, LLC and Bioniche Teoranta, an affiliate of Mylan, Inc., for the supply of Delcath's branded melphalan hydrochloride for injection ("melphalan"). Melphalan is the chemotherapeutic drug used with Delcath's Chemosaturation system in its Phase III clinical study for the treatment of patients with hepatic metastases from ocular or cutaneous melanoma.

This agreement provides Delcath an exclusive right of reference to the Synerx Abbreviated New Drug Application (ANDA) for use with the Delcath ChemoSaturation system as well as a reliable, long-term and already United States Food and Drug Administration (FDA) approved source of melphalan for the U.S. market. The approved ANDA and its associated filesare registered to Synerx and licensed to Bioniche Teoranta. Under the terms of the agreement,Synerx will grant Delcath a limited license to reference the ANDA and associated data files in Delcath's New Drug Application ("NDA") submission, and Bioniche Teoranta shall manufacture and supply Delcath with Delcath-branded melphalan hydrochloride through its FDA-approved cGMP (current Good Manufacturing Practices) contract manufacturer. The term of the agreement is seven years following FDA approval of Delcath's NDA.

"We are extremely pleased to have signed an agreement with such established and market-leading companies as Synerx and Mylan's Bioniche. We believe that the right to reference an approved ANDA for melphalan and utilize a proven supply chain will greatly simplify and enhance the quality of our own NDA submission," said Eamonn P. Hobbs, President and CEO of Delcath Systems. "We are presently preparing the remaining modules for our NDA submission to the FDA, and continue to expect to complete our NDA filing during the fourth quarter of 2010."

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 III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company has not yet received FDA or any foreign regulatory approval for commercial sale of its system. 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 the acceptability of the Phase III clinical trial data by the FDA, our ability to successfully complete an FDA New Drug Application (NDA) during the fourth quarter of 2010, benefits to our NDA submission to the FDA from the Synerx/Bioniche agreement, if any, acceptance of the new drug application by the FDA, approval by the FDA or other regulatory authorities of the current or future drug delivery system for the treatment of metastatic melanoma, the future reliability of melphalan supply for the U.S. market, our ability to successfully complete other clinical trials and secure regulatory approval of our current or future drug-delivery system for the treatment of other liver cancers and other organs, the potential of chemosaturation therapy via PHP as a treatment for patients with terminal metastatic disease in the liver, actions by the FDA or other regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, 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.

SOURCE Delcath Systems, Inc.