



U.S. FDA GRANTS ORPHAN DRUG DESIGNATION TO DELCATH SYSTEMS FOR USE OF MELPHALAN HYDROCHLORIDE IN HCC

New York, NY – October 1, 2013 – Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology, announced today that the U.S. Food & Drug Administration (FDA) has granted the Company orphan drug designation for melphalan in the treatment of patients with hepatocellular carcinoma (HCC, or primary liver cancer).

Orphan-drug designation is granted by the FDA Office of Orphan Products Development to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy, or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication. It also provides tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

Melphalan for use with the Delcath Hepatic Delivery System is not currently approved in the United States for the treatment of patients with HCC.

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 the liver, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic 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® Delivery System for melphalan hydrochloride. 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 addition, the Company has initiated plans to investigate the Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System for primary liver cancer. 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: the timing and results of the Company's future clinical trials including without limitation the HCC trials, FDA approval of the melphalan Delcath Hepatic Delivery System for the treatment of HCC,, the

Company's ability to benefit from the orphan drug designation for melphalan for the treatment of HCC, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe, 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, our ability to obtain reimbursement for the CHEMOSAT system in various markets, 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 and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects,, and uncertainties regarding our ability to obtain financial and other resources for any research, development, clinical trials 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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