Delcath Announces Special Protocol Agreement Modification With FDA

NEW YORK, Jan. 10, 2018 — Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that it has concluded a modification agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with hepatic dominant ocular melanoma (The FOCUS Trial). The modification agreement revises the FOCUS trial's eligibility criteria to permit a greater extent of extra-hepatic disease by removing the size restriction, number and location of extra-hepatic lesions, in conjunction with a treatment plan for the extra-hepatic metastases.

Commenting on the announcement, Jennifer K. Simpson, Ph.D., President and CEO of Delcath Systems, "We requested this protocol modification to improve patient access to this important clinical trial for appropriately selected and managed patients. In an ultra-orphan indication like ocular melanoma, striking the appropriate balance between eligibility criteria and patient access can be a challenge. We are pleased that the FDA agreed to this modification, and hope that once approved by the institutional review boards of our participating clinical trial sites, that this modification will help accelerate enrollment in this registrational trial."

PHP Therapy with Melphalan/HDS was developed by Delcath Systems as a targeted, whole organ therapy for the liver. It is commercially available as a device in Europe, where it is marketed as CHEMOSAT®. The system has not been approved by the U.S. Food and Drug Administration, and is undergoing Phase 3 clinical testing in the U.S. as an investigational product**.**

About Delcath Systems

Delcath Systems, Inc. is an interventional oncology Company focused on the treatment of primary and metastatic liver cancers. Our investigational product – Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) – is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. We have commenced a global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and plan to initiate a Registration trial for intrahepatic cholangiocarcinoma (ICC) in the fall of 2017. Melphalan/HDS has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system has been commercially available since 2012 under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Forward Looking Statements

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 clinical trials including without limitation the OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM clinical trial, IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact of the presentations at major medical conferences and future clinical results consistent with the data presented, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact, if any of ZE reimbursement on potential CHEMOSAT product use and sales in Germany, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK, the Company's ability to successfully commercialize the Melphalan HDS/CHEMOSAT system and the potential of the Melphalan HDS/CHEMOSAT 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 Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects and uncertainties regarding the Company's 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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