Delcath Announces Special Protocol Assessment Agreement With FDA for Pivotal Trial With Melphalan/HDS in Intrahepatic Cholangiocarcinoma

Company Plans to file 2016 Fourth Quarter and Year End Financial Results by March 30, 2017

NEW YORK, March 27, 2017 — Delcath Systems, Inc. (NASDAQ:DCTH), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces it has reached a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of Delcath's pivotal trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with intrahepatic cholangiocarcinoma (ICC). The SPA agreement indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS.

The pivotal trial is titled *"A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma*." Under the SPA, the study will enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint is overall survival (OS) and secondary and exploratory endpoints include safety, progression-free survival (PFS), overall response rate (ORR) and quality-of-life measures. The Company expects to initiate the study in the Fall of 2017.

Full details of the registration trial will be made public upon the launch of the study and will be available at www.clinicaltrials.gov.

"We look forward to initiating this important study in ICC under a SPA with the FDA," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "The promising outcomes and observations in this tumor type identified by European investigators at our global Key Opinion Leader Forum last year were discussed at length with the agency, and provide us with considerable confidence in the potential of our therapy as a treatment for ICC. A manuscript of the European investigator data will be submitted to a peer-reviewed journal for publication."

"This pivotal study in ICC is designed to be cost effective and pursued in a financially prudent manner. Given the sequential nature of the trial design, Delcath's investment in this study will be modest in 2017 as the Melphalan/HDS segment of the study will not occur until late in the year," added Dr. Simpson.

Separately, the Company announces that it intends to file financial results for the three and 12 months ending December 31, 2016 on Form 10-K with the U.S. Securities and Exchange Committee on or before March 30, 2017.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

About Intrahepatic Cholangiocarcinoma

Intrahepatic cholangiocarcinoma is the second most common primary liver tumor and represents approximately 10-20% of new hepatocellular carcinoma (primary liver cancer or HCC) cases diagnosed annually, or approximately 3,100 new cases every year in the U.S.[1] Surgical resection, the standard of care, is not possible for an estimated 80% to 90% of patients diagnosed with ICC.

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.

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, our ability to maintain NASDAQ listing, 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.

[1] M. Tucker "Model Predicts Survival in Intrahepatic Cholangiocarcinoma" http://www.medscape.com/viewarticle/821759 (Accessed March 24, 2017)

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