Delcath Announces Ongoing Patient Treatment And Data Collection In Intrahepatic Cholangiocarcinoma Study Cohort

Company Accepts Invitation from Cholangiocarcinoma Foundation to Present Initial Signals in ICC

NEW YORK, Jan. 12, 2017 — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces that patient treatment and data collection for the intrahepatic cholangiocarcinoma (ICC) cohort of its European Phase 2 HCC/ICC study is ongoing, and that the Company will announce interim results for the cohort once the data are fully mature. Additionally, the Company believes that the original goal to obtain an efficacy signal for the Phase 2 ICC cohort has been satisfied by the result of multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These promising outcomes and observations were discussed with Key Opinion Leaders (KOL) at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP® therapy does, indeed, "demonstrate an efficacy signal in ICC and is worthy of full clinical investigation."

The Company also announces that it has accepted an invitation from *The Cholangiocarcinoma Foundation* (CCF) to present its initial research plans for use of PHP® therapy in the treatment ICC. The CCF is the largest patient advocacy organization devoted to finding a cure and improving the quality of life for patients with cholangiocarcinoma, or bile duct cancers. Company representatives will present a summary of European investigator findings and its clinical development plans for ICC to the Foundation's medical advisory board at the CCF's 2017 Annual Meeting, to be held in Salt Lake City, UT from February 1-3, 2017. Delcath will also provide a sponsorship grant to support the work of the CCF as part of its participation in the CCF Annual Meeting.

"Though the interim data we expected for ICC cohort in our Phase 2 trial in HCC/ICC are not yet available, the objectives for this study have largely been satisfied by the independent retrospective analysis conducted by our European investigators" said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "The promising outcomes and observations identified at our global KOL forum last year provide us with considerable confidence in the potential of our therapy in the ICC tumor type and helped form our initial research plan. The future research in ICC is designed to be cost effective and pursued in a financially prudent manner."

Dr. Simpson continued, "the CCF is one of the most important organizations for patients diagnosed with bile duct cancers, and the organization has attracted the participation of some of the leading researchers working on this difficult to treat disease. We are delighted with the opportunity to present to KOLs in this space the potential that the European

investigators have identified for our therapy in the treatment of ICC."

About ICC

ICC is the second most common primary liver tumor and represents approximately 15% of new hepatocellular carcinoma (primary liver cancer or HCC) cases diagnosed annually. Surgical resection, the standard of care, is not possible for an estimated 80% to 90% of patients diagnosed with ICC.

About the Cholangiocarcinoma Foundation

Now celebrating its 10th Anniversary, CCF is a global 501(c) (3) non-profit organization whose mission is to find a cure and improve the quality of life for those affected by bile duct cancer through advocacy, education, collaboration and research. Visit www.cholangiocarcinoma.org to learn more.

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 a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC). 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: our ability to repay and comply with the obligations under our senior secured convertible notes, the timing and results of the Company's clinical trials including without limitation the OM, HCC ,and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma and the global Phase 2 HCC and ICC clinical trials, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, the impact of the presentations at major medical conferences and future clinical results consistent with the data presented, 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, the Company's ability to successfully commercialize the CHEMOSAT/Melphalan HDS system and the potential of the CHEMOSAT/Melphalan HDS 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, the Company's ability to satisfy the remaining requirements of the FDA's Complete Response Letter and provide the same in a timely manner, approval of the current or future Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan 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.

Contact Information:

Investor Contact:
Anne Marie Fields
LHA
212-838-3777
afields@lhai.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delcath-announces-ongoing-patient-treatment-and-data-collection-in-intrahepatic-cholangiocarcinoma-study-cohort-300389971.html

SOURCE Delcath Systems, Inc.