Data Supporting CHEMOSAT Presented at the Cardiovascular and Interventional Radiology Society of Europe Conference

Single-Institution Studies Add to Growing Body of Research Supporting CHEMOSAT for Treatment of Cancers of the Liver

NEW YORK –
Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology Company focused on developing safe and effective treatments for primary and metastatic liver cancers, announces that results from two single-institution studies conducted in Germany of use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with liver metastases were presented as posters at the *Cardiovascular and Interventional Radiology Society of Europ*e (CIRSE) annual meeting.

The first study, *Secondary Resectability of Ocular Melanoma Liver Metastases (OMLM) Following Percutaneous Hepatic Perfusion (PFP)* by M. Zeile, *et al*. of the Asklepios Barmbek Clinic in Hamburg, Germany, evaluated 7 patients with unresectable ocular melanoma liver metastases treated with CHEMOSAT. There were 12 CHEMOSAT procedures administered in total, with a median of 2 cycles per patient, and a range of 1 to 3. The objective response rate after 1-2 treatments was 71.4%. Two patients showed secondary resectability on imaging after completing two treatments and remain alive for over 26 months following resections. Progression free survival was 9.9 months and hepatic progression free survival was 11.2 months. Median survival for the study has not yet been reached, but is higher than 16.9 months. There were no adverse events of grade 3 or higher. Investigators concluded that CHEMOSAT is safe to use in these patients and that significant downsizing of ocular melanoma liver metastases can be achieved with CHEMOSAT. These researchers concluded that if these promising results were further validated it “may lead to a new standard of therapy for the treatment of patients with ocular melanoma liver metastases.”

The second study, *Percutaneous Isolated Hepatic Perfusion (Chemosaturation) In Patients With Primary Or Secondary Liver Tumours: Experience In 20 Patients*, by S. Marquardt *et al*., of Hanover Medical School in Hanover, Germany, retrospectively evaluated patients with advanced disease from primary or metastatic cancers of the liver. The local response rate (stable disease or partial response) was 80%. Mean progression free survival was 3.2 months. The investigators

reported no major complications and that bone marrow suppression was common but controllable. The investigators concluded that patients with primary or secondary liver tumors that have disease progression under standard therapy “may profit from PHP with Melphalan,” that technical execution is problem-free, and complications are manageable.

We are very pleased with the results of these studies, which both show noteworthy results achieved with CHEMOSAT in difficult to treat patients with few effective options,” said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. “These single-institution studies add to the growing body of research that support a significant role for CHEMOSAT in the management of patients with cancers of the liver.”

The CIRSE conference is being held in Barcelona, Spain at the Centre de Convencions Internacional de Barcelona from September 10-14, 2016. Additional information for the CIRSE Scientific Program is available here.

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.

View source version on businesswire.com:

http://www.businesswire.com/news/home/20160914005646/en/

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