



European Data Supporting Survival Benefit With Delcath's CHEMOSAT System Presented At 6th European Post-Chicago Melanoma/Skin Cancer Meeting

July 6, 2016

Unprecedented Progression Free and Overall Survival Observed in University Hospital Southampton Retrospective Analysis

NEW YORK, July 6, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on treatment of primary and metastatic liver cancers, announces that data from a large single hospital experience conducted at Southampton University Hospital in the United Kingdom were presented in an oral presentation at the 6th European Post-Chicago Melanoma/Skin Cancer Meeting held in Munich, Germany from June 30 – July 1, 2016.

The abstract, *Chemosaturation Via Percutaneous Hepatic Perfusion – An Update On A Single Centre Experience Of Treating Metastatic Uveal Melanoma*, Southampton University (United Kingdom) was presented by lead author, Ioannis Karydis, M.D, of Southampton University Hospital. Researchers conducted a retrospective evaluation of 27 metastatic uveal melanoma patients treated with CHEMOSAT over four years, analyzing survival, tumor response, time to progression and treatment related adverse events. Two patients could not be treated and were excluded from analysis; 25 patients received 43 treatments. Results showed that 14 patients remained alive after a median 290 days. Of 24 evaluable patients, one patient had a complete response (4%), five patients had partial responses (21%), and 12 patients had stable disease for greater than 90 days (50%). Progression free survival for patients who had progressed was 181 days at the time of data cut off, and 11 patients were alive for greater than one year following their first treatment with a projected median overall survival of 511 days. Eleven deaths from disease progression occurred at a median of 264 days following first treatment, and there were no treatment related deaths. Treatment overall was well tolerated, and non-hematological adverse events (6) were relatively rare. Most common adverse events were transient, mild \leq grade 2 and included transaminitis (64%) and thrombocytopenia (88%); grade 3 anemia was seen in 36% of patients and grade 3-4 neutropenia was seen in 6 patients.

Researchers concluded that "PHP can be used safely by an experienced team to deliver liver-directed therapy in selected uveal melanoma patients, and achieves unprecedented progression free and overall survival."

"The progression free and overall survival benefits observed in this study are dramatic, especially given the limited treatment options for patients suffering with these life-threatening cancers. Importantly, these supportive data provide us with considerable confidence that similar results may be formally validated by our FOCUS Phase 3 Trial in hepatic dominant ocular melanoma that is currently underway in the U.S. and Europe to secure marketing authorization in the U.S.," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and CEO of Delcath Systems. "The quality and pace of global research being presented and published continues to strongly support CHEMOSAT as a therapy for metastatic liver cancer. We look forward to building on this momentum to further advance the commercial and clinical adoption of CHEMOSAT in Europe, the U.S. and around the world."

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced our 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).

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, 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, 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, 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, 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 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.

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/european-data-supporting-survival-benefit-with-delcaths-chemosat-system-presented-at-6th-european-post-chicago-melanomaskin-cancer-meeting-300294307.html>

SOURCE Delcath Systems, Inc.