



Analysis From Two Institutions Shows Strong Tumor Response, Overall Survival Potential of Delcath Investigational PHP Therapy

February 21, 2017

Retrospective Analysis of Outcomes with Investigational Melphalan/HDS and Commercial CHEMOSAT® Projects Median Overall Survival to be 657 Days; 1,207 Days for Responders

NEW YORK, Feb. 21, 2017 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (NASDAQ:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announced that a retrospective, multicenter study demonstrated that 45.7 percent of patients with ocular melanoma that metastasized to the liver who underwent percutaneous hepatic perfusion (PHP) using investigational Melphalan/HDS experienced a complete or partial response. The study further showed that among those who responded to treatment, overall survival was projected to be more than three years.

The findings were reported at the Regional Cancer Therapies 12th International Symposium in an oral presentation titled, "*Percutaneous Hepatic Perfusion for Unresectable Metastatic Ocular Melanoma to the Liver: A Multi-Institutional Report of Outcomes.*" The analysis was conducted by teams from Moffitt Cancer Center in Tampa, Fla., and the University Hospital Southampton in the United Kingdom. The presentation was led by Dr. Alexandra Gangi of the Moffitt Cancer Center.

The analysis reviewed outcomes of 49 patients treated between 2008 and 2016 with Melphalan/HDS at either the Moffitt Cancer Center or the University Hospital Southampton. Patients underwent a total of 115 PHP treatments. The median number of treatments per patient was two, with patients receiving one-to-six treatments. PHP is a minimally invasive procedure that isolates the liver from the body's circulatory system, so that a high dose of chemotherapy (melphalan hydrochloride) may be infused directly into the liver. Blood from the liver is then filtered to remove the chemotherapeutic agent thereby minimizing systemic exposure.

Hepatic response to PHP was evaluable in 46 patients, among whom 45.7 percent showed complete or partial response, and 37.0 percent had stable disease. Median overall survival was not reached, but was projected to be 657 days (1.8 years). Among patients with a complete or partial response, overall survival was projected to be 1,207 days (3.4 years). Most common side effects following treatment were anemia, thrombocytopenia and neutropenia.

"Patients diagnosed with metastatic ocular melanoma to the liver have an average of 6-8 months of survival. This retrospective analysis reported a much longer survival after Melphalan/HDS, and provided an interesting long-term look at patient outcomes after treatment with Delcath Melphalan/HDS," said Dr. Jennifer K. Simpson, President & CEO of Delcath. "The projected 657-day median OS and 1,207 day median OS in those with a partial or complete response is very impressive, and we believe speaks to the potential of the system to provide meaningful durable response."

PHP 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 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.

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: 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.

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Delcath Systems, Inc.