Delcath's European Key Opinion Leader Forum On CHEMOSAT Therapy Affirms Benefits To Liver Cancer Patients

May 27, 2015

NEW YORK, May 27, 2015 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces findings from its recent three-day Key Opinion Leader Forum that focused on CHEMOSAT®, the Company's percutaneous hepatic perfusion (PHP) therapy for the treatment of liver cancers. The Forum took place near Paris and included more than 20 medical specialists in oncology, surgical oncology, anesthesiology and interventional radiology from across Europe where CHEMOSAT is commercially available. CHEMOSAT is not commercially available in the US.

The Forum featured a discussion of hands-on commercial experiences with CHEMOSAT. Key findings from the Forum were:

- Clinicians continue to produce positive, life-extending results treating liver cancer patients with CHEMOSAT in multiple tumor types
- CHEMOSAT is well tolerated and is an easy-to-learn procedure for an experienced treatment team
- Multiple treatment courses of at least four procedures have been shown to be safe and well tolerated while continuing to provide clinical benefit and good quality of life
- Reimbursement continues to be covered through individual funding requests
- Clinicians are encouraged by the potential for CHEMOSAT to treat many tumor types and support the generation of additional data in these potential indications

"This 3-day forum on CHEMOSAT provided a unique opportunity for us to share our patient experiences from multiple treatment centers in Europe using CHEMOSAT to treat liver cancer patients. The exchange of ideas and practices among a diverse field of leading clinicians in the various medical specialties that implement CHEMOSAT therapy was illuminating and compelling, especially given the meaningful clinical benefits it brings to patients. The discussions were very valuable and have given me new perspectives on the implementation of CHEMOSAT for my liver cancer patients," noted Prof. Arndt Vogel, M.D., Clinic of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany.

Alex Vahrmeijer, M.D., Ph.D., a surgical oncologist at Leiden University Medical Centre, the Netherlands, commented, "Delcath's CHEMOSAT is an effective new therapy for metastases confined to the liver for patients with very limited treatment options. We have demonstrated the ability to perform repeat PHP procedures with CHEMOSAT that showed continued tolerability and significant clinical benefit for patients in this life-limiting cancer indication. We believe this procedure has strong potential to treat a number of other tumor types and is worthy of further clinical investigation in those indications."

"We were delighted to convene this Forum as it brought together clinicians from across Europe who are commercially using CHEMOSAT to share their treatment center's patient experiences and to exchange ideas on optimizing the procedure and expanding the clinical benefits of CHEMOSAT in other tumor types," stated Jennifer Simpson, Ph.D., President and Chief Executive Officer of Delcath. "This Forum produced valuable data both for the commercialization of CHEMOSAT and for its expanded clinical development. European clinicians who participated in the Forum are in the process of developing a white paper on their findings and recommendations. We look forward to the publication of their report and expect it will further the awareness and understanding of the benefits of CHEMOSAT to treat liver cancers, while supporting continued adoption in key European markets."

About Delcath Systems
Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with an emphasis 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). The Melphalan/HDS system has not been approved for sale in the U.S. We have commenced 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 expect to initiate a global Phase 3 trial in ocular melanoma (OM) that has metastasized to the liver and plan to evaluate intrahepatic cholangiocarcinoma (ICC) in a Phase 2 clinical study.

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: timely patient enrollment the ability to complete an interim evaluation of the Company's Global Phase 2 HCC program, acceptance and publication of the Phase 3 trial manuscript and the impact of publication to support the Company's efforts, the timing and results of the Company's clinical trials including without limitation the HCC, ICC and OM clinical trial programs timely enrollment and treatment of patients in the global Phase 2 HCC and ICC clinical trial, FDA approval of the global Phase 3 OM clinical trial protocol, 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 of the presentations at ESSO 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 Value 4 status 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, the Company's ability to

satisfy the 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.

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