# Positive Data With Delcath's CHEMOSAT Highlighted At ASCO 2015

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**Single-center experience in Europe illustrates safe control of hepatic metastases with the Delcath Hepatic CHEMOSAT Delivery System**

NEW YORK, May 29, 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 that results of a large, European single-center experience of the treatment of uveal melanoma patients with hepatic metastases with the Delcath Hepatic CHEMOSAT® Delivery System, were highlighted in an on-line abstract at the American Society of Clinical Oncology Annual Meeting 2015. The abstract is titled, "Single Centre Experience of Chemosaturation Percutaneous Hepatic Perfusion in the Treatment of Metastatic Uveal Melanoma" and can be accessed here.

Uveal melanoma (UM), also known as ocular melanoma, is a rare cancer of the eye with a very poor prognosis. According to the study authors, "50% of patients develop distant disease, mainly in the liver (90%), with a mean survival of 6 months and 1-year survival rate of 15-20%."

In this study, 20 patients received 34 treatments with CHEMOSAT (1-3 treatments per patient). Radiologically, 2 patients (10%) demonstrated stable disease for >3 months, 13 patients (65%) had a partial response in the liver with complete responses in 2 patients (10%). Nine deaths from disease progression occurred after a median of 264 days from the first procedure. Eleven patients remain alive after a median of 280 days with one complete response ongoing at >1 year. From the diagnosis of liver metastases, 11 patients (55%) have survived to one year and 3 (15%) for >2 years. No procedure related deaths were seen.

Adverse events (AEs) seen were grade 1 (n=12), 2 (n=13), 3 (n=5) and 4 (n=1). The grade 4 complication was pulmonary edema due to fluid overload. Early AEs often expected with percutaneous hepatic perfusion (PHP) were observed including coagulopathy, electrolyte disturbances and transient transaminases (elevated liver enzymes). Rare late AEs (1 patient each) included hair loss, skin rash, myelosuppression and persistent transaminases (elevated liver enzymes).

"Our results show that PHP (CHEMOSAT) can be used safely to control hepatic metastases in selected UM patients with a high rate of hepatic progression free and excellent overall survival," concluded lead study author, Guy Hickson, M.D., Southampton Hospital, Interventional Radiology, Southampton, United Kingdom.

"We are especially pleased to have these data shared with the thousands of oncology specialists from around the world who attend ASCO. We continue to be encouraged by the growing body of European commercial patient experience that illustrates CHEMOSAT's ability to safely and effectively enhance hepatic progression free and overall survival rates in cancer patients with limited treatment options and life-limiting disease," noted Jennifer Simpson, Ph.D., President and Chief Executive Officer of Delcath.

CHEMOSAT is a CE Marked approved product in Europe and is not approved in the United States.

**About Ocular (Uveal) Melanoma**
According to the National Cancer Institute, ocular (uveal) melanoma is a rare cancer that forms from cells that make melanin in the iris, ciliary body, and choroid. It is the most common eye cancer in adults, affecting one in every 5 million people in the U.S., with comparable incident rates in Europe.

**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: the impact of the poster presentation at ASCO 2015 and future clinical results consistent with the data presented, timely patient enrollment the ability to complete an interim evaluation of the Company's Global Phase 2 HCC program, , 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 for certain 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, 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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