



## Summary of Recent Published Research on Delcath's PHP Therapy Presented at Society of Surgical Oncology Annual Symposia

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NEW YORK, March 29, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that a comparative summary of recently published research on the Company's PHP<sup>®</sup> Therapy was presented at the 2018 Society of Surgical Oncology Annual Cancer Symposium (SSO), held in Chicago, IL March 21-24, 2018.

In a presentation entitled *Percutaneous Hepatic Perfusion (PHP) in Hepatic Liver Metastases*, Jonathan Zager, MD, FACS, Chair of Graduate Medical Education at Moffitt Cancer Center and Professor of Surgery at the University of South Florida School of Medicine, compared the results from the Company's prior Phase 3 study, published by [Hughes](#), et al (Annals of Surgical Oncology, 2015) with more recent results published by [Karydis](#), et al (Journal of Surgical Oncology, 2017) and [Abbott](#), et al (American Journal of Clinical Oncology, 2017). The Hughes study was conducted from 2005 to 2010, and used an earlier generation of the Melphalan/HDS system, whereas the Karydis and Abbott studies evaluated patients primarily treated with the Generation Two version of the Melphalan/HDS system along with other refinements to the peri- and post-procedure management of patients.

Dr. Zager highlighted that in all three studies results with PHP provided evidence of improved efficacy, with Hughes showing a 5x increase in hPFS over the study control arm (PHP 245 days vs BAC 49 days), and Abbott showing significantly longer hPFS for PHP than treatment with chemoembolization (CE) and Yttrium-90 beads (Y90) (PHP 310 days, CE 80 days, Y-90 54 days). Karydis showed an overall response rate with PHP of 47%, a >84% disease control rate and hPFS of 9.1 months.

Regarding safety, Dr. Zager compared select safety data in the Hughes study conducted with the generation one system with data from the Karydis study conducted primarily in patients treated with the generation two system. The Hughes study was characterized by high percentages of hematologic side effects ranging from 60%-86% (anemia, thrombocytopenia, neutropenia). In the Karydis study, Grade 3 and 4 hematologic side effects (anemia, neutropenia, thrombocytopenia) were seen in approximately 30% of patients treated with PHP. Dr. Zager attributed this improvement in the safety profile to improvements in filtration with the generation two system, improved peri- and post-procedure management of patients, and greater experience in the treating centers. Dr. Zager concluded that PHP Therapy can be administered safely in high-volume cancer centers.

"Dr. Zager's presentation at SSO provided a very useful overview of the efficacy consistently seen with PHP Therapy in appropriately selected patients, both in our original Phase 3 trial and in the more recent research," said Jennifer K. Simpson Ph.D., MSN, CRNP President and CEO of Delcath. "Importantly, the improvement in the safety profile noted by Dr. Zager provides confidence that our current Phase 3 FOCUS Trial in ocular melanoma liver metastases can address safety concerns expressed by the FDA after our original Phase 3 trial data was submitted, and can meet its objective of supporting an application for FDA approval for this important therapy."

### 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 plan to initiate a Registration trial for 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<sup>®</sup> 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: the timing and results of the Company's clinical trials including without limitation the OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM clinical trial, IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial, 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 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, 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, 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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