Published Review Shows Delcath Investigational PHP Doubles Overall Survival Over Other Targeted Liver Therapies

Single-Center Retrospective Data Also Demonstrate Therapy Extends Progression-Free Survival by 9 Months

NEW YORK, Feb. 22, 2017 — Delcath Systems, Inc. (NASDAQ:DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announced today that the *American Journal of Clinical Oncology* has published a single-center retrospective review, in which authors found that investigational PHP with Melphalan/HDS offers promising results with a doubling of overall survival and significantly longer progression-free survival (PFS) and hepatic progression-free survival (HPFS) than other targeted therapies. Percutaneous hepatic perfusion (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.

The review, *"Hepatic Progression-free and Overall Survival After Regional Therapy to the Liver for Metastatic Melanoma,"* was written by a team from the Moffitt Cancer Center, including co-first authors Drs. Andrea M. Abbott and Matthew P. Doepker, and Jonathan S. Zager, the principal investigator in Delcath's ongoing Phase 3 FOCUS study. Drs. Abbott, et al, analyzed clinical outcomes of three different non-randomized approaches used to treat 30 patients with liver metastases primarily resulting from ocular melanoma and skin melanoma. A third of the patients received PHP using melphalan delivered via the Delcath Hepatic Delivery System (Melphalan/HDS), 12 received chemoembolization (CE) and six received radioembolization with yttrium-90 (Y90). Two patients crossed over once their cancer progressed – one from PHP to Y90 and one from CE to PHP.

The paper's authors concluded that patients who received PHP with Melphalan/HDS had significantly longer median HPFS at 361 days compared to 54 days for Y90 and 80 days for CE, as well as a longer median PFS at 245 days compared to 54 days for Y90 and 52 days for CE. Median overall survival was also longest for PHP at 608 days compared to 295 days for Y90 and 265 days for CE. The authors noted that further studies, including a randomized controlled trial, would be needed to confirm whether clinically superior outcomes can be achieved with PHP compared to other liver-targeted treatments.

Side effects following all treatments were similar, with most complications recorded as anorexia, abdominal pain, fatigue and nausea. Laboratory irregularities, such as thrombocytopenia and abnormal liver function tests, were seen immediately after treatment in some patients, but returned to baseline within a few days.

"The vast majority of patients with metastatic ocular melanoma survive less than a year, due

to the difficulty in treating metastases to the liver, which are a hallmark of this cancer. It is therefore especially gratifying to see patients with this rare disease survive almost two years after receiving PHP with Melphalan/HDS," said Dr. Jennifer K. Simpson, President & CEO of Delcath. "We are hopeful that our ongoing Global Phase 3 FOCUS study for patient with ocular melanoma liver metastases will yield similar results, further reinforcing the benefits of our technology, and bringing us one step closer to U.S. market availability."

PHP with Melphalan/HDS was developed by Delcath Systems as a targeted, whole organ therapy for the liver. The product is commercially available in Europe under the trade name CHEMOSAT®, and is being evaluated as an experimental therapy in the U.S., where a global Phase 3 clinical trial is enrolling patients with ocular melanoma that has metastasized to the liver.

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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