Delcath Amends Phase 3 Ocular Melanoma Trial Protocol

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Revision to Nonrandomized (Single Arm) Study Reduces Trial Size Enrollment Requirement

Enrollment Anticipated to be Completed by First Half 2019

NEW YORK, July 27, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that the Company has filed an amendment with the U.S. Food & Drug Administration to revise the protocol for its Phase 3 clinical trial in ocular melanoma liver metastases. Under the terms of the amendment, the trial, now entitled, *A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma,* will enroll 80 patients with ocular melanoma metastatic to the liver. Overall, the enrollment of 80 patients represents a 66% reduction in trial size from the previous randomized trial, which required 240 patients to reach statistical significance. Patients currently enrolled in the Melphalan/HDS arm of the trial under the previous randomized protocol will continue to be treated and evaluated as part of the amended trial. With this amendment, the Company anticipates completing trial enrollment by the end of the first half of 2019.

"For the last eighteen months, we have been working closely with the FDA, our trial investigators, and the patient advocacy community to address accrual challenges for The FOCUS trial under its previous randomized protocol," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "The feedback we received was clear. The rarity of ocular melanoma, absence of crossover to the experimental trial arm, and the availability of PHP® Therapy in a commercial setting in Europe all combined to inhibit enrollment in the trial. With this amendment, we believe that we will now be able to complete trial enrollment in a timely fashion while providing a strong scientific case to support an application for approval."

"Given the rarity of ocular melanoma and the existing level of global institutional data supporting the use of PHP Therapy in this patient population, I believe this amendment is in the best interests of patients," said Jonathan Zager, MD, FACS, principal investigator for the FOCUS Trial, Chair of Graduate Medical Education at Moffitt Cancer Center and Professor of Surgery at the University of South Florida School of Medicine. "In my experience, patients in the U.S. in particular have been frustrated by the randomization requirement of the prior protocol and the unavailability of this therapy outside of a clinical trial setting. I believe that the amended, single-arm trial will provide greater access to this therapy for appropriately selected patients while evaluating efficacy and safety in a manner consistent with other recently approved cancer therapies."

Under the new protocol, the primary endpoint for the amended FOCUS trial will be objective response rate (ORR). Secondary endpoints will include duration of response, disease control rate, overall survival and progression-free survival. Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety and other pharmacokinetic measures. Inclusion and exclusion criteria remain unchanged. In filing this amendment, the Company has effectively annulled the Special Protocol Assessment (SPA) agreement for the prior protocol for the randomized trial, however, FDA has communicated that it does not object to the Company conducting the trial outside of a SPA agreement. FDA and Delcath have worked consistently together over the last 18 months and FDA has responded to all of Delcath's questions focusing on the revised non-randomized protocol design, conduct, execution, data analysis, and labeling implications. Full details of the registration clinical trial will be made public upon the launch of the study and will be available at **www.clinicaltrials.gov**.

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® 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: successful completion of the Company's Rights Offering and related transactions and the amount of gross proceeds, if any; 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 and ICC clinical trials, 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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