Delcath Systems, Inc. Shares Additional Information Regarding FOCUS Trial Power Calculation

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20.1% Lower Bound of Preliminary ORR Analysis Exceeds Required 8.3% Threshold

NEW YORK, March 31, 2021 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today provided additional information regarding the power calculation for the Phase 3 FOCUS trial of HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM).

In the summer of 2018, the Company amended the protocol for the FOCUS trial to a single arm design. In consultation with FDA, the FOCUS single arm trial was powered to demonstrate a superior Overall Response Rate (ORR) versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications.

A point estimate of 21.0% ORR was calculated as the requirement to demonstrate superiority over the checkpoint inhibitors given the planned trial size and this threshold was shared with investors. The checkpoint inhibitor ORR was calculated based on a meta-analysis covering 16 different publications and 476 patients. The pooled overall response rate was 5.5% with a 95% Confidence Interval of 3.6% - 8.3%. To achieve statistical significance at a 95% Confidence Interval the lower bound of the ORR for HEPZATO needs to exceed the 8.3% upper bound of the meta-analysis. A preliminary analysis of 87% of enrolled patients analyses by the Independent Review Committee yielded an ORR of 29.2% [95% CI: 20.1, 39.8] in the Intent to Treat population, which substantially exceeds the 21.0%-point-estimate requirement. For further clarity, since the 20.1% lower bound exceeds the 8.3% upper bound of the meta-analysis the predefined success threshold was met. Further detail is available on the events and presentations section of the company website.

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

Safe Harbor / Forward-Looking Statements

The 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 mOM and ICC clinical trial programs, as well as the receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial and the impact of the COVID-19 pandemic on the completion of our clinical trials; 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 HEPZATO KIT/CHEMOSAT system and the potential of the HEPZATO KIT/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 HEPZATO KIT/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 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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