Results of Single Center Study on Delcath's CHEMOSAT® Hepatic Delivery System Published in Melanoma Research

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Retrospective Study by University Hospital Southampton in metastatic uveal melanoma (mUM) patients with liver dominant disease shows hepatic disease control rate of 88.9%, hepatic response rate of 66.7% and overall response rate of 60.5%

After a median follow-up of 12.9 months, median overall progression-free survival (PFS) and median overall survival (OS) were 8.4 and 14.9 months, respectively

NEW YORK, Feb. 03, 2022 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that results from a single-institution retrospective study, conducted by University Hospital Southampton NHS Foundation Trust (UHS) in England on the use of the Delcath CHEMOSAT® Hepatic Delivery System for the treatment of patients with liver dominant metastatic uveal melanoma (mUM), were published in the journal *Melanoma Research*.

The study, *Chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma*, by Dr. Sachin Modi, et al, evaluated the safety and efficacy of the CHEMOSAT Hepatic Delivery System in 81 patients with liver dominant metastatic uveal melanoma treated with CHEMOSAT between August 2012 and September 2020. Forty-one (50.6%) patients had received other treatments, either systemic or liver-directed, before PHP treatment. The median time to treatment from diagnosis of stage IV disease was 158 days. Tumor response was evaluated following each PHP treatment using Response Evaluation Criteria in Solid Tumors (RECIST), and serious adverse events (SAEs) were evaluated using Common Terminology Criteria for Adverse Events (CTCAE).

250 PHP procedures were performed in 81 patients (median of three per patient). The analysis demonstrated a hepatic disease control rate of 88.9% (72/81), a hepatic response rate of 66.7% (54/81), and an overall response rate of 60.5% (49/81). After a median follow-up of 12.9 months, median overall progression-free survival (PFS) and median overall survival (OS) were 8.4 and 14.9 months, respectively.

Treatment-emergent adverse events of Grade 3 or 4 occurred in 23 patients (27.7%) The most common Grade 3 or 4 hematological toxicities were anemia observed in 11 patients (13.3%) and thrombocytopenia observed in 10 patients (12%). There were no fatal treatment-related adverse events.

Investigators concluded that PHP provides excellent response rates and progression free survival compared with other available treatments, with a decreasing side effect profile with experience. Combination therapy with systemic agents may be viable to further advance overall survival.

"This study adds to the growing body of published research of the efficacy of our CHEMOSAT system in the European commercial setting," said Gerard Michel, CEO of Delcath. "The improved safety profile of the Gen2 device is consistent with our recently released phase 3 FOCUS trial data as well as the progression-free-survival efficacy results."

A PDF of the open access article can be viewed in its entirety, via immediate download link, by clicking here.

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, for the treatment of metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM) and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is regulated as a Class IIb medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

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 receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, the impact of the COVID-19 pandemic on the timely monitoring of patients in the global Phase 3 mOM clinical trial and resubmission of the NDA; 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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