Delcath Systems Announces New Data Presented at ESMO 2024 Demonstrating Efficacy of HEPZATO KIT™ in Metastatic Uveal Melanoma Subgroups

September 16, 2024

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Sep. 16, 2024-- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on liver-directed cancer therapies, today announced the presentation of new subgroup analysis data from the FOCUS Phase 3 trial of HEPZATO KIT™ (melphalan/Hepatic Delivery System (HDS)) in patients with metastatic uveal melanoma (mUM). The data were presented by Dr. Matthew Wheater from University Hospital Southampton at the European Society for Medical Oncology (ESMO) Congress in Barcelona.

The FOCUS trial was a pivotal Phase 3 study designed to evaluate the efficacy and safety of HEPZATO KIT™ in patients with unresectable hepatic metastases from mUM. The primary endpoint of the study was objective response rate (ORR), with secondary endpoints including progression-free survival (PFS) and overall survival (OS). The trial enrolled 102 patients, of whom 91 received treatment. The full results of the FOCUS trial were published on May 4, 2024, in the Annals of Surgical Oncology.

The subgroup analysis evaluated patients with and without extrahepatic disease, treatment-naive versus previously treated patients, and those with low (1-25%) versus high (26-50%) liver tumor burden. There were no significant differences in OS, ORR, or PFS between patients with and without extrahepatic lesions or based on prior therapy. While ORR and PFS remained consistent regardless of liver tumor burden, more extensive liver involvement was associated with worse OS outcomes.

Objective tumor responses were observed throughout the entire treatment period; the earliest following completion of the first treatment cycle, and the latest following treatment cycle 6. This result supports the strategy to continue treatment until best response is achieved. Rates of serious adverse events (SAEs) and Grade 3/4 adverse events (AEs) remained consistent, indicating an absence of cumulative toxicity. These findings underscore the favorable benefit-risk profile of HEPZATO KIT™ in this patient population, offering a meaningful option for patients who typically have limited treatment options.

Dr. Wheater commented, "The lack of significant differences in outcomes between patients with and without extrahepatic disease is encouraging, particularly for a liver-directed therapy like Melphalan/HDS. Additionally, the fact that responses were observed through all six treatment cycles supports the strategy of continuing treatment beyond two cycles in patients with stable disease."

About Delcath Systems, Inc., HEPZATO KIT and CHEMOSAT

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary products, HEPZATO KIT™ (HEPZATO (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to isolate the hepatic venous blood from the systemic circulation while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of

percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers of the liver.

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Investor Relations:
ICR Westwicke
investorrelations@delcath.com

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