Delcath Systems Announces First Patient Dosed in Phase 2 Clinical Trial of HEPZATO™ in Liver-Dominant Metastatic Colorectal Cancer

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QUEENSBURY, N.Y.--(BUSINESS WIRE)--Aug. 19, 2025-- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced that the first patient has been dosed at the City of Hope National Medical Center in its global Phase 2 Clinical Trial evaluating HEPZATO™ in combination with standard of care (SOC) treatment for liver-dominant metastatic colorectal cancer (mCRC).

The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with trifluridine-tipiracil and bevacizumab compared to trifluridine-tipiracil and bevacizumab alone in patients with liver-dominant mCRC receiving third-line treatment. Approximately 90 patients will be enrolled in this randomized, controlled trial. The study will be conducted at more than 20 sites across the United States and Europe. Results from the trial's primary endpoint, hepatic progression-free survival (hPFS), are anticipated by mid-2028, while overall survival (OS), a secondary endpoint, is expected in late 2028.

The company estimates that the total addressable market for liver-dominant mCRC receiving third-line treatment is between 6,000 and 10,000 patients annually in the United States. This market includes patients who present with significant liver disease burden, determined through radiological and clinical criteria. Delcath aims to provide a novel treatment option for this patient population with limited therapeutic alternatives.

"This milestone marks a significant advancement in our mission to address unmet needs in liver-dominant cancers," said Vojislav Vukovic, Chief Medical Officer of Delcath Systems, Inc. "Dosing the first patient in this Phase 2 trial is an exciting step toward exploring HEPZATO's potential to provide a new treatment option for patients with metastatic colorectal cancer, building on its proven role in metastatic uveal melanoma."

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 (HDS) 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 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.

Forward-Looking Statements

This release contains forward-looking statements, including statements regarding the expected timeline for trial enrollment and data readouts, which are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, delays in regulatory review, site activation, patient enrollment, or unforeseen clinical trial results. For a detailed

discussion of these and other risks, please refer to Delcath's filings with the SEC.

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