Delcath Systems Announces Publication of 10-Year Single-Center Experience with Percutaneous Hepatic Perfusion in Liver-Dominant Metastatic Uveal Melanoma

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QUEENSBURY, N.Y.--(BUSINESS WIRE)--Dec. 3, 2025-- Delcath Systems, Inc. (Nasdaq: DCTH), ("Delcath" or the "Company") an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced the publication of a retrospective study by leading interventional radiologists and oncologists from Asklepios Hospital Barmbek in Hamburg, Germany. The study, titled "Survival Outcome After Percutaneous Hepatic Perfusion with High-Dose Melphalan for Liver-Dominant Metastatic Uveal Melanoma: A 10-Year Single-Center Experience," was published in the journal *Cancers* and reports outcomes from 38 consecutive patients with liver-dominant metastatic uveal melanoma (mUM) who underwent 99 procedures using Delcath's CHEMOSAT ® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP). The article highlights the procedure's safety and efficacy, demonstrating a median overall survival (OS) of 29.1 months from the first PHP treatment, with improved outcomes associated with additional treatment cycles.

"The publication of this 10-year experience in *Cancers* underscores the significant clinical evidence supporting the use of PHP as an effective liver-directed therapy for patients with liver-dominant metastatic uveal melanoma," said Gerard Michel, Chief Executive Officer of Delcath Systems. "These results from a high-volume specialized center show a median OS approaching 2.5 years, surpassing prior reports and reinforcing the potential survival benefits of treatment with repeated PHP cycles. We are pleased to see this data add to the collection of research supporting HEPZATO KIT and CHEMOSAT, which aligns with our commitment to advancing treatment options in interventional oncology."

The retrospective study synthesizes data from consecutive patients treated between April 2014 and March 2024, demonstrating safety and efficacy of CHEMOSAT in a real-world setting. Key highlights include:

- Median OS of 29.1 months (95% CI: 18.4–38.9 months) from the first PHP treatment, with 1-, 2-, and 3-year OS rates of 79.5%, 53.2%, and 28.5%, respectively
- Numerically improved median OS with ≥3 PHP cycles (29.8 months) versus ≤2 cycles (21.4 months; p=0.058), with each additional cycle associated with a ~40% reduction in risk of death (HR=0.414)
- No treatment-related deaths, with procedure-related adverse events graded ≥2 occurring in 10.5% of patients
- Patient population with ECOG-PS 0-1, ≤70% liver involvement, and limited extrahepatic disease, reflecting appropriate selection for PHP
- Support for institutional experience and volume as factors in optimizing outcomes, providing a reference for novel mUM management strategies

The article is available here: https://doi.org/10.3390/cancers17233834.

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
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by Delcath or on its behalf. This press release contains forward-looking statements, including statements regarding the potential of CHEMOSAT Hepatic Delivery System and HEPZATO KIT to improve outcomes for patients with metastatic uveal melanoma; statements regarding the potential synergy seen in the reported retrospective analysis being transferable to other cancers with liver-dominant disease. All forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. Factors that may cause such differences include, but are not limited to, those discussed in the Company's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Delcath undertakes no obligation to publicly update or revise these forward-looking statements except as required by applicable law.

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