Delcath Systems Announces Publication of Real-World Evidence Supporting Early Use of Liver-Directed Therapy with PHP in Achieving Long-Term Survival for Metastatic Uveal Melanoma Patients

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QUEENSBURY, N.Y.--(BUSINESS WIRE)--Nov. 13, 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 results from a retrospective analysis conducted by researchers at the University of Tubingen, Germany. The study, titled "Characterization of long-term survivors with liver metastases from uveal melanoma diagnosed between 2005 and 2021," was published in the *International Journal of Cancer* and highlights the potential benefits of early use of liver-directed therapies, including chemosaturation (also known as percutaneous hepatic perfusion or PHP), in achieving long-term survival for patients with metastatic uveal melanoma (mUM) and liver metastases. The analysis underscores PHP's advantages in disease control compared to other therapies, supporting its early integration potentially ahead of systemic options or in combination with systemic therapies.

The retrospective analysis evaluated 167 patients with mUM who developed liver metastases between 2005 and 2021, focusing on the 33 long-term survivors (20% of the cohort) who lived three or more years following the initial diagnosis of liver metastases. Key findings include:

- The majority of long-term survivors (82%) received liver-directed therapy as their first-line treatment in the metastatic setting
- 90% of long-term survivors received at least one liver-directed therapy at any time, with 85% also receiving immune checkpoint inhibitors (ICI) at some point
- In patients who received first line liver-specific therapy, response evaluation showed a disease control rate of 93% (complete response, partial response, or stable disease) versus 63% for patients who received first line systemic therapy
- 52% percent of long-term survivors received PHP at any time point, achieving a median overall survival of 37.35 months and progression-free survival of 10.28 months

"The retrospective analysis from the University of Tubingen provides compelling real-world evidence supporting the early integration of liver-directed therapies such as PHP into the treatment of metastatic uveal melanoma. This potentially contributes to long-term survival in a disease with historically poor outcomes-particularly through PHP's demonstrated 100% disease control rate when used as first line liver-specific therapy, outperforming other options," said Gerard Michel, Chief Executive Officer of Delcath Systems. "Building on the positive results from the CHOPIN trial, which demonstrated significant improvements in progression-free and overall survival when combining PHP with immune checkpoint inhibitors in first-line treatment of patients with metastatic uveal melanoma, the results reinforce the value of HEPZATO KIT and CHEMOSAT as foundational components of multimodal treatment strategies, including initiating PHP as part of a first line treatment strategy that includes immune checkpoint inhibitors."

Notably, all patients (100%) who received PHP as their first liver-directed therapy achieved disease control, with 69% experiencing partial tumor response - demonstrating superior efficacy compared to other liver-directed therapies.

The authors highlight the combination of PHP for hepatic metastases control and ICI for extrahepatic metastases control appears reasonable and shows association with better outcomes, with 15 patients in the cohort of long-term survivors receiving both therapies. They suggest initiating PHP first in multimodal strategies to potentially enhance ICI efficacy, especially given the liver's role in inducing tumor immune tolerance to ICI therapy.

The study utilized chemosaturation with Delcath's CHEMOSAT ® Hepatic Delivery System, which employs the same proprietary technology as the U.S. Food and Drug Administration (FDA) approved HEPZATO KIT ™ (HEPZATO (melphalan) for Injection/Hepatic Delivery System). This analysis builds on prior publications from the same research group, including Wiens et al. (2024) in *Therapeutic Advances in Medical Oncology*, which reported significantly improved melanoma-specific survival (28 months) with first-line liver-directed therapies compared to systemic therapies (10 months), and a poster presentation by Laukhuf

et al. at the European Association of Dermato-Oncology (EADO) Congress in April 2025, which initially characterized long-term survivors in this cohort.

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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