



Delcath Systems, Inc. Announces Inclusion of CHEMOSAT Hepatic Delivery System for Melphalan as a Recommended Liver-Directed Regional Therapy Option in the ESMO–EURACAN Clinical Practice Guidelines for Uveal Melanoma

April 6, 2026

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Apr. 6, 2026-- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on liver-directed cancer therapies, today announced that its proprietary CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (M-PHP) has been included as a recommended liver-directed regional therapy option in the newly published [*Uveal Melanoma: ESMO–EURACAN Clinical Practice Guideline for diagnosis, treatment and follow-up \(April 2026\)*](#).

M-PHP is also recognized in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Metastatic Uveal Melanoma. HEPZATO KIT™ (also referred to as melphalan/HDS), is included as a Category 2A recommended treatment option for appropriate patients with hepatic-dominant metastatic uveal melanoma (mUM). M-PHP has been listed as a liver-directed therapy option in NCCN guidelines for several years, predating the 2023 FDA approval of HEPZATO KIT.

The ESMO-EURACAN guideline recognizes M-PHP under regional treatments for patients with liver-dominant mUM. Two Phase 3 trials of M-PHP (NCT02678572 and NCT00324727) are cited as key supporting data, demonstrating improved hepatic and overall progression-free survival, and overall response rates compared with best alternative care. The guideline also assigns an ESMO-Magnitude of Clinical Benefit Scale score of 3 to M-PHP in the supplementary materials, for patients with unresectable hepatic metastases affecting <50% of the liver and no extrahepatic disease or limited extrahepatic disease amenable to local therapy.

M-PHP is listed first among regional treatment options for patients with multifocal liver-only metastases, either as monotherapy or in combination with systemic treatments, based on HLA-A*02:01 status. In addition, the guideline notes that the M-PHP may be an option in HLA-A*02:01-positive cases (e.g., following tebentafusp or when systemic options are not suitable), as well as HLA-A*02:01-negative cases or those not candidates for other systemic therapies. The ESMO–EURACAN guidelines emphasize a multidisciplinary approach for mUM and position liver-directed therapies such as M-PHP alongside systemic options including tebentafusp and anti-PD-1 immunotherapy in the treatment algorithm for metastatic disease.

"This inclusion in the ESMO–EURACAN guidelines represents an important validation of PHP with melphalan as a meaningful liver-directed therapy for patients with mUM," said Gerard Michel, Chief Executive Officer of Delcath Systems. "With up to 90% of mUM patients developing liver metastases, and limited effective options available, the recognition of our therapy in the European guidelines further supports its role in multidisciplinary care and highlights the clinical benefit observed in the FOCUS trial and real-world experience. We are pleased that the CHEMOSAT platform is now explicitly addressed in this updated standard of care."

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 filtering 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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