Delcath Systems Announces Presentation of New Data on Percutaneous Hepatic Perfusion with Melphalan in Liver-Dominant Metastatic Breast Cancer at ESMO Breast Cancer 2026

May 7, 2026

QUEENSBURY, N.Y.--(BUSINESS WIRE)--May 7, 2026-- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced that new data from a retrospective analysis by independent investigators on percutaneous hepatic perfusion with melphalan (M-PHP) using the CHEMOSAT® Hepatic Delivery System was presented today at the ESMO Breast Cancer Congress 2026.

Presentation details

- **Congress:** ESMO Breast Cancer Congress 2026
- **Date:** May 7, 2026
- **Session:** 13:15 (local congress time)
- **Format:** E-poster
- **Title:** Safety and Feasibility of Percutaneous Hepatic Perfusion with Melphalan in Patients with Liver-Dominant Metastatic Breast Cancer
- **Presenter:** Cornelia Lieselotte Angelika Dewald, MD (Hannover Medical School)
- **Abstract number:** 574eP

Background

Liver-dominant metastatic breast cancer remains a significant clinical challenge, as progression in the liver can be a major driver of morbidity and may limit the effectiveness of systemic therapies. M-PHP is a liver-directed procedure designed to deliver high-dose melphalan to the liver while reducing systemic exposure through extracorporeal hemofiltration.

About the analysis

Independent investigators at three European centers retrospectively identified 15 patients with liver-dominant metastatic breast cancer treated with M-PHP (CHEMOSAT) at three European centers. The analysis evaluated feasibility, safety, and tumor response per RECIST v1.1.

Key findings (retrospective cohort; N=15)

- **Patient population:** Fifteen patients were treated between September 2015 and May 2024 after a median of 4 prior systemic therapy lines (range 1–6).
- **Treatment delivery:** Patients received a median of 1 M-PHP cycle (range 1–7), typically followed by ICU admission of 1–2 days.
- **Safety:** 67% of patients required blood transfusions (primarily packed red blood cells). Intra-/peri-procedural adverse events occurred in 60% of patients (primarily hematologic or hemodynamic). Grade 3–4 post-procedure adverse events occurred in 80% of patients, predominantly bone marrow suppression with neutropenic-related infections; events typically onset early (median 1 day) and resolved in a median of 7 days.
- **Liver response:** Hepatic partial response was observed in 9 of 15 treated patients (60%); 3 patients were not evaluable for response.
- **Overall survival:** Median overall survival from first M-PHP was 6.0 months (95% CI, 2.9–NR; range 0.1–76.5); 33% (5/15) of patients were alive at last follow-up. Median follow-up was 55.6 months (95% CI, 53.7–NR).

“These data from independent European investigators represent real-world evidence supporting the use of HEPZATO KIT and CHEMOSAT in liver-dominant metastatic breast cancer and underscore the need for further evaluation in this heavily pretreated

population," said Gerard Michel, Chief Executive Officer of Delcath Systems.

HEPZATO KIT is currently being evaluated in a randomized Phase 2 trial in metastatic breast cancer patients with liver dominant disease (PHP-MBC-202; ClinicalTrials.gov identifier NCT06875128).

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 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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