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

July 9, 2026

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Jul. 9, 2026-- 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 European Institute of Oncology (IEO) in Milan, Italy in its global Phase 2 clinical trial evaluating HEPZATO in combination with standard of care (SOC) treatment for liver-dominant metastatic breast cancer (mBC).

The Phase 2 trial (DELUMA; NCT06875128) will evaluate the safety and efficacy of HEPZATO in combination with standard of care (SOC) versus SOC alone in patients with liver-dominant HER2-negative mBC following the failure of previous treatments. The SOC options will be physician's choice of eribulin, vinorelbine or capecitabine. Approximately 90 patients will be enrolled in this randomized, controlled trial, which is expected to be conducted at more than 20 sites across the United States and Europe. The trial's primary endpoint is hepatic progression-free survival, with several secondary endpoints, including progression-free survival, overall response rate, disease control rate and overall survival.

Company management estimates that approximately 7,000 patients annually in the United States are affected by HER2-negative metastatic breast cancer with liver metastases and are candidates for third-line treatment. This population includes patients with a significant burden of liver metastases, which are likely to be the primary cause of mortality. Delcath aims to provide a novel treatment option for these patients, who have limited therapeutic alternatives.

"Dosing the first patient in this Phase 2 trial at the IEO in Milan, Italy is an important milestone in our effort to expand the clinical investigation of HEPZATO into liver-dominant metastatic breast cancer," said Gerard Michel, Chief Executive Officer of Delcath Systems, Inc. "Building on encouraging efficacy signals in real-world evidence presented at ESMO Breast Cancer 2026 and our commercial success in metastatic uveal melanoma, we're strengthening how we engage sites, educate physicians on liver-directed therapy, and identify appropriate patients. We are encouraged by the momentum we are seeing and look forward to advancing our evaluation of HEPZATO's potential to address significant unmet needs in oncology beyond 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 Hepatic Delivery System. The HDS is used to isolate the liver from general circulation, allowing for the delivery of high-dose melphalan directly to the liver while limiting 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, where it has been used at major medical centers to treat a wide range of liver cancers.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning the clinical development of HEPZATO, the timing, conduct and

expected enrollment of clinical trials, the potential benefits of HEPZATO for patients with liver-dominant metastatic breast cancer, and the company's plans to expand the use of its hepatic delivery system platform. These statements are based on management's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements.

Factors that may cause actual results to differ materially include, but are not limited to, risks related to clinical trial initiation, enrollment, execution and results; regulatory review and approval processes; the company's ability to commercialize HEPZATO KIT and CHEMOSAT; market acceptance; competition; reimbursement; intellectual property protection; and other risks described in Delcath's filings with the Securities and Exchange Commission. Delcath undertakes no obligation to update forward-looking statements except as required by law.

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Source: Delcath Systems, Inc.