Delcath Systems Announces FDA Clearance of IND Application for Phase 2 Clinical Trial of HEPZATO™ in Liver-Dominant Metastatic Breast Cancer

April 28, 2025

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Apr. 28, 2025-- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced that the U.S. Food and Drug Administration (FDA) has completed its 30-day review of the Company's Investigational New Drug (IND) application for a Phase 2 clinical trial evaluating HEPZATO™ in combination with standard of care (SOC) for liver-dominant metastatic breast cancer (mBC). With the FDA's review complete, Delcath is now cleared to initiate patient enrollment in the U.S.

The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with SOC versus SOC alone in patients with liver-dominant HER2-negative mBC following the failure of previous treatments. The SOC options will be the physician’s choice of eribulin, vinorelbine or capecitabine. Approximately 90 patients will be enrolled in this randomized, controlled trial. The study will take place at more than 20 sites across the United States and Europe, with patient enrollment expected to begin in the fourth quarter of 2025. The trial’s primary endpoint, hepatic progression-free survival, is anticipated to be announced by the end of 2028, while results for overall survival, a secondary endpoint, are expected in 2029.

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. By focusing on this demographic, Delcath intends to offer a novel therapeutic option to those patients with limited treatment alternatives.

“This randomized Phase 2 trial marks an important milestone as we expand the clinical investigation of HEPZATO into patients with liver-dominant metastatic breast cancer,” said Gerard Michel, Chief Executive Officer of Delcath Systems, Inc. “We are excited to bring new hope to patient populations in indications beyond metastatic uveal melanoma and to further demonstrate the potential of HEPZATO to address unmet needs in oncology. This study underscores our commitment to broadening the applications of HEPZATO and the underlying hepatic delivery system, positioning us as a platform technology that can offer directed treatment options for a variety of liver-dominant cancers.”

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 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

This release contains forward-looking statements, including statements regarding the expected timeline for trial enrollment and data readouts, which are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, delays in regulatory review, site activation, patient enrollment, or unforeseen clinical trial results. For a detailed discussion of these and other risks, please refer to Delcath's filings with the SEC.

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