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

December 2, 2024

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Dec. 2, 2024-- 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 colorectal cancer (mCRC). With the FDA's review complete, Delcath is now authorized to initiate patient enrollment.

The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with trifluridine-tipiracil and bevacizumab compared to trifluridine-tipiracil and bevacizumab alone in patients with liver-dominant mCRC receiving third-line treatment. 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 second half of 2025. The trial's primary endpoint, hepatic progression-free survival (hPFS), is anticipated to read out by the end of 2027, while overall survival (OS), a secondary endpoint, is expected in 2028.

The company estimates that the total addressable market (TAM) for liver-dominant mCRC receiving third-line treatment is between 6,000 and 10,000 patients annually in the United States. This market includes patients who present with significant liver disease burden, with liver-dominant status determined through radiological and clinical criteria. By targeting this patient population, Delcath aims to provide a novel treatment option for those with limited therapeutic alternatives.

"This Phase 2 trial represents an exciting step forward in evaluating HEPZATO as a treatment for patients with liver-dominant metastatic colorectal cancer," said Gerard Michel, Chief Executive Officer of Delcath Systems, Inc. "The study reflects our commitment to expand the potential applications of HEPZATO beyond metastatic uveal melanoma, offering new hope to an additional group of patients with 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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