Delcath Systems Announces CMS Approval for NTAP for HEPZATO KIT™

QUEENSBURY, N.Y. – Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announced today that the Centers for Medicare & Medicaid Services (CMS) has granted New Technology Add-on Payment (NTAP) status for its HEPZATO KIT™ (melphalan/Hepatic Delivery System). This approval will be effective for the fiscal year starting October 1, 2024.

The NTAP designation under the CMS Inpatient Prospective Payment System (IPPS) is designed to support the adoption of innovative medical technologies that provide substantial clinical improvement over existing treatments. HEPZATO KIT™ is used primarily in the outpatient setting, however there are instances where it is used in the inpatient setting. This additional payment will help to cover the costs associated with the HEPZATO KIT for eligible Medicare inpatients, ensuring that more patients can benefit from this advanced liver-directed therapy.

“The NTAP approval for HEPZATO KIT is a significant milestone that underscores the clinical value of our therapy. This will facilitate broader access to HEPZATO KIT for eligible patients and support the oncology community in delivering this important treatment,” stated Gerard Michel, CEO of Delcath Systems.

The HEPZATO KIT is a combination product that delivers melphalan, a chemotherapeutic agent, directly to the liver using Delcath’s proprietary Hepatic Delivery System (HDS). This system isolates the liver during the infusion process, allowing for high-dose chemotherapy administration while minimizing systemic exposure. The HEPZATO KIT is indicated for the treatment of adult patients with unresectable hepatic-dominant 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 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 surgically isolate the liver 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.

Safe Harbor / Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This press release contains forward-looking statements, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

View source version on businesswire.com:

https://www.businesswire.com/news/home/20240805478333/en/

Investor Relations:

ICR Westwicke

investorrelations@delcath.com