Delcath Systems Announces U.S. Launch and First Commercial Treatment Utilizing HEPZATO KIT™

NEW YORK, Jan. 16, 2024 — Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced the first commercial use of HEPZATO KIT for the treatment of metastatic uveal melanoma (mUM).

The procedure took place at Moffitt Cancer Center in Tampa, Florida by Dr. Jonathan S. Zager, M.D., Chief Academic Officer; Senior Member, Department of Cutaneous, Oncology; Director of Regional Therapies, Moffitt Cancer Center. Dr. Zager was the global Lead Investigator for the FOCUS Phase 3 trial.

“The fact that patients with difficult to treat metastatic uveal melanoma with limited treatment options now have another alternative is truly remarkable and exciting. There has been a large unmet need for liver directed therapy options to treat this patient population and we intend to incorporate this as standard of care for appropriate patients,” said Dr. Zager. Dr. Zager enrolled and treated the first and last patients on the FOCUS Phase 3 trial and the team at Moffitt has performed the procedure over 200 times to date.

The company is working with numerous other leading cancer centers across the U.S. which have indicated interest in HEPZATO KIT to ensure patients nationwide have access to this important treatment. In conjunction with the first commercial treatment, Delcath also launched websites relating to the HEPZATO KIT, including HEPZATO KIT, HEPZATO KIT REMS, and HEPZATO KIT Access, to support the commercial launch.

“The first commercial procedure utilizing HEPZATO KIT in the U.S. is a significant milestone for Delcath and patients suffering from metastatic uveal melanoma. We are proud to continue our relationship with Dr. Zager and the team at Moffitt Cancer Center to bring this unique treatment to appropriate patients in need. I want to thank all the collaborators and patients who participated in the long but necessary process to bring HEPZATO KIT to market,” said Gerard Michel, Delcath’s Chief Executive Officer.

About HEPZATO KIT

HEPZATO KIT (melphalan for Injection/Hepatic Delivery System), approved for use in the

United States by FDA, is a combination drug/device product which administers HEPZATO (melphalan) directly to the liver through the HDS, which permits higher drug exposure in target tissues while limiting systemic toxicity.

HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with uveal melanoma 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.

HEPZATO KIT Important Safety Information
Patients eligible for HEPZATO KIT should NOT have any of the following medical conditions:

- Active intracranial metastases or brain lesions with a propensity to bleed
- Liver failure, portal hypertension, or known varices at risk for bleeding
- Surgery or medical treatment of the liver in the previous 4 weeks
- Active cardiac conditions including unstable or severe angina or myocardial infarction), worsening or new-onset congestive heart failure, significant arrhythmias, or severe valvular disease
- History of allergies or known hypersensitivity to melphalan or a component or material utilized within the HEPZATO KIT including natural rubber latex, heparin, and severe hypersensitivity to iodinated contrast not controlled by antihistamines and steroids

Most common adverse reactions or laboratory abnormalities occurring with HEPZATO KIT treatment are thrombocytopenia, fatigue, anemia, nausea, musculoskeletal pain, leukopenia, abdominal pain, neutropenia, vomiting, increased alanine aminotransferase, prolonged activated partial thromboplastin time, increased alkaline phosphatase, increased aspartate aminotransferase and dyspnea.

Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events may occur via hepatic intra-arterial administration of HEPZATO. HEPZATO KIT is available only through a restricted program under a Risk Evaluation and Mitigation Strategy called the HEPZATO KIT REMS. Myelosuppression with resulting severe infection, bleeding, or symptomatic anemia may occur with HEPZATO. Additional cycles of HEPZATO KIT therapy will be delayed until blood counts have improved.

Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

About Delcath Systems, Inc.
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 (melphalan for Injection/Hepatic Delivery System), approved for use in the United States by FDA, and CHEMOSAT Hepatic Delivery System for Melphalan percutaneous hepatic perfusion, designated under the medical device regulation for use in Europe and the United Kingdom,

are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

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.

Contact:

Investor Relations Contact:
Ben Shamsian
Lytham Partners
646-829-9701
shamsian@lythampartners.com

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