



Delcath Systems, Inc. Announces Additional \$35 Million in Funding Tied to the FDA Approval of HEPZATO KIT™

September 1, 2023

NEW YORK, Sept. 1, 2023 /PRNewswire/ -- [Delcath Systems, Inc.](#) (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced today that it raised approximately \$35 million through the exercise of all the Tranche A warrants issued as part the previously announced March 29, 2023 Private Investment in Public Equity (PIPE) financing. The warrants were exercisable until the earlier of 3/31/2026 or 21 days after the U.S. Food and Drug Administration (FDA) approval of the [HEPZATO KIT](#) (melphalan) for Injection/Hepatic Delivery System, which occurred on August 14, 2023. Tranche B warrants, also issued as part of the PIPE financing, could generate approximately \$25 million in additional proceeds and are exercisable until the earlier of 3/31/2026 or 21 days following the Company's public announcement of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO.



The FDA approval and additional financing triggers an extension of the interest-only period from September 30, 2023, to December 31, 2023, for an existing loan agreement with Avenue Venture Opportunities Fund, L.P.

"With the exercise of these warrants we have, as planned, accessed adequate capital to fund the commercial launch of HEPZATO KIT without adding to our fully diluted share count," said Gerard Michel, Delcath's Chief Executive Officer. Mr. Michel continued, "We can now focus on providing access to HEPZATO KIT to uveal melanoma patients as well as expanding our development efforts to treat other liver dominant cancers."

The Company plans to have commercial product available for uveal melanoma patients by the end of 2023. Until that time patients will continue to be enrolled and treated at Expanded Access Program (EAP) sites.

About HEPZATO KIT

HEPZATO KIT is 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.

HEPZATO KIT is a combination product that administers HEPZATO (melphalan), a well-known and long-approved chemotherapeutic agent, directly to the liver through Delcath's novel Hepatic Delivery System (HDS), which permits higher drug exposure in target tissues while limiting systemic toxicity. The use of the HDS allows a healthcare provider team to surgically isolate the liver while the hepatic venous blood is filtered during melphalan infusion and subsequent washout during a Percutaneous Hepatic Perfusion (PHP) procedure. PHP, which can only be performed with Delcath's HDS, resulting in loco-regional delivery of a relatively high melphalan dose.

Please see the full [Prescribing Information](#), including BOXED WARNING for the HEPZATO KIT.

Important Safety Information

Patients eligible for HEPZATO 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 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 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 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 (PHP), 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. For more information regarding HEPZATO KIT and its use, including Important Safety Information and Boxed Warning, please visit HEPZATOKIT.com. For more information regarding CHEMOSAT and its use, please visit Chemosat.com.

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.

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