Delcath Systems Announces Publication of Comparative Analysis from Randomized Portion of FOCUS Study in Metastatic Uveal Melanoma

April 9, 2025

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Apr. 9, 2025-- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced the publication of a comparative analysis from the randomized cohort of the Company's Phase 3 FOCUS study in *Annals of Surgical Oncology*. The study, titled "*An Open-label, Randomized Study of Melphalan/Hepatic Delivery System Versus Best Alternative Care in Patients with Unresectable Metastatic Uveal Melanoma,*" indicates that treatment with the Melphalan/Hepatic Delivery System (Melphalan/HDS) shows a trend toward favorable clinical outcomes compared to best alternative care (BAC), which included the physician's choice of dacarbazine, transarterial chemoembolization (TACE), ipilimumab or pembrolizumab in patients with unresectable metastatic uveal melanoma (mUM) with liver involvement.

The FOCUS study was initially designed and conducted as a randomized controlled trial but was amended to a single-arm design. As a result, comparative efficacy analyses were designated as exploratory. A total of 85 patients were enrolled during the randomized portion of the trial, with 72 receiving study treatment (40 Melphalan/HDS; 32 BAC).

Key Findings from the Randomized Portion of the FOCUS Study:

- All efficacy endpoints of the trial demonstrated substantial and consistent improvements in patients treated with Melphalan/HDS over BAC, including:
  - Median progression-free survival in patients treated with Melphalan/HDS was 9.1 months, nearly three times longer than the 3.3 months observed in patients treated with BAC
  - Median overall survival was 18.5 months for Melphalan/HDS compared to 14.5 months with BAC
  - Objective response rate was 27.5% with Melphalan/HDS, nearly three times higher than 9.4% with BAC
  - Disease control rate was 80.0% with Melphalan/HDS, substantially higher than the 46.9% observed with BAC
  - Median hepatic progression-free survival was 11.4 months for Melphalan/HDS – more than three times longer than the 3.3 months for BAC
- The safety profile of patients treated with Melphalan/HDS was consistent with prior reports and primarily hematologic in nature. No treatment-related deaths were observed.

"These results further support the use of our hepatic delivery system as a liver-directed treatment option for patients with metastatic uveal melanoma," said Dr. Vojislav Vukovic, Chief Medical Officer at Delcath. "Melphalan/HDS delivered meaningful improvements across all clinical endpoints, including progression-free survival, overall survival, disease control, and hepatic outcomes. The findings, while exploratory in nature, reinforce our belief that effective management of liver disease is key to improving outcomes in this patient population, and we are proud to contribute a therapy with both clinical impact and the ability to be administered repeatedly."

The publication is available online at: https://doi.org/10.1245/s10434-025-17231-x

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 regulated and approved as a combination drug and device product by the FDA. HEPZATO KIT is approved 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 full Prescribing Information, including

BOXED WARNING, at www.hepzatokit.com.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is marketed under the trade name CHEMOSAT®, where it has been used in major cancer 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; contributions to adjusted EBITDA; 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 and the managing of any trade restrictions; 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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