Delcath Systems Announces Publication of Subgroup Analyses of the Phase 3 FOCUS Study of Melphalan/Hepatic Delivery System in Patients with Unresectable Metastatic Uveal Melanoma

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QUEENSBURY, N.Y.--(BUSINESS WIRE)--Dec. 31, 2025-- Delcath Systems, Inc. (Nasdaq: DCTH), ("Delcath" or the "Company") an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced the publication of results from subgroup analyses of the phase 3 FOCUS study. The publication, titled "Subgroup Analyses of the Phase 3 FOCUS Study of Melphalan/Hepatic Delivery System in Patients with Unresectable Metastatic Uveal Melanoma" was published in the *Journal of Cancer Research and Clinical Oncology*. The analysis assessed efficacy and safety in subgroups of patients treated with Delcath's HEPZATO KIT, a drug/device combination for liver-directed treatment of mUM patients. The HEPZATO KIT is currently the only liver-directed treatment to be approved by the FDA for patients with unresectable mUM. The article provides clinically relevant subgroup analyses of key efficacy endpoints, including overall response rate (ORR), progression-free survival (PFS) and overall survival (OS), and safety categories. Prespecified subgroups included age (<65 or ≥65 years), sex (male or female) geographic region (ex-US or US) extent of tumor liver involvement (1-25% or 26-50%), hepatic tumor burden (above or below median), presence of extrahepatic lesions (yes or no), baseline LDH (low/normal or elevated) and number of prior therapies (0 or 1+).

This prespecified analysis of clinically relevant subgroups included 91 patients treated in the FOCUS study. Key efficacy and safety findings include:

- Consistent tumor response was observed regardless of age, sex, geographic region, presence/absence of extrahepatic lesions, and prior therapy.
- ORR: significantly higher ORR for patients with tumor burden below the median (51.1% vs. 22.2%, p=0.008). No significant differences for other subgroups.
- PFS: significantly longer median PFS for patients with tumor burden below the median (11.3 vs. 5.8 months, p=0.007). No significant differences for other subgroups.
- OS: significantly longer median OS for patients with smaller extent of tumor liver involvement (22.4 vs 16.8 months, p=0.032), tumor burden below the median (26.7 vs 15.4 months, p=0.008) and low/normal LDH (23.4 vs 15.3 months, p=0.019)
- Of the 33 patients achieving an objective response (CR or PR), 57.6% (19 patients) responded within the first or second treatment cycle, while one-third (33.3%; 11 patients) of responses were observed in Cycles 4–6, highlighting the importance of continued treatment up to the maximum of 6 cycles to optimize tumor response.
- The overall safety profile was similar across subgroups, with no evidence of cumulative toxicity with successive treatment cycles. The incidence of serious adverse events and Grade 3/4 adverse events was consistent with the overall study population, and no treatment-related deaths occurred. "These subgroup analyses provide valuable insights into optimizing treatment with Melphalan/HDS for patients with unresectable metastatic uveal melanoma, underscoring the importance of early intervention in patients with lower tumor burden to maximize clinical benefits," said Vojislav Vukovic, MD, MSc, PhD, Chief Medical Officer of Delcath. "The consistent efficacy and manageable safety profile across diverse patient groups further validate this liver-directed therapy as a key option in managing this challenging disease."

The FOCUS study utilized HEPZATO KIT (HEPZATO (melphalan) for Injection/Hepatic Delivery System), and results from the FOCUS study lead to the approval of HEPZATO by the U.S. Food and Drug Administration (FDA).

The article is available here.

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 (HDS) 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 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
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by Delcath or on its behalf. This press release contains forward-looking statements, including statements regarding the potential of CHEMOSAT Hepatic Delivery System and HEPZATO KIT to improve outcomes for patients with metastatic uveal melanoma. All forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. Factors that may cause such differences include, but are not limited to, those discussed in the Company's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Delcath undertakes no obligation to publicly update or revise these forward-looking statements except as required by applicable law.

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