Publication of Results from Pivotal FOCUS Study in Metastatic Uveal Melanoma Patients treated with HEPZATO KIT

Significantly Higher Overall Response Rate vs Meta-analysis of Historical Controls (36.3% vs. 5.5%)

Other Efficacy Endpoints Include a 73.6% Disease Control Rate with a 7.7% Complete Response Rate

NEW YORK, May 6, 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 publication of results from the pivotal Phase 3 FOCUS study of HEPZATO KIT (melphalan/Hepatic Delivery System) in patients with unresectable metastatic Uveal Melanoma (mUM) on May 5, 2024 in the journal *Annals of Surgical Oncology*.

The Food and Drug Administration (FDA) approved HEPZATO KIT on August 14, 2023 based on the results from the pivotal FOCUS study. A total of 91 patients with unresectable mUM were treated with HEPZATO KIT at 23 treatment centers in the US and Europe. Preliminary results from the FOCUS study were presented at the American Society of Clinical Oncology Annual Meeting in 2022.

The FOCUS study was designed to provide a robust evaluation of efficacy and safety of HEPZATO KIT treatment, and enrolled a heterogeneous mUM patient population, including treatment-naïve and pretreated patients, patients with and without extrahepatic disease and patients with a range of baseline tumor burden.

The primary efficacy endpoint of the FOCUS study was Overall Response Rate (ORR), which was 36.3%, including 7.7% of patients with Complete Response (CR), as determined by an Independent Review Committee. 37.4% of patients had Stable Disease (SD). ORR achieved in the FOCUS study was compared to a Meta-analysis of historic data, encompassing 16 published clinical studies with a total of 476 mUM patients treated with contemporary immunotherapy drugs. ORR of 36.3% in the FOCUS study was statistically significantly better than the pooled ORR estimate (a weighted mean of the observed ORR) of 5.5% in the historical control group.

Secondary efficacy endpoints included Duration of Response (DOR), median Progression-free

Survival (mPFS) and median Overall Survival (mOS), which were 14, 9 and 20.5 months, respectively.

Safety and tolerability of HEPZATO KIT treatment reported in the FOCUS study was comparable with published clinical experience with Chemosat in Europe. Median number of administered HEPZATO KIT treatment cycles in the FOCUS study was 4. The most common serious treatment-emergent adverse events (SAE) were thrombocytopenia (15.8%) and neutropenia (10.5%), managed with standard supportive care and resolved with no ongoing complications. No treatment-related deaths were observed.

“My team at the Moffitt Cancer Center and I are very excited about the publication of results from the FOCUS study. The study results are consistent with data obtained from previous clinical studies, as well as our own experience with percutaneous hepatic perfusion (PHP) with more than 200 treatments performed at Moffitt over the past 15 years,” said Dr. Jonathan Zager, MD Chief Academic Officer and Director of Regional Therapies at Moffitt Cancer Center. “Since HEPZATO KIT became available in January, the treatment has become the liver directed standard of care for appropriate patients with mUM at our institution.”

“Results from the pivotal FOCUS study demonstrate that the PHP procedure, whether utilizing the FDA approved HEPZATO KIT or melphalan delivered by the Chemosat device available in Europe, is an important treatment option for patients with liver-dominant mUM,” said Dr. Vojo Vukovic, MD, PhD Delcath’s Chief Medical Officer. “Delcath is looking forward to publishing additional results from the FOCUS study later this year.”

The vast majority of patients with mUM will have liver metastases, often leading to liver failure, and the National Comprehensive Cancer Network guidelines recommend liver-directed therapies be considered for the treatment of mUM. HEPZATO is the only liver-directed treatment for unresectable mUM patients approved by the FDA.

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.

Contact:

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

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