Delcath Systems, Inc. Announces Positive Outcomes from Independent Study on Hepatic Perfusion for Uveal Melanoma Patients

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NEW YORK--(BUSINESS WIRE)--Aug. 27, 2024-- Delcath Systems, Inc. (Nasdaq: DCTH) (the “Company” or “Delcath”), an interventional oncology company specializing in the treatment of primary and metastatic liver cancers, today announced the publication of a retrospective study by independent investigators in the *Annals of Surgical Oncology*. The study, titled “Hepatic and Overall Progression-Free Survival After Percutaneous Hepatic Perfusion (PHP) as First-Line or Second-Line Therapy for Metastatic Uveal Melanoma,” was conducted by researchers at Moffitt Cancer Center in Tampa, Florida. The 30-patient study reported that Delcath’s HEPZATO KIT™ (melphalan/Hepatic Delivery System (HDS)) provided better disease control in the liver and improved progression-free survival in patients with hepatic metastases from uveal melanoma, compared to both immunotherapy and other liver-directed therapies.

Key Findings from the Study:

- **Overall Survival (OS):** The study reported median OS of 22.4 months for patients treated with HEPZATO KIT as a first-line therapy (N=17) and 18.4 months as a second-line therapy (N=6).
- **Hepatic Progression-Free Survival (hPFS):** Patients receiving HEPZATO KIT as first-line therapy had a median hPFS of 17.6 months (N=17), compared to 8.8 months (N=6) for immunotherapy and 9.2 months (N=7) for other liver-directed therapies. When used as a second-line therapy, HEPZATO KIT resulted in a median hPFS that was not reached (N=6), showing better outcomes than immunotherapy (14.7 months, N=5) and other liver-directed therapies (7.5 months, N=3) in this patient cohort.
- **Progression-Free Survival (PFS):** The median overall PFS was 15.4 months (N=17) for patients receiving HEPZATO KIT as first-line therapy, compared to 8.8 months (N=6) for immunotherapy and 9.2 months (N=7) for other liver-directed therapies. In the second-line setting, HEPZATO KIT resulted in a median PFS of 22.2 months (N=6), compared to 14.7 months (N=5) for immunotherapy and 7.5 months (N=3) for other liver-directed therapies, reflecting longer disease control in this group.

Jonathan Zager, MD Chief Academic Officer and Director of Regional Therapies at Moffitt Cancer Center, remarked, “The findings from this study reaffirm the critical role of melphalan/HDS in managing liver-dominant metastatic uveal melanoma. These results highlight the potential benefits melphalan/HDS offers to patients, particularly in the context of first- and second-line treatments. My team is committed to further exploring the potential of combining melphalan/HDS with systemic therapies to continue improving patient outcomes.”

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 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.

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