

Delcath Systems, Inc. Announces Positive Results from Independent Study on Liver-Directed Therapy for Uveal Melanoma Patients

NEW YORK – Delcath Systems, Inc. (Nasdaq: DCTH) (the “Company” or “Delcath”), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced the publication of a clinical study in the journal *Therapeutic Advances in Medical Oncology*. The publication, entitled “Melanoma-specific survival of patients with uveal melanoma and liver metastases diagnosed between 2005 and 2021”, was based on an independent retrospective clinical study conducted by investigators from the University of Tübingen, Germany. The study demonstrates that first-line liver-directed therapies, including Delcath’s CHEMOSAT® Hepatic Delivery System, significantly improve melanoma-specific survival (MSS) in patients with liver metastases from uveal melanoma, compared to first-line systemic therapies.

Key Findings from the Study:

- **Positive Trends in Survival with First-Line Liver-Directed Therapies:** The study analyzed 167 patients diagnosed with metastatic uveal melanoma between 2005 and 2021. Among those receiving first-line liver-directed therapy (N=89), the median MSS was 28 months, compared to 10 months for patients who received first-line systemic therapy (N=45).
- **Comparison of Outcomes Over Time with First-Line Liver-Directed Therapies:** The study found that patients diagnosed with liver metastases between 2016 and 2021 (N=56) and treated with first-line liver-directed therapy, including CHEMOSAT, had a median MSS of 30 months. In comparison, patients diagnosed between 2005 and 2015 (N=33) who received first-line liver-directed therapy had a median MSS of 20 months.

During the 2005-2015 period, 33 patients received liver-directed therapy, with 8 of those receiving CHEMOSAT. In the 2016-2021 period, 56 patients received liver-directed therapy, with 30 of those receiving CHEMOSAT.

Dr. Vojislav Vukovic, Chief Medical Officer of Delcath Systems, commented, “We are encouraged by the findings from this independent study, which reinforce the critical role of liver-directed therapies in the first-line setting, including our CHEMOSAT system, in treating patients with liver metastases from uveal melanoma.”

The publication 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 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 filtering 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20240828085931/en/>

Investor Relations Contact:

ICR Westwicke

investorrelations@delcath.com