Delcath Systems Announces Publication by Independent Investigators of a Retrospective Analysis of Quality of Life in the Journal Melanoma Research

Retrospective Analysis of Changes in Patients with Metastatic Uveal Melanoma treated with Chemosat Hepatic Delivery System

Results Support that Utilizing Delcath's HDS to Administer High-Dose Melphalan to the Liver Is Well Tolerated by Patients

NEW YORK, Dec. 7, 2023 — 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 a clinical study in the journal Melanoma Research. The publication, entitled "Quality of Life After Melphalan Hepatic Perfusion for Uveal Melanoma", was based on an independent clinical study conducted by investigators from University Hospital Southampton, UK and focused on the impact of melphalan percutaneous hepatic perfusion treatment on the quality of life (QoL) of patients with metastatic uveal melanoma. Melphalan Hepatic Perfusion, also known as Percutaneous Hepatic Perfusion (PHP), utilizes CHEMOSAT, Delcath's proprietary European CE Marked Hepatic Delivery System (HDS), to administer high-dose melphalan to the liver, while controlling systemic exposure and associated side effects.

Uveal melanoma usually shows a liver-dominant metastatic spread and is often treated with liver directed therapies. While the safety and efficacy profile of utilizing Delcath's HDS to administer high-dose melphalan to the liver is favorable and well established based on results from several clinical studies, the impact of this treatment on QoL has not been widely investigated. When assessing the value of a treatment, clinicians often weigh its efficacy and effect on overall survival against any negative impact of the treatment on QoL.

Investigators used the FACT-G (Functional Assessment of Cancer Therapy – General) questionnaire which has been specifically developed for and validated in oncology patients. The FACT-G questionnaire consists of 4 subdomains: physical (PWB), social (SWB), emotional (EWB) and functional (FWB) wellbeing.

The study included 20 patients with metastatic uveal melanoma treated at the University Hospital Southampton between August 2020 and January 2023. The FACT-G questionnaire

was administered pre-treatment and post-treatment on day 1, day of discharge, day 7, 14 and 28. Immediately following treatment, PWB and FWB decreased relative to baseline; by day 14 no residual significant difference was observed and on day 28 overall scores were almost at baseline. Interestingly, an improvement over baseline in EWB was observed by day 28.

The authors conclude their results support the growing body of evidence that utilizing Delcath's HDS to administer high-dose melphalan to the liver is well tolerated by patients does not negatively effect their quality of life. A link to the publication's abstract can be found here.

"The publication of these results by independent investigators supports the rationale for the percutaneous hepatic perfusion procedure, whether utilizing melphalan delivered by Delcath's CE marked Chemosat or the FDA approved HEPZATO KIT, as an important treatment option for patients with liver-dominant uveal melanoma," said Dr. Vojo Vukovic, Delcath's Chief Medical Officer. "We look forward to making this treatment option available to patients in the US in January 2024."

About Chemosat and HEPZATO KIT

CHEMOSAT Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP) is designated a class lll medical device under the Medical Device Regulation for use in Europe and the United Kingdom. The Hepatic Delivery System (HDS) is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure. The use of the HDS allows a healthcare provider team to surgically isolate the liver while the hepatic venous blood is filtered during melphalan infusion and subsequent washout during a Percutaneous Hepatic Perfusion (PHP) procedure. PHP, which can only be performed with Delcath's HDS, results in loco-regional delivery of a relatively high melphalan dose. For more information regarding CHEMOSAT and its use, please visit Chemosat.com.

HEPZATO KIT (melphalan for Injection/Hepatic Delivery System), approved for use in the United States by FDA, is a combination drug/device product which administers HEPZATO (melphalan) directly to the liver through the HDS, which permits higher drug exposure in target tissues while limiting systemic toxicity.

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.

About Delcath Systems, Inc.

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 (melphalan for Injection/Hepatic Delivery System), approved for use in the United States by FDA, and CHEMOSAT Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP), designated under the medical device regulation for use in Europe and the United Kingdom, are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

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.

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