Delcath Systems Announces New Drug Application Resubmission for HEPZATO Kit

February 14, 2023

NEW YORK, Feb. 14, 2023 /PRNewswire/ -- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced it submitted a new drug application (NDA) resubmission to the US Food and Drug Administration (FDA) for the HEPZATO™ Kit (melphalan hydrochloride for Injection/Hepatic Delivery System or Melphalan/HDS) seeking approval for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM).

The resubmission is in response to a September 12, 2013 Complete Response Letter (CRL) from the FDA. The NDA resubmission contains comprehensive data and information to address all issues identified in the CRL. The FDA is expected to determine whether the resubmission constitutes a complete response and is eligible for review within 30 days. Once accepted for review by the FDA, a new PDUFA action date will be established for the HEPZATO Kit application.

"The submission is a critical milestone for Delcath and represents the culmination of years of work by investigators and employees," said Gerard Michel, CEO of Delcath. "We look forward to receiving feedback from the FDA regarding a PDUFA date within 30 days."

About the FOCUS Trial

The FOCUS trial evaluated the safety and efficacy of treatment with HEPZATO Kit for patients with mOM. The primary endpoint of Overall Response Rate (ORR) was assessed by an Independent Review Committee per RECIST v1.1. Per protocol, patients were treated every 6 to 8 weeks for a maximum of 6 cycles. Tumor responses were assessed every 12 weeks (+/- 2 weeks) until disease progression.

Delcath powered the single arm trial to demonstrate a superior ORR versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications. The checkpoint inhibitor ORR was calculated based on a meta-analysis covering 16 different publications and 476 patients. Based on those assumptions, a 21.0% ORR was required to demonstrate superiority over the checkpoint inhibitors at a 95% confidence interval. The FOCUS study's intent-to-treat (ITT) population was comprised of a total of 102 mOM subjects. In the ITT population, 91 patients were administered at least one study treatment. Of the 91 patients in the treated population, 51 (56.0%) had no prior therapy for liver metastases and 40 (44.0%) had at least one line of prior therapy. As previously reported, treatment with HEPZATO Kit in the treated population resulted in an ORR of 36.3% [95% CI: 26.44, 47.01] including 7.7% of patients with a complete response (CR). The median duration of response was 14.00 months [95% CI: 8.31, 17.74] and the disease control rate (DCR) was 73.6% [95% CI: 63.35, 82.31].

In addition, the NDA resubmission includes updated estimated median overall survival (OS) of 20.53 months [95% CI: 16.79, 25.26] and updated estimated OS at 1 year of 0.80 [95% CI: 0.70, 0.87]. Delcath will continue to follow patients until May 2023 (24 months after the last patient's last treatment).

In the FOCUS trial safety population (95 patients), 39 patients (41.1%) experienced a treatment-related serious adverse event. The most commonly reported treatment-related serious adverse events were thrombocytopenia, neutropenia and febrile neutropenia which were well-manageable. Five percent of patients experienced treatment-related serious cardiac adverse events;

in all cases the events resolved with no ongoing complications. There were no treatment-related deaths in the trial. This is consistent with CHEMOSAT, the HDS device component of HEPZATO Kit, approved in Europe under a CE mark to deliver melphalan to the liver. The safety data submitted in the NDA is consistent with the CHEMOSAT safety data documented in numerous European single-center and multi-center publications.

About the HEPZATO Kit

The HEPZATO Kit is a drug-device combination product comprised of the drug (melphalan) and device (HDS) constituent parts. Melphalan is a well-established, broadly effective anticancer chemotherapeutic agent belonging to the alkylating class and is responsible for the combination product's primary mode of action. The procedure of surgical isolation and simultaneous filtration of hepatic venous blood during drug infusion and washout, known as percutaneous hepatic perfusion, or PHP, 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 relative to the comparable intravenous (IV) dose.

In the US, the efficacy and safety of HEPZATO Kit have not been established for any indication and it is not presently approved by the FDA.

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 hydrochloride 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 an investigational drug/device combination product regulated as a drug by the United States Food and Drug Administration (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. In the US, HEPZATO Kit was the subject of a February 14, 2023 new drug application resubmission to FDA for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM). 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 news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: actions by the FDA relating to the application; the ability of the Company to respond to FDA queries related to the application; the Company's successful inspections by the FDA or foreign regulatory agencies; the timing and results of the Company's clinical trials, our determination whether to continue a clinical trial program or to focus on other alternative indications, and the impact of the COVID-19 pandemic on the completion of our clinical trials; the impact of the presentations at major medical conferences and future clinical results consistent with the data presented; the Company's ability to successfully commercialize the HEPZATO Kit and the potential of the HEPZATO Kit/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for commercialized product in various markets; the Company's ability to successfully enter into strategic partnership and distribution arrangements and the timing and revenue, if any, of the same; uncertainties relating to the timing and results of research and development projects; and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. 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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