Results of a Multicenter Study on Delcath's CHEMOSAT® Hepatic Delivery System Published in Cardiovascular and Interventional Radiology

August 5, 2022

Retrospective study in metastatic uveal melanoma patients with liver dominant disease shows an objective response rate of 59.4% and a disease control rate of 89.1%.

The study finds that achieving complete response, partial response, or stable disease is associated with improved survival.

NEW YORK, Aug. 5, 2022 /PRNewswire/ -- Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced the publication of a retrospective analysis of patients who underwent a percutaneous hepatic perfusion procedure (PHP) with CHEMOSAT® at three European centers, one in the Netherlands and two in Germany, between February 2014 and December 2019. The study involved 101 patients who completed a minimum of one PHP procedure for the treatment of unresectable uveal melanoma (UM) liver metastases.

The study, *Predictive Parameters in Patients Undergoing Percutaneous Hepatic Perfusion with Melphalan for Unresectable Liver Metastases from Uveal Melanoma: A Retrospective Pooled Analysis,* by Dr. T. M. L. Tong, et al,, included a total of 212 PHP procedures for the 101 patients included in the study. Of the 101 patients, 66 received PHP as first line treatment and 33 had received prior therapy (status of 2 patients was unknown). Approximately 50% of patients had greater than 9 metastases. Seventy-seven patients underwent at least two procedures and 25 patients received more than two PHP procedures. After a median follow-up time of 15 months, a complete response (CR) was reported in five (5.0%) patients; partial response (PR) in 55 (54.5%), and stable disease (SD) in 30 (29.7%), resulting in an objective response rate (ORR) of 59.4% and a disease control rate (DCR) of 89.1%.

The median progression-free survival (PFS), liver progression-free survival (LPFS), and overall survival (OS) were 9.0 months (95% CI 7.7 -10.3); 11.0 months (95% CI 9.0 – 13.0); and 20.0 months (95% CI 13.7 – 26.3), respectively. Twelve patients who were lost to follow-up were censored in the survival analyses. The study also found statistically significant differences in median PFS, median LPFS, and OS between patients who had CR, PR, or SD; and patients with progressive disease (PD). For example, for patients with CR or PR the median OS was 27 months (95% CI 17.5 – 36.5); for patients with SD the median OS was 21 months (95% CI 11.2 – 30.8); and 8 months (95% CI 5.7 - 10.3) for patients with PD.

Although the study did not find a statistically significant difference in either median PFS and LPFS for patients treated with two or more PHP procedures compared to patients treated with one PHP procedures, the study did find a statistically significant difference in OS (20 months vs. 8 months) for patients who had two or more PHP procedures compared to patients who were treated with one PHP procedure.

The safety analysis was conducted on the first treatment cycle (183 PHP procedures). The most common adverse events were hematological toxicities which were grade 1/2 and self- limiting in the majority of patients and consistent with previous reports on PHP. Other adverse events were thromboembolic in nature. The mortality rate was 1.1% within 30 days after PHP.

"Delcath welcomes this publication and believes its results provide healthcare professionals with further evidence of Chemosat's utility in patients suffering from metastatic uveal melanoma," said Johnny John, MD, Delcath's Senior Vice President of Clinical Operations and Medical Affairs. "We look forward to resubmitting the NDA for Hepzato Kit, the combination of the Chemosat device packaged with melphalan, to FDA by the end of the third quarter."

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 percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM) and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is now regulated as a Class lll medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

View original content to download multimedia:https://www.prnewswire.com/news-releases/results-of-a-multicenter-study-on-delcaths-chemosat-

hepatic-delivery-system-published-in-cardiovascular-and-interventional-radiology-301600607.html

SOURCE Delcath Systems, Inc.

Delcath Investor Relations, Email: investorrelations@delcath.com