Results of a Single Center Study on Delcath's CHEMOSAT® Hepatic Delivery System In the Treatment of Cholangiocarcinoma Published in the Journal Clinical & Experimental Metastasis

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Results show that percutaneous hepatic perfusion with CHEMOSAT® is an effective and safe treatment option for patients with advanced cholangiocarcinoma and has the potential to prolong life in patients with inoperable, treatment-refractory liver metastases.

NEW YORK, Dec. 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 for the treatment of either inoperable intrahepatic cholangiocarcinomas (iCCA) or extrahepatic cholangiocarcinoma (eCCA) with liver metastases.

The article, *New perspectives in unresectable cholangiocarcinoma? Evaluation of chemosaturation with percutaneous hepatic perfusion as a palliative treatment option* by Dr. Cornelia L. A. Dewald, et al, was a retrospective analysis of 17 patients who underwent a total of 42 PHP procedures between October 2014 and September 2020 at the Hannover Medical School in Germany. The aim of the retrospective, monocentric study was to analyze PHP as a palliative treatment for unresectable liver dominant CCA.

16 of the 17 patients were evaluable for response as one patient died without follow-up imaging 13 weeks after the first PHP with no identifiable relationship to the PHP treatment. After the first PHP, one patient (6%) presented with a complete response (CR). Three patients (18%) had a partial response (PR) in the first follow-up exam and seven patients (44%) presented with stable disease (SD). Five patients (31%) had progressive disease (PD), one of which was limited to extrahepatic progression only. In total, in 17 treated patients an overall response rate (ORR) of 25% and a disease control rate (DCR) of 75% was achieved. Two patients with PR, six patients with SD and the patient with PD limited to extrahepatic progression received further PHP treatments. In the subsequent follow-up exams, the overall best therapy response in these patients was PR in 78% and SD in 22%. One patient was treated in total with 8 PHP treatments within 30 months.

The median progression free survival (PFS) was 3.5 (95% CI:2.2–7.4) months with a similar median hepatic PFS of 3.6 [95% CI: 2.6–9.5] months. Calculated from first diagnosis of iCCA (or CCA liver metastases), the median survival was 27.6 [95% CI: 16.5–37] months. From first PHP, a median survival of 9.9 [95% CI: 3.8–21] months was observed, with a 1-year survival rate of 41%. For context, the authors noted that for inoperable CCA, the treatment options are limited and a median survival of 2.5 – 6 months is to be expected, which can be extended to approximately 12 months under first-line chemotherapy with gemcitabine and cisplatin. In this study all patients were previously treated with at least systemic therapy and the authors note that the results of their analyses confirms the potential for survival extension by PHP treatment even after the exhaustion of systemic therapies.

No significant complications occurred during the PHP treatments. Significant, but transient and clinically manageable, hemotoxicity was reported with grade 3/4 thrombocytopenia after 50%, anemia after 26% and leukopenia after 21% of the PHP treatments. There were no PHP-related deaths. The authors stated that the toxicity rates were consistent both with previously published PHP values and with first-line systemic therapy with gemcitabine/cisplatin in CCA.

The authors highlighted the increasing importance of locoregional forms of therapy in the treatment of CCA and that the new edition of the German S3 cancer guideline "Diagnostics and Therapy of Hepatocellular Carcinoma and Biliary Carcinomas" now includes PHP with melphalan for the treatment of inoperable iCCA or eCCA liver metastases. Based on the results of this study the authors concluded that for patients with inoperable, treatment-refractory iCCA and CCA liver metastases PHP is an effective and safe treatment option that has the potential to prolong life in a palliative setting.

CCA are the second most common primary liver tumors, with an incidence of approximately 1.6 per 100,000 in the US and Europe, the majority of which are either iCCA or eCCA which become liver dominant. Radical surgical resection to tumor-free margins is the only curative therapy for non-metastatic CCA. Particularly in the case of iCCA however, due to long asymptomatic phases which often lead to an advanced tumor stage at initial diagnosis, less than 30–40% of patients are operable and there is a high risk of recurrence at 40–80% after surgical tumor resection.

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 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.

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