Positive Initial Results from CHOPIN Phase 1b Trial, FOCUS Trial Update and QoL Study Presented at the 2022 ASCO Annual Meeting

Initial results from the Phase 1b portion of the CHOPIN trial of PHP in combination with ipilimumab plus nivolumab in advanced uveal melanoma in seven patients resulted in 85.7% Best Overall Response and 100% Disease Control Rate. Median progression free survival currently is 22.4 months with all patients still alive as of last follow-up

FOCUS trial update presented with maturing results consistent with earlier presentations

Abstract published reporting on a retrospective analysis in the change of Quality of Life in PHP treated patients at the University of Southampton

NEW YORK, June 06, 2022 — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced further details regarding presentations relating to its proprietary percutaneous hepatic perfusion (PHP) system at the American Society of Clinical Oncology (ASCO) Annual Meeting being held June 3-7, 2022, in Chicago, Illinois and virtually.

Initial CHOPIN Trial Results

The goal of the CHOPIN trial is to study the safety and potential synergistic effects of systemic immunotherapy ipilimumab plus nivolumab (IPI+NIVO) when combined with Delcath's proprietary liver-targeted PHP treatment in metastatic uveal melanoma patients. The poster presented initial safety and efficacy results from the Phase 1b portion of the trial which enrolled seven patients who were treated with two courses of six-weekly PHPs (melphalan 3mg/kg, max 220mg) combined with four courses IPI+NIVO three-weekly escalating the dosing from 1mg/kg each IPI+NIVO (cohort 1) to IPI 1mg/kg + NIVO 3mg/kg (cohort 2). The poster reports a Best Overall Response of 1 complete response, 5 partial responses and 1 stable disease accounting for an Objective Response Rate of 85.7%. At a median follow up time of 20.2 months, 4 patients have an ongoing response. Currently the median progression free survival is 22.4 months, and all patients are still alive.

"Initial CHOPIN data suggests that combining Delcath's proprietary PHP liver targeted therapy with systemic immunotherapy is tolerated and can potentially achieve promising overall disease control rates in patients that otherwise would have limited treatment options. Uveal melanoma predominantly metastasizes to the liver and to date, the efficacy of immunotherapy in achieving meaningful disease control rates in this setting has been limited," said Johnny John, MD Delcath's Senior Vice President of Clinical Development and Medical Affairs. "We are excited by the results of the Phase 1b portion of the study and look

forward to the additional study of this this combination therapy to address both hepatic and extra hepatic lesions and meaningfully alter the course of this disease.”

Updated FOCUS Trial Results

Updated efficacy and safety results from the single-arm phase 3 FOCUS trial in metastatic uveal melanoma including Overall Response Rate (ORR), median Duration of Response (mDOR), Disease Control Rate (DCR), median Progression Free Survival (mPFS) and Overall Survival (OS) data were presented that were largely consistent with prior presentations. In addition, predefined exploratory analyses comparing PHP to a Best-Alternative-Care (BAC) arm enrolled prior to the trial’s protocol amendment to a single-arm study were included.

Updated values reflect the latest data from clinical sites. OS data continues to mature with a final, predefined analysis expected in May 2023, two years after the study’s last treatment. As of last analysis the FOCUS trial results are as follows:

- A 36.3% ORR in the Treated Population, including 8% Complete Responses (CR) with a mDOR of 14 months. A DCR of 73.6%, a median PFS of 9.03 months and a median OS of 19.25 months.
- PHP analyses against the BAC arm yielded statistically significant ($p<0.05$) results on ORR (36.3% vs. 12.5%), DCR (73.6% vs. 37.5%) and mPFS (9.03 months vs. 3.12).
- While OS data continues to mature, as of the last analysis, the median OS for the PHP arm is 19.25 months vs. 14.49 months for BAC (HR=0.70, p=0.14). Final analysis expected in 2023.

Retrospective Quality of Life Analysis

This abstract reported on a retrospective analysis in the change of Quality of Life (QoL) using the Functional Assessment of Cancer Therapy – General scores for 13 PHP treated patients at the University of Southampton. The analysis found no significant difference in QoL score on discharge post procedure versus baseline (prior to treatment) and noted a trend for overall improved QoL on day 28 from baseline.

Additional details about these three PHP-related ASCO presentations can be found below:

Title: Safety and efficacy of combined melphalan percutaneous hepatic perfusion (M-PHP) and ipilimumab plus nivolumab (IPI+NIVO) in metastasized uveal melanoma: First results of the phase Ib part of the CHOPIN trial.
Session Title: Melanoma/Skin Cancers
Session Date and Time: June 6, 2022, 1:15-4:15 PM CDT (Display)

Abstract Number: 9560
Presenter: Thaïs M.L. Tong Leiden University Medical Center, Department of Medical Oncology/Radiology, Leiden, Netherlands

Title: FOCUS Phase 3 Trial Results: Percutaneous Hepatic Perfusion (PHP) With Melphalan for Patients With Ocular Melanoma Liver Metastases (PHP-OCM-301/301A)
Session Title: Melanoma/Skin Cancers
Session Date and Time: June 6, 2022, 1:15-4:15 PM CDT (Display) and 4:30-6:30 PM CDT (Discussion)
Abstract Number: 9510
Presenter: Dr. Jonathan Zager, Director of Regional Therapies and Chief Academic Officer, Moffitt Cancer Center; Professor and Chair, Department of Oncologic Sciences, USF Morsani School of Medicine.

The Poster will be available at **https://delcath.com/investors/events-presentations/.**

Title: Temporal evolution in quality-of-life following melphalan percutaneous hepatic perfusion for patients with metastatic uveal melanoma.
Session Title: Melanoma/Skin Cancers
Abstract Number: e21520
Presenter: Ganesh Vigneswaran University of Southampton, Southampton, United Kingdom

Visit the ASCO Annual Meeting **website** for further information regarding the conference.

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.

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