Delcath Systems, Inc. Announces Positive Phase 3 FOCUS Trial Results for Hepzato™ in Liver-Dominant Metastatic Ocular Melanoma, Including Initial Survival Data Analysis

On final analysis of the primary overall response (ORR) endpoint, HEPZATO further exceeded the predefined threshold for success with a median duration of response of 14 months

While overall survival data continues to mature, a Hazard Ratio (HR) analysis of survival at 12-months yielded a statistically significant advantage for HEPZATO over a Best Alternative Care (BAC) arm [HR=0.37, p=0.01] in patients who received one or more treatments

HEPZATO had statistically significant improvements over BAC in predefined exploratory analyses on ORR, DCR and PFS

NDA resubmission for HEPZATO expected by mid-2022

NEW YORK, Dec. 02, 2021 — Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced positive results from the phase 3 FOCUS study. The FOCUS study's intent-to-treat (ITT) population was comprised of a total of 102 subjects, across various lines of therapy. Of the ITT group, 91 evaluable patients were administered at least one study treatment.

Treatment with HEPZATO in the ITT analysis resulted in an objective-response-rate (ORR) of 31.4% [95% CI: 22.55-41.31], including 6.9% of patients with a complete response (CR). Median duration of response was 14 months [95% CI: 8.54, NC], with over half of responders continuing to be monitored for progression events. Disease control rate (DCR) was 65.7% [95% CI, 55.63, 74.81].

On the primary ORR endpoint, the lower bound 95% Confidence Interval (CI) of 22.55% exceeded the FOCUS trial's prespecified 8.3% upper bound 95% CI threshold for success. This threshold was derived from a meta-analysis of sixteen checkpoint inhibitor publications documenting the treatment of 476 metastatic ocular melanoma patients.

Supportive, predefined, exploratory analyses were conducted comparing patients in the HEPZATO arm versus a BAC group. The BAC arm was comprised of a total of 42 patients, originally randomized in the FOCUS trial prior to its amendment, in consultation with FDA, to a single-arm pivotal study in 2018. The evaluable BAC subjects were treated predominantly with liver-targeted Transarterial Chemoembolization (TACE).

Among patients who received at least one study treatment, patients in the HEPZATO arm had

statistically significant improvements over BAC in the following prespecified endpoints:

- ORR of 35.2% versus 12.5% for the BAC arm (p=0.0154).
- Disease Control Rate of 73.6% versus 37.5% for patients in the BAC arm (p=0.0002).
- Median Progression Free Survival of 9.03 months versus 3.12 months for the BAC arm (HR=0.39; p=0.0002).

Enrollment in the FOCUS trial HEPZATO arm ended in late 2020 with overall survival data continuing to mature. Per the statistical plan, a final predefined exploratory survival analysis, versus BAC, will be conducted at 24-months after last patient last treatment.

As of this analysis, survival at 12-months in the evaluable patients was 75% in the HEPZATO arm versus 47% for BAC [HR=0.37, p=0.01]. Delcath will provide future overall survival analysis updates, as patient follow-up continues, and the Kaplan-Meier analysis matures.

In the HEPZATO safety population, the most commonly reported treatment-emergent serious adverse events were anemia (29.7% of patients), thrombocytopenia (26.4% of patients) and neutropenia (19.8% of patients), which were well-manageable. 5.3% of patients experienced treatment-emergent serious cardiac adverse events. In all cases the events resolved with no ongoing complications. There were no treatment-related deaths in the trial.

“Metastatic ocular melanoma is a disease with a dismal prognosis and new therapies are urgently needed. The FOCUS study results, along with the predefined analyses versus a relevant BAC group, clarify HEPZATO overall clinical benefit in this difficult-to-treat patient population,” noted Dr. Jonathan Zager MD FACS, global lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center. “The overall efficacy, coupled with an improved safety profile versus the first-generation product, suggests that HEPZATO would offer a compelling clinical benefit were it approved by FDA.”

“We are thrilled by the HEPZATO response rates and duration of response which far exceed that which has been seen with other agents in this difficult-to-treat patient population. Our data further highlights HEPZATO’s potential superiority to other available liver-targeted therapies, which suggests a broader utility for our platform across multiple liver-metastatic tumor types. In addition to re-filing our NDA by mid-2022, Delcath, along with key opinion leaders, intend to study HEPZATO in additional indications in the near future.”

The FOCUS trial results will be presented at a comprehensive Investor Update Meeting taking place today from 10:00am EST – 1:30pm EST. In addition to the FOCUS trial, a distinguished panel of physicians will discuss their personal clinical experience with HEPZATO in both the clinical trial setting and the commercial setting in Europe, as well as the potential for

HEPZATO to treat liver metastatic tumor types beyond metastatic ocular melanoma.

Event Details:

Event: Delcath Systems Virtual Investor Update Meeting
Date: Thursday, December 2, 2021
Time: 10:00am – 1:30 p.m. EST

To register for this event, please click **here**.

The live webcast of the event may be accessed through the **Events and Presentation** page of Delcath's website, under the Investors section. The archived webcast and presentation will be available on the Company's website after the event.

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, 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 IIb 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.

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: the timing and results of the Company's clinical trials, including without limitation the mOM and ICC clinical trial programs, as well as the receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial 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; approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure; the impact, if any, of ZE reimbursement on potential CHEMOSAT product use and sales in Germany; clinical

adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK; the Company's ability to successfully commercialize the HEPZATO KIT/CHEMOSAT system 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 the CHEMOSAT system in various markets; approval of the current or future HEPZATO KIT/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets; actions by the FDA or foreign regulatory agencies; the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets 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:

Delcath Investor Relations

Email: **investorrelations@delcath.com**

Hayden IR

James Carbonara
(646)-755-7412
james@haydenir.com