Positive Preliminary Results from Delcath Systems' FOCUS Trial Presented at the 2021 ASCO Annual Meeting

As Previously Disclosed, the Prespecified Primary Endpoint, Objective Response Rate, Has Been Met by Exceeding the 95% CI Lower Bound Threshold for Success

Newly Disclosed Patient Level Data Demonstrates a 44% Best Overall Response for the HEPZATO Arm Versus 17% for the Best Alternative Care Arm

Company Q&A Webinar Today at 8:30am ET

NEW YORK, June 07, 2021 — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced an oral presentation of positive preliminary efficacy results from its FOCUS Phase III trial of HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM) at the American Society of Clinical Oncology (ASCO) Annual Meeting being held virtually June 4-8, 2021.

The oral presentation by Dr. Jonathan Zager, Director of Regional Therapies and Chief Academic Officer, Moffitt Cancer Center; Professor and Chair, Department of Oncologic Sciences, USF Morsani College of Medicine, presented previously announced preliminary data based on 79 of 91 treated HEPZATO patients. Patient level response data were also presented for this same patient set, indicating that 44% of evaluable patients in the HEPZATO arm had a 30% or greater reduction in target tumor lesions at one or more time points versus 17% for patients enrolled in the Best Alternative Care arm. Dr. Sapna Patel, Associate Professor and Uveal Melanoma Program Director, Department of Melanoma Medical Oncology, MD Anderson Cancer Center, the discussant for the session, provided valuable perspective regarding both the efficacy and safety preliminary results.

Delcath CEO Gerard Michel stated, "The oral presentation by Dr. Zager covered previously announced preliminary data showing an overall response rate of 29.2% with a 95% confidence interval lower bound of 20%. Given the magnitude by which the lower bound exceeds the 8.3% prespecified threshold for success, we can confidently state the primary endpoint has been met regardless of the outcome of patients who have not yet been evaluated."

Mr. Michel added, "Importantly, the 44% Best Overall Response, combined with the previously disclosed statistically significant improvement over Best Alternative Care in Progression Free Survival and Disease Control Rate, further strengthens the case that HEPZATO would offer a compelling clinical benefit to patients were it approved by FDA."

The material presented at ASCO, as well as additional data from the preliminary analysis of the FOCUS trial, is available on the Company's website.

Q&A Webinar

The company invites investors to join a Q&A webinar today at 8:30am ET, hosted by Gerard Michel, CEO. Mr. Michel will review the company and its strategy, as well as discuss these positive preliminary results from its Phase 3 FOCUS Trial of HEPZATO in patients with metastatic ocular melanoma. Management will also provide answers on the live call to any questions submitted by attendees. Participants will be able to listen to the webinar and submit questions via the “ask a question” tab, during the live event or can email questions to **investorrelations@delcath.com** before the event. To participate in this event, connect approximately 5 to 10 minutes before the beginning of the call.

Webinar Link: **https://www.webcaster4.com/Webcast/Page/2475/41223**

To Join By Phone:
Toll Free: 888-506-0062
International: 973-528-0011
Conference Entry Code: 815206

About Delcath Systems, Inc., HEPZATO and CHEMOSAT

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. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

About the FOCUS Trial and the Preliminary Analysis

HEPZATO is being studied in the FOCUS trial which is a single-arm, multi-center, open-label trial to treat patients with hepatic-dominant metastatic ocular melanoma (mOM). The FOCUS Trial is being conducted at approximately 30 sites in the United States and Europe. The primary endpoint of the FOCUS Trial is Objective Response Rate (ORR) as measured by RECISTv1.1, in the Intent to Treat (ITT) population. The single arm trial was powered 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 which included 476 patients. The pooled overall response rate was 5.5% [95% CI: 3.6, 8.3]. To achieve statistical significance at a 95% Confidence Interval the lower bound of the ORR for HEPZATO is required to exceed the 8.3% upper bound of the meta-analysis.

Secondary endpoints include Duration of Response (DOR), Disease Control Rate (DCR), Overall Survival (OS), and Progression-Free Survival (PFS). Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety, and other pharmacokinetic measures. Initially, the trial was a randomized controlled trial which was amended to a single arm trial given slow enrollment due to the rarity of ocular melanoma, absence of crossover to the experimental trial arm, competing clinical trials and the commercial availability of CHEMOSAT in Europe. Included in the prespecified analyses are comparisons against the Best Alternative Care (BAC) arm which enrolled 32 patients prior to the amendment to a single-arm trial.

On March 31, 2021 Delcath released a preliminary analysis of the FOCUS trial data using prespecified analyses based on a data cut on March 12, 2021 which included 87% of treated patients. An Independent Review Committee assessed an ORR of 29.2% [95% CI: 20.1, 39.8] in the ITT population, the lower bound of which exceeded the upper bound of the predefined success criteria (8.3%) for the primary ORR endpoint. In the per protocol populations, evaluable patients in the HEPZATO arm had a statistically significant improvement over BAC in prespecified endpoints including: ORR of 32.9% [95% CI: 22.8, 44.4] versus 13.8% [CI: 3.9, 31.7] for the BAC arm (Chi-square $P<0.05$), Median PFS of 9.0 months [95% CI: 6.2, 11.8] versus 3.1 months ([95% CI: 2.7, 5.7] for the BAC arm (HR=0.41 $p<0.001$), and DCR of 70.9% [95% CI: 59.6, 80.6] versus 37.9% [95% CI: 20.7, 57.7] for the BAC arm ($p<0.002$). In this preliminary analysis, DOR and OS were not yet evaluable. Since not all patients were evaluable for all time points, these preliminary analyses may change as data matures.

In the HEPZATO safety population of 94 patients, 38 patients (40.4%) experienced a treatment-emergent serious adverse event. The most commonly reported treatment-emergent serious adverse events were thrombocytopenia (14.9% of patients), neutropenia (10.6% of patients), and leukopenia (4.2% of patients), which were well-manageable. 5% 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.

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.

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Concentrating the Power of Chemotherapy™