Delcath Systems, Inc. Announces Positive Preliminary Results from Phase 3 FOCUS Trial of HEPZATO in Patients with Metastatic Ocular Melanoma

Based on Preliminary Data, FOCUS Trial Achieves Prespecified Success Threshold

Conference Call Today at 8:00am Eastern Time

NEW YORK, March 31, 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 top-line preliminary results from the company's Phase 3 FOCUS trial of HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM).

Based on the preliminary analysis of 87% of enrolled patients using prespecified analyses the Independent Review Committee (IRC) assessed Overall Response Rate (ORR) of 29.2% [95% Confidence Interval (CI): 20.1, 39.8] in the Intent to Treat (ITT) population which exceeded the predefined success criteria (21.0%) for the primary ORR endpoint.

Based on predefined exploratory analyses, evaluable patients in the HEPZATO arm had a statistically significant improvement over Best Alternative Care (BAC) in the following prespecified endpoints:

- ORR of 32.9% [95% CI: 22.8, 44.4] versus 13.8% [95% CI: 3.9, 31.7] for the BAC arm (Chi-square $P<0.05$).
- Median Progression Free Survival 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; $p<0.001$).
- Disease Control Rate of 70.9% [95% CI: 59.6, 80.6] versus 37.9% [95% CI: 20.7, 57.7] for patients in the BAC arm ($p<0.002$).

Duration of Response and Overall Survival are not yet evaluable. Since not all patients were evaluable for all time points, these preliminary analyses may change as data matures.

The safety profile in this trial was consistent with the safety profile of PHP treatment described in European single-center and multi-center publications with no new safety signals observed in this patient population. 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.

“Metastatic ocular melanoma is a disease with a dismal prognosis and new therapies are urgently needed,” noted Dr. Jonathan Zager MD FACS, lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center. “The strength of these preliminary efficacy data, including progression free survival and overall response rates, 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.”

“While the analysis is preliminary and the trial is still ongoing, these results strongly suggest that the final FOCUS dataset will demonstrate a significantly improved benefit-risk profile compared with BAC that could form the basis of our NDA resubmission to the FDA,” said Gerard Michel, CEO of Delcath. “We look forward to reporting additional results later in the year as the data matures.”

About the FOCUS Trial and the Preliminary Analysis

These preliminary results are based on a data cut on March 12, 2021 and include 79 treated HEPZATO patients for whom there are at least 2 imaging timepoints from which to evaluate response or were censored after the first scan due to progression or death. 11 additional patients were treated but are not yet evaluable in the HEPZATO arm. Another 11 patients were enrolled in the HEPZATO arm and not treated. 29 of 32 treated BAC patients were available for analysis. 10 patients were enrolled in the BAC arm and not treated. Data are expected to continue to evolve as additional patients and time points become evaluable.

The FOCUS trial is intended to evaluate the efficacy of HEPZATO treatment for patients with mOM with the primary endpoint of ORR as assessed by an IRC per RECIST v1.1. Per protocol, patients were to be treated every 6 weeks to 8 weeks until the earlier of 6 cycles or progression. Tumor responses were to be assessed every 12 weeks (+/- 2 weeks) until progression.

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 and 476 patients. Based on those assumptions a 21.0% ORR was required to demonstrate superiority over the checkpoint inhibitors at a 95% confidence interval.

The single arm trial was initially designed and conducted as a randomized controlled study with a BAC comparator arm before being amended to a single arm trial. While the modified trial was not powered to test superiority versus BAC, comparative analyses against the BAC arm were included in the revised statistical analysis plan

Conference Call Information

Dr. Jonathan Zager MD FACS, lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center will join the Delcath management team during today's conference call.

Date: March 31, 2021
Time: 8:00 AM Eastern Time
Toll Free: 877-407-8035
International: 201-689-8035

The call will also be available over the Internet and accessible at:
https://www.webcaster4.com/Webcast/Page/2475/40544

About HEPZATO™ KIT and CHEMOSAT®

The HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO™, is a drug/device combination product. HEPZATO is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our commercial product is a stand-alone 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. In the United States, HEPZATO is considered a combination drug and device product regulated by the United States Food and Drug Administration, or the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the hepatocellular carcinoma indication). HEPZATO has not been approved for sale in the United States.

In Europe, CHEMOSAT is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing CHEMOSAT in select markets in the United Kingdom and the European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

About Metastatic Ocular Melanoma

Approximately 5,000-6,200 cases of ocular melanoma are diagnosed in the United States and Europe annually, and approximately 50% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is

generally 3.9 months (untreated) to 6.3 months (treated). There is no one standard of care for patients with ocular melanoma liver metastases. Based on 2018 research, an estimated 2,500-3,100 patients with ocular melanoma liver metastases in the United States, the United Kingdom and the EU may be eligible for treatment with HEPZATO annually.

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S.

In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and 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.

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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