Delcath Systems, Inc. Announces Revised NICE Guidance for CHEMOSAT in the United Kingdom

Recommends Special Arrangement Designation Which Increases Reimbursement Options

NEW YORK, April 21, 2021 — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced that the United Kingdom's (UK) National Institute for Health and Care Excellence (NICE), through the Interventional Procedures Advisory Committee, has updated its guidance for the Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) in the treatment of patients with metastases in the liver from Ocular Melanoma.

Previously, the NICE guidance recommended CHEMOSAT only be used in the context of formal research studies. Due to that guidance, both private insurance and regional funding were generally not available for treatments with CHEMOSAT, nor was it possible to apply for national coverage. Under the revised NICE guidance, CHEMOSAT has been categorized under a Special Arrangement designation. Under this designation, private insurance may be more likely to fund treatment with CHEMOSAT, some regional funding may be more accessible, and a process is now available to seek national reimbursement.

The revised guidance which formed the basis in the designation change can be found at https://www.nice.org.uk/guidance/ipg691.

"We welcome this Special Arrangements designation from NICE for the treatment of patients with metastases in the liver from ocular melanoma and the recommendations within the final guidance. We look forward to working with specialist treatment centers to increase the availability of this treatment to patients with metastases in the liver from ocular melanoma in the UK" said Gerard Michel, CEO of Delcath. "This change in designation, combined with the recently announced positive preliminary results from the FOCUS trial, is further evidence of the potential value of the HEPZATO and CHEMOSAT platform to patients worldwide suffering from metastatic ocular melanoma."

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, the 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 (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. Delcath is commercializing CHEMOSAT in select markets in the European Union (EU), where the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

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 based on 87% of enrolled patients using prespecified analyses. 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.

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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