# Delcath Systems, Inc. Announces FDA Acceptance of New Drug Application Resubmission of Hepzato Kit with a PDUFA Date of August 14, 2023

NEW YORK, March 27, 2023 — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced that the US Food and Drug Administration (FDA) has accepted Delcath Systems, Inc.'s (Delcath) new drug application resubmission for HEPZATO™ Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). The FDA also communicated to Delcath that they consider the submission a complete class 2 response and the PDUFA date for the resubmission is August 14, 2023.

"The FDA's acceptance of the NDA resubmission is a significant milestone for Delcath and we look forward to working with the agency throughout its review of the application," stated Gerard Michel, Delcath's Chief Executive Officer. "We believe that HEPZATO, if approved, will be an important option for treating patients with mOM."

## About the HEPZATO Kit

The HEPZATO Kit is a drug-device combination product comprised of the drug (melphalan) and device (HDS) constituent parts. Melphalan is a well-established, broadly effective anticancer chemotherapeutic agent belonging to the alkylating class and is responsible for the combination product's primary mode of action. The procedure of surgical isolation and simultaneous filtration of hepatic venous blood during drug infusion and washout, known as percutaneous hepatic perfusion, or PHP, results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure relative to the comparable intravenous (IV) dose.

In the U.S., the efficacy and safety of Hepzato Kit have not been established for any indication and it is not presently approved by the FDA.

## 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 products, HEPZATO™ KIT (melphalan hydrochloride for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP) are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO is considered an investigational drug/device combination product regulated as a drug by the United States Food and Drug Administration (FDA). HEPZATO is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to surgically isolate the liver while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. In the US, HEPZATO was the subject of a February 14, 2023 new drug application resubmission to FDA for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM). In Europe, the device-only configuration of the HDS is 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 in the conduct of percutaneous hepatic perfusion procedures 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: actions by the FDA relating to the application; the likelihood and timing of the FDA's potential approval of the NDA for HEZPATO by the FDA by the PDUFA date of August 14, 2023; the ability of the Company to respond to FDA queries related to the application; the Company's successful inspections by the FDA or foreign regulatory agencies; the timing and results of the Company's clinical trials, our determination whether to continue a clinical trial program or to focus on other alternative indications, 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; the Company's ability to successfully commercialize the HEPZATO 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 commercialized product in various markets; the Company's ability to successfully enter into strategic partnership and distribution arrangements 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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