Delcath Announces Rotation of the Board of Directors Chairmanship; John R. Sylvester Appointed New Chairman as Company Prepares for US Commercial Launch

February 16, 2023

NEW YORK, Feb. 16, 2023 /PRNewswire/ -- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announced that its Board of Directors has voted to appoint John R. Sylvester as Delcath's new Chairman. Mr. Sylvester has served as a Director of Delcath since July 2019 and has extensive experience building interventional oncology businesses, most recently serving as Chief Executive Officer of both Curium's SPECT and International business units. In addition, Mr. Sylvester served as BTG plc's Chief Commercial Officer, leading both their Interventional Oncology and Interventional Vascular businesses, as well as BTG's Chief Development Officer accountable for Strategy, M&A and Market access. His role at BTG culminated with Boston Scientific's 2019 purchase of BTG for $4.2 billion. Mr. Sylvester also built Biocompatibles International plc's Interventional Oncology business, which BTG purchased for £166.0 million in 2010.

Dr. Roger Stoll, who has served as Delcath's Chairman since October 2015 and has been a Delcath Director since December 2008, will continue to serve as an active member of Delcath's Board of Directors and Committees. "I look forward to my continued service as a Director at Delcath. Given John's strong commercial background in developing new markets, he is ideally suited to take the Board leadership role at this time," said Dr. Stoll.

Gerard Michel, Delcath's CEO stated, "We thank Roger for his many years of guidance and leadership as the Company worked to secure approval for HEPZATO Kit, and will value his continued contribution as an active member of the Board. I look forward to partnering with John in his new role and know that the Company will greatly benefit from his extensive experience in commercializing innovative interventional oncology products, as we prepare for launch in the US."

Mr. Sylvester stated, "I also want to thank Roger for his leadership during the conduct of the FOCUS trial and the writing and resubmission of the HEPZATO Kit NDA. The HEPZATO Kit is a truly unique interventional oncology product which, if approved, will offer unique advantages to healthcare professionals and patients and I look forward to guiding the Company through its planned growth."

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, the HEPZATO Kit is considered an investigational drug/device combination product regulated as a drug by the United States Food and Drug Administration (FDA). HEPZATO Kit 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 Kit 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 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 Kit 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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