Delcath Systems Announces Resumption of Interest-Only Period for Company's Debt Facility

April 3, 2023

Amendment with Avenue Venture Opportunities Fund, L.P. provides for an interest-only period from March 31, 2023 to September 30, 2023 and defers $4.3 million in principal payments

NEW YORK, April 3, 2023 /PRNewswire/ -- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced it reached an agreement to amend its existing loan agreement with Avenue Venture Opportunities Fund, L.P. ("Avenue").

Avenue agreed to provide an interest-only ("I/O") period from March 31, 2023 to September 30, 2023. The I/O period defers approximately $4.3 million in principal payments to beyond September 30, 2023. The I/O period may be extended at Delcath's option to December 31, 2023 if, by September 30, 2023, Delcath has (a) received FDA approval for the HEPZATO Kit and (b) received net proceeds of at least $10 million from the sale and issuance of equity securities or exercise of existing warrants. In exchange for this extension, Delcath has agreed to provide Avenue 34,025 warrants to purchase shares of common stock. The exercise price of the warrants is $0.01.

"We appreciate the ongoing support of Avenue in resuming the interest-only period to help us preserve near-term cash," said Gerard Michel, Chief Executive Officer of Delcath. "This amendment in combination with the recent equity financing, extends our cash runway well beyond our August 14th PDUFA date for HEPZATO Kit."

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 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). FDA has established an August 14, 2023 PDUFA date for the resubmission. In Europe, the device-only configuration of the HDS is regulated as a Class III 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 in particular, the statements regarding our private placement and expected gross proceeds and the expected uses of the proceeds from the private placement. Factors that may cause such differences include, but are not limited to, uncertainties relating to: anticipated use of proceeds from the private placement, achievement of milestones, the likelihood and timing of the potential approval of HEPZATO by the FDA by the PDUFA date of August 14, 2023, the Company's ability to commercialize HEPZATO, the receipt of stockholder approval to allow for the conversion of the Series F Preferred Stock into shares of the Company's common stock and the exercisability of the warrants; the sufficiency of the aggregate proceeds from the financing to fund commercialization of HEPZATO in the U.S., the Company's ability to generate revenue from HEPZATO, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in; 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; 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; 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 SEC. 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.

Investor Relations Contact:
Ben Shamsian
Lytham Partners
646-829-9701

View original content to download multimedia:https://www.prnewswire.com/news-releases/delcath-systems-announces-resumption-of-interest-only-period-for-companys-debt-facility-301788806.html

SOURCE Delcath Systems, Inc.