

Delcath Systems Achieves Medical Device Regulation Certification for CHEMOSAT® in Europe

NEW YORK, March 02, 2022 — Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, is pleased to announce that on February 28 its CHEMOSAT Hepatic Delivery System received Medical Device Regulation (MDR) certification under the new European Medical Devices Regulation [2017/745/EU]. Since April 2012, Chemosat had been certified under a previous regulation, the Medical Device Directive [2007/47/EC] (MDD), which is being replaced by MDR.

Achieving MDR certification entails a detailed evaluation from a designated EU Notified Body, including an audit of quality systems and a review of documentation supporting safety and performance claims for the device. MDR greatly expands upon existing MDD requirements including the level of clinical evidence supporting claims, post-marketing surveillance, database traceability, unique device identification (UDI) and increased supply chain oversight. Under MDR, CHEMOSAT's designation has changed from a Class IIb to a Class III medical device.

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 percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, for the treatment of metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM) and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is now 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 at major medical centers to treat a wide range of cancers of the liver.

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