



## Delcath Announces Health Authority Approval for CHEMOSAT in Brazil

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### Discussions Underway With Potential Commercialization Partners

NEW YORK, Feb. 11, 2019 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, announces that the Company has received medical device approval for the CHEMOSAT<sup>®</sup> Hepatic Delivery System (CHEMOSAT) from the national health authority in Brazil. The approval of CHEMOSAT as a Class 3 medical device was issued by the Agência Nacional de Vigilância Sanitária (ANVISA), and permits the marketing and utilization of CHEMOSAT under the same percutaneous intra-arterial administration of melphalan hydrochloride to the liver with subsequent extracorporeal filtration of blood indication, as in Europe.

To develop Brazilian market access for CHEMOSAT, Delcath intends to align with a local strategic partner. The Company is already in discussion with several potential candidates with the aim of securing a partnership for the Brazilian market in the first half of 2019, and the intent of commencing revenue generation from that partnership by the end of the year. The Company also intends to expand with partners more broadly across Latin America.

"According to the World Health Organization, liver and bile duct cancers account for over 10,000 deaths in Brazil annually," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "With a population of approximately 200 million, we believe there is a significant unmet medical need in Brazil for CHEMOSAT in both primary and metastatic liver cancers.

"Obtaining approval from ANVISA also provides Delcath with a starting point from which the company can launch other sales channels in the Latin American region," Dr. Simpson concluded.

### About Delcath Systems

Delcath Systems, Inc. is an interventional oncology Company focused on the treatment of primary and metastatic liver cancers. Our investigational product – Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) – is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. We have been enrolling a global Registration clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) called The FOCUS Trial and have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called The ALIGN Trial. Melphalan/HDS 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 Hepatic CHEMOSAT<sup>®</sup> Delivery System for Melphalan (CHEMOSAT) and has been used at major medical centers to treat a wide range of cancers of the liver. Since January 2019 CHEMOSAT is marketed under an exclusive licensing agreement with medac, a privately held multi-national pharmaceutical company headquartered in Germany and specializing in the treatment and diagnosis of oncological, urological and autoimmune diseases.

### Forward Looking Statements

*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: successful completion of the Company's Rights Offering and related transactions and the amount of gross proceeds, if any; the timing and results of the Company's clinical trials including without limitation the OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM and ICC clinical trials, IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial, 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 Melphalan HDS/CHEMOSAT system and the potential of the Melphalan HDS/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 Melphalan HDS/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 other 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.*

### Contact:

Delcath Investor Relations

Email: [investorrelations@delcath.com](mailto:investorrelations@delcath.com)

Delcath Systems, Inc.