

## **Delcath Announces Commercial Licensing Agreement for CHEMOSAT®**

### **7 Year Agreement with medac to Maximize Potential of CHEMOSAT in Europe**

### **Upfront and Milestone Payments Provide Additional Resources to Advance Clinical Development in the U.S.**

NEW YORK, Dec. 26, 2018 — Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the company has entered into a definitive licensing agreement for CHEMOSAT® commercialization in Europe with medac Gesellschaft für klinische Spezialpräparate mbH (medac), a privately held, multi-national pharmaceutical company based in Hamburg area, Germany. Founded in 1970, medac specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases. The company has offices globally, worldwide partner agreements in over 90 countries, and approximately 1,200 employees.

Under the terms of the seven-year agreement, Delcath's European subsidiary, Delcath Systems, Ltd. exclusively licenses medac to sell and market CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland, and the United Kingdom. medac will pay Delcath €6,000,000 in a combination of upfront and success-based milestone payments. Additionally, Delcath will receive a fixed transfer price per unit of CHEMOSAT as well as royalties. The agreement has a projected value of up to \$45 million over the first seven-year term and includes an optional five-year extension.

"With offices throughout Europe and a well-established network among oncology key opinion leaders, medac is a well-suited partner to help advance CHEMOSAT commercialization in the European Union and neighboring countries," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "medac provides the organizational scale, expertise and market reach necessary to help us strive to firmly establish CHEMOSAT in the European treatment landscape for cancers of the liver. Additionally, through this agreement, we obtain immediate resources to support our efforts to advance our clinical development program. This is a highly significant development for Delcath, and we are pleased to be working with a market leader like medac to help this therapy fully realize its potential."

Heiner Will, Chief Marketing Officer of medac, said, "We are excited to build upon the growing customer and revenue base that Delcath has built in Europe to provide patients with liver metastases a promising treatment modality. We are convinced by the assessment of European clinicians about the very meaningful impact CHEMOSAT has on the quality of life of these patients who, because of the safety profile of CHEMOSAT can receive multiple treatments." This substantial new business opportunity strengthens and expands medac's expertise in the treatment of cancer. medac is currently working diligently with Delcath

launching commercial efforts in Europe in January 2019.

## **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 has been commercially available since 2012 under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT), where it has been used at major medical centers to treat a wide range of cancers of the liver.

## **About medac**

medac Gesellschaft für klinische Spezialpräparate mbH is a privately held pharmaceutical company with a growing pharmaceutical and diagnostics business. Established in the Hamburg area, medac provides a range of high-quality basic and speciality therapeutics within oncology and haematology, autoimmune diseases and urology. Approximately 1,200 employees work together in development, manufacturing and commercialization of pharmaceutical drugs. This makes medac products available in more than 90 countries.

## **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: 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.*

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