Delcath Completes Enrollment in its United States Registration Pivotal Trial (FOCUS) Investigating Melphalan/HDS in the Treatment of Patients with Unresectable Hepatic-Dominant Ocular Melanoma

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FOCUS Top-line Results Expected Mid-2020

NEW YORK, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTH), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, today announced it has completed patient enrollment in its FOCUS registration trial intended to confirm the potential of its investigational combination treatment for patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). A total of 80 patients have been enrolled in the trial.

Delcath expects to announce top-line results of the FOCUS trial by the middle of 2020.

Because of a lack of effective treatments for patients with unresectable hepatic-dominant ocular melanoma, Delcath will continue to enroll eligible patients in the trial until Delcath determines the feasibility of an Expanded Access Program (EAP) and subsequent commercial availability.

Melphalan/HDS (melphalan hydrochloride for injection for use with the Delcath hepatic delivery system) is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects via filtration of the chemotherapeutic agent from the blood.

"We are pleased to have reached the minimum endpoint target enrollment in the FOCUS trial and we expect to announce top-line results around the middle of this year, commented Jennifer Simpson, PhD., M.S.N., C.R.N.P. - President & Chief Executive Officer. “Delcath is fully committed to advancing its clinical development program and working with the FDA to bring this significant therapy to metastatic ocular melanoma patients in the United States market.”

Dr. Simpson continued, “We believe Melphalan/HDS has the potential to be an essential therapy in the treatment of mOM, which is an orphan disease and area of unmet medical need.”

About the FOCUS Trial

FOCUS is an open label, single-arm, multicenter (United States and Europe) study in a minimum of 80 patients with metastatic ocular melanoma. The primary endpoint is overall response rate defined as the proportion of patients with a best overall response of a confirmed complete response or partial response (CR+PR) determined by Independent Central Review Committee. Secondary endpoints are duration of response, disease control rate, overall survival and progression free survival, each as determined by Independent Central Review Committee. All patients are followed for survival status until death.

About Delcath System, Inc.

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 minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial, we 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® Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

Safe Harbor / 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: the timing and results of the Company's clinical trials, including without limitation the OM and ICC clinical trial programs, and 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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