Delcath Joins the Ocular Melanoma Community in Recognizing Rare Disease Day

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NEW YORK, Feb. 28, 2019 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, highlights the experiences of patients with ocular melanoma as part of *Rare Disease Day*® — a global awareness campaign observed each year on February 28th. Delcath sponsors a global Registration clinical trial for Patients with Hepatic Dominant Ocular Melanoma called The FOCUS Trial.

"Rare Disease Day is an opportunity for the global healthcare community to recognize the unmet medical needs among patients suffering from orphan diseases," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "Approximately 4,500 patients in the U.S. and Europe are diagnosed with ocular melanoma each year. For patients, it's a diagnosis that seems to come out of nowhere which often carries devastating consequences. We are committed to improving the prognosis and changing the treatment paradigm for these patients."

To highlight the experiences of ocular melanoma, Delcath profiled two patients treated with PHP® Therapy for liver metastases from ocular melanoma.

Reverend Gary Desalvo – Pastor, Temple Bible Church, Temple, TX
Reverend Desalvo was diagnosed with ocular melanoma in 2013 when he had blurry vision evaluated by his family ophthalmologist. The diagnosis was the first he had heard of the disease, and his case was the first seen by physicians in the practice. The implications of the diagnosis were immediately apparent: removal of the eye followed by a high risk of potentially fatal liver metastases. Fortunately Reverend Desalvo's congregation immediately rallied around him and his family with fellowship, offering prayer, support and research assistance. Through these efforts, clinical trials at some of the leading cancer hospitals in the country were found, so that when Reverend Desalvo was diagnosed with liver metastases in 2017 he was familiar with his options. "I already had PHP Therapy on my radar by the time the liver mets were discovered, so I enrolled in the FOCUS trial under its previous randomized protocol. I was randomized to the control arm, so instead I sought treatment with PHP in England at SPIRE Southampton Hospital. The team there was wonderful, and I tolerated my four cycles of PHP very well. I am happy to say that with the grace of God my liver mets are now controlled and I am able to seek additional therapy for my extra-hepatic disease. I believe that PHP has given me time I would not otherwise have."

Sabrina Frey – Mother of Four, Madison, WI
Sabrina Frey was also diagnosed with ocular melanoma in 2013 when she had a detached retina evaluated. Though familiar with the disease from a previous experience with cutaneous melanoma, the diagnosis and its implications still came as a shock. Genetic testing indicated that she had a high likelihood of developing liver metastases, so when liver mets were detected in 2014 she had already researched her options. Surgical resection was her first treatment, but when the liver tumors progressed again she sought treatment with PHP at Moffitt Cancer Center. After five courses of PHP, her liver metastases were almost completely reduced. "My experience with PHP Therapy wasn't easy, but without it I don't think I would be here. Today my liver mets are under control and I am able to obtain other treatment for my extra-hepatic disease that would not otherwise be an option."

Both Sabrina and Reverend Desalvo have the same advice for ocular melanoma patients. "Keep fighting, do your research and be your own advocate. For thirty years the options for ocular melanoma patients had not changed, but in the last 10 years everything has."

About Rare Disease Day
Rare Disease Day takes place on the last day of February each year. The main objective of Rare Disease Day is to raise awareness amongst the general public and decision-makers about rare diseases and their impact on patients' lives. The campaign was begun by EURODIS in 2008. The theme for this year's campaign is *Bridging Health and Social Care* #ShowYou'reRare

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® 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 Registration OM clinical trial, IRB or ethics committee clearance of the Registration trial for OM and the Phase 3 ICC 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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