



## Delcath Issues Letter to Stockholders

August 17, 2018

NEW YORK, Aug. 17, 2018 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB: DCTH) ("Delcath" or the "Company"), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer, has issued a Letter to Stockholders providing a business update. The full text of the Letter, which has also been posted to the Company's website, is as follows.

Dear Stockholders:

Over the past several weeks, we have taken important steps designed to put our Clinical Development Program on an accelerated path. The steps we announced recently are the result of many months of behind the scenes work with the FDA and are intended to significantly reduce the time to submission of a New Drug Application (NDA) in the ocular melanoma indication, to provide this critical therapy to patients in a more timely manner and to fully realize the commercial potential of our PHP® Therapy. I write to you today to discuss what these steps mean for our shared future and why we believe they can lead to shareholder value.

### **The FOCUS Trial - Amended design shortens time to completion**

On July 27, we announced an amendment to our ongoing Phase 3 trial in ocular melanoma liver metastases. The trial—now called *A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma* (The FOCUS Trial) will now operate as a single-arm trial in which all eligible patients will receive treatment with Melphalan/HDS.

The resulting amendment has been achieved through extensive dialog with the FDA, our investigators and patient advocacy groups about the appropriate trial design for this orphan disease patient population. The feedback from patients and investigators was clear. A combination of the low incidence of ocular melanoma, the randomized trial design, the absence of a crossover option to the experimental Melphalan/HDS arm and the commercial availability of CHEMOSAT in Europe was inhibiting timely enrollment. Considering the substantial body of preliminary research and experience with this therapy in this patient population, a new approach was warranted.

Under the amended protocol, the FOCUS Trial will now enroll a minimum of 80 patients with ocular melanoma metastatic to the liver in a single Melphalan/HDS arm. Patients already enrolled in the Melphalan/HDS arm of the trial under its previous protocol will continue to be treated and evaluated as part of the 80-patient target. As a result, we anticipate completing enrollment by June 2019. The clinical endpoints have been modified to reflect the single-arm design, and safety data for all Melphalan/HDS patients treated in both versions of the trial will be pooled.

With these changes we believe we will be able to complete trial enrollment within the next year, while at the same time evaluating efficacy and safety in a manner consistent with other recently approved cancer therapies. Most importantly, these changes dramatically shorten our timeline to the resubmission of an NDA.

### **The ALIGN Trial – Second Pathway to NDA Approval**

In May of this year, we announced the initiation of our registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC). Called the ALIGN Trial, this trial seeks to enroll ICC patients at clinical sites in the U.S. and Europe.

The ALIGN Trial protocol was informed by experience in commercial setting with CHEMOSAT in Europe, which observed a strong efficacy signal worthy of formal investigation in a clinical trial. We are leveraging our existing network of trial sites from our FOCUS Phase 3 trial to rollout the ALIGN Trial protocol as efficiently as possible. We currently have three centers open for enrollment and will expand to additional centers as appropriate.

Intrahepatic cholangiocarcinoma is an orphan disease with a large unmet medical need. The ALIGN Trial provides us with a mechanism to investigate our therapy in this tumor type and a second pathway to NDA approval in the United States. If successful we believe this will be an important value driver for the Company and will be a next step in pursuing the larger number of metastatic diseases to the liver, with our PHP Therapy.

### **RIGHTS OFFERING – Provides Funding Source for Development Program**

To fund the advancement of these trials, we have initiated the \$50 million rights offering we announced on July 16, 2018. This new equity financing offers shareholders of record as of August 3 an opportunity to make a direct investment in Delcath in a way that supports the achievement of these critical regulatory milestones. Completion of these trials and submission of NDA applications for approval are the fastest ways to bring PHP therapy to patients in need and are the path through which shareholder value will be ultimately created.

Details of this offering are contained in the prospectus filed on August 6, 2018 and have been provided to shareholders of record. The deadline for shareholders to participate in the rights offering is August 27, 2018. Investors are advised that many brokers have their own internal deadlines that are several days earlier. Please contact D.F. King at (212) 269-5550 (bankers and brokers) or (877) 732-3612 (all others) or email at [DCTH@dfking.com](mailto:DCTH@dfking.com) with any questions on the Rights Offering process.

To conclude, we believe the combination of the near-term completion of the amended FOCUS Trial resulting in a shortened timeline for FDA submission, initiation of The ALIGN Trial in a second value driving indication, steady increase of commercial adoption with over 600 treatments completed and the rights offering provide a clear path toward realizing PHP Therapy's potential in the shortest timeline.

On behalf of my colleagues and our Company's board of directors, thank you for supporting Delcath as we endeavor to bring this potentially lifesaving therapy to patients.

Sincerely,

Jennifer K. Simpson, Ph.D., MSN, CRNP  
President and Chief Executive Officer

### **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 commenced a global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and have initiated a Registration trial for intrahepatic cholangiocarcinoma (ICC). 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 commercially available 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.

### **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 clinical trial, 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, our ability to maintain NASDAQ listing, 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 Information:**

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

D.F. King  
(212) 269-5550 (bankers and brokers)  
(877) 732-3612 (all others)  
Email: [DCTH@dfking.com](mailto:DCTH@dfking.com)

Delcath Systems, Inc.