Delcath Announces Special Protocol Assessment Agreement With FDA For New Phase 3 Trial In Hepatic Dominant Ocular Melanoma

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Agreement Provides Regulatory Pathway for Melphalan/HDS with a Single Phase 3 Trial; Satisfies Substantial Number of Requirements in FDA's September 2013 Complete Response Letter

NEW YORK, Jan. 19, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces that the Company has reached a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of Delcath's new Phase 3 clinical trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with hepatic dominant ocular melanoma. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS.

The agreement also represents the satisfactory resolution of a substantial number of the FDA's issues in the Complete Response Letter (CRL) issued in September 2013. These issues were related to safety of a previous generation of the Melphalan/HDS device and procedure. Delcath completed the work necessary to satisfy these requirements prior to submitting its request for the SPA agreement.

The new pivotal trial, the *FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (*the FOCUS trial), will evaluate the safety and efficacy profile of the Melphalan/HDS versus best alternative care. The primary endpoint will be overall survival, and secondary endpoints will include progression-free survival, overall response rate and quality-of-life measures. Full details of the Phase 3 clinical trial will be made public upon the launch of the study and will be available at www.clinicaltrials.gov.

"This agreement marks a major milestone for Delcath," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "Under this SPA our new FOCUS trial, if successful, will provide a clear pathway to an indication in hepatic dominant ocular melanoma for Melphalan/HDS. Additionally, through the dedicated work of our team and in close collaboration with the FDA, we have satisfied a substantial number of the requirements of the FDA's 2013 CRL. Based on our commercial experience in Europe, the continued support and enthusiasm from Key Opinion Leaders and the clinical data that have been presented and published recently, we have confidence that our FOCUS trial can demonstrate the efficacy and safety necessary for a positive benefit/risk profile for Melphalan/HDS, and that the study's objectives can be met. There is strong interest from leading cancer centers in the U.S. and Europe to participate in this study and we look forward to beginning enrollment in this registrational trial."

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC), and expect to initiate a global Phase 3 trial in ocular

melanoma (OM) that has metastasized to the liver and plan to evaluate intrahepatic cholangiocarcinoma (ICC) in a Phase 2 clinical study.

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 impact, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, the timing and results of the Company's clinical trials including without limitation the HCC, ICC and OM clinical trial programs timely enrollment and treatment of patients in the global Phase 2 HCC and ICC clinical trial, FDA approval of the global Phase 3 OM clinical trial protocol, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM 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, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, 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.

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