Delcath launches pivotal study to treat ICC patients

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Singapore– Delcath Systems, an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that the Company has initiated its pivotal trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with intrahepatic cholangiocarcinoma (ICC). Duke Medical Center in Durham, North Carolina is the first cancer center to open for patient enrollment. Dr. Sabino Zani, a surgical oncologist with Duke Medical Center, is serving as the principal investigator for the trial in the United States.

The trial, entitled A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma, (the ALIGN Trial) will seek to enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe.

"The ALIGN Trial is based on a strong efficacy signal observed in the ICC tumor type through our commercial experience with CHEMOSAT in Europe," said Jennifer K. Simpson, PhD, MSN, CRNP, President and Chief Executive Officer of Delcath Systems. "The sequential design of the therapies under investigation in the trial will allow us to minimize capital investment requirements in 2018. We are also leveraging our existing network of trial sites from our FOCUS Phase 3 trial to rollout the trial protocol as efficiently as possible, and intend to conduct the trial in a financially prudent manner. In this orphan population where there exists a huge unmet need, this trial provides us with a second pathway to commercial drug approval in the United States, and if successful we believe will be an important value driver for the Company."