Delcath Systems Announces a KOL Call on November 5, 2020 to discuss the Results of a Prospective Phase II Study in Patients with Metastatic Ocular Melanoma

Overall Response Rate of 72% observed in patients with metastases confined to the liver

NEW YORK, Oct. 29, 2020 — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on liver-directed treatment of primary and metastatic cancers, today announced that the Company will be hosting a Key Opinion Leader (KOL) call with Dr. Mark Burgmans, an Interventional Radiologist at the Leiden University Medical Center (LUMC) in The Netherlands, on Thursday, November 5, 2020, at 11:30am ET.

Dr. Mark Burgmans will discuss results from a prospective phase II study conducted at Leiden University Medical Center on the use of the Delcath CHEMOSAT® Hepatic Delivery System with Melphalan (CHEMOSAT) to treat patients with metastatic ocular melanoma with liver metastases. The publication is entitled “Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase ll Study” and was published in Annals of Surgical Oncology.[1]

Unlike other published and ongoing studies investigating the use of CHEMOSAT to treat patients with metastatic ocular melanoma, this study enrolled a patient population which had not yet progressed to extra-hepatic metastases. In addition, for 60% of the patients, treatment with CHEMOSAT was used in a first line setting. The overall response rate observed in these earlier stage patients was 72% (complete response of 3% and partial response of 69%) with a median overall survival of 19.1 months. The investigators noted that while this prospective study was not designed for direct comparison, the results indicate that CHEMOSAT is more effective in treating liver metastases from ocular melanoma than systemic therapies.

Although grade 3 or 4 hematologic events were observed in the majority of patients, they were all well manageable or self-limiting and there were no treatment-related deaths. In an earlier publication of this study, the investigators noted that the hematologic and hepatic toxicity percentages were significantly lower compared to studies using an earlier generation of CHEMOSAT which utilized a different filter system.[2] Based on a validated quality of life tool used in the trial, the investigators concluded that CHEMOSAT is well-tolerated with maintenance of quality of life, with only a mild and temporary impairment of physical functioning noted at 6 weeks after the second CHEMOSAT treatment.

The full article is available online at:

https://rdcu.be/b9nnn

The presentation will be live webcast at http://investors.delcath.com/events-presentations. For those not available to listen to the live broadcast, a replay will be archived and available at http://investors.delcath.com/events-presentations.

The CHEMOSAT Hepatic Delivery System is not approved in the United States. In the United States the Melphalan/Hepatic Delivery System is currently being investigated in a phase 3 trial in patients with metastatic ocular melanoma.

1) Meijer, T.S., Burgmans, M.C., de Leede, E.M. *et al.* Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase II Study. *Ann Surg Oncol* (2020). https://doi.org/10.1245/s10434-020-08741-x

2) Meijer, T. S., Burgmans, M. C., Fiocco, M., de Geus-Oei, L. F., Kapiteijn, E., de Leede, E. M., Martini, C. H., van der Meer, R. W., Tijl, F., & Vahrmeijer, A. L. (2019). Safety of Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Liver Metastases from Ocular Melanoma Using the Delcath Systems' Second-Generation Hemofiltration System: A Prospective Non-randomized Phase II Trial. *Cardiovascular and interventional radiology*, *42*(6), 841-852. https://doi.org/10.1007/s00270-019-02177-x

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