Delcath Systems Announces Publication of CHOPIN Clinical Trial Results in The Lancet Oncology

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Publication Highlights Promise of Combined Percutaneous Hepatic Perfusion and Immunotherapy in Metastatic Uveal Melanoma

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Mar. 3, 2026-- Delcath Systems, Inc. (Nasdaq: DCTH), ("Delcath" or the "Company") an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced the publication of the full results from the investigator-initiated CHOPIN randomized Phase 2 clinical trial, led by Principal Investigator Professor Ellen Kapiteijn, MD, from Leiden University Medical Center's Department of Medical Oncology. The publication, titled "Percutaneous hepatic perfusion combined with ipilimumab and nivolumab for metastatic uveal melanoma (CHOPIN): a single-centre, open-label, randomised, phase 2 trial" is published in *The Lancet Oncology* and presents detailed analyses from the trial, building on the positive topline results previously presented at the European Society for Medical Oncology (ESMO) Congress in October 2025. The link to the article can be found at: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(25)00720-X/abstract.

"The detailed analyses in this publication reinforce the synergistic potential of combining PHP with immunotherapy, showing not only superior PFS and OS but also enhanced hepatic control and deeper, more durable responses. This approach represents a significant advancement for patients with this challenging disease, where liver-dominant metastases drive poor outcomes," said Professor Ellen Kapiteijn, MD, Principal Investigator and Lead Author from Leiden University Medical Center's Department of Medical Oncology.

"The full publication in The Lancet Oncology validates the impressive efficacy of combining our liver-directed PHP therapy with immune checkpoint inhibition," said Gerard Michel, Chief Executive Officer of Delcath Systems. "By more than tripling the 1-year progression-free survival rate and nearly doubling the 2-year overall survival, these results strongly underscore the clinical value of this combination and give us even greater confidence in adoption by treating physicians and patients. We are also encouraged by the potential to explore this paradigm in other liver-dominant cancers."

The CHOPIN trial randomized 76 patients with metastatic uveal melanoma (mUM; n=38 per arm) to percutaneous hepatic perfusion (PHP) with melphalan using Delcath's CHEMOSAT® Hepatic Delivery System (HDS) alone or in combination with ipilimumab plus nivolumab. In both arms patients received two PHP treatments (weeks 1 and 7). In the combination arm patients also received ipilimumab (1 mg/kg) plus nivolumab (3 mg/kg) in weeks 0, 3, 6, and 9, with no maintenance therapy.

Key results (intention-to-treat population):

- **Primary endpoint – 1-year progression-free survival (PFS)**: 54.7% vs 15.8% (adjusted HR 0.34 [95% CI 0.19–0.60]; p=0.0002), Median PFS: 12.8 months vs 8.3 months
- **Overall Survival (OS)**: Median 23.1 months vs 19.6 months (HR 0.39 [95% CI 0.20–0.77]; p=0.0065) 2-year OS: 49.6% vs 22.1%
- **Objective Response Rate (ORR)**: 76.3% vs 39.5% Complete response (CR) rate: 13% vs 3%

Safety

Grade 3 or higher treatment-related adverse events occurred significantly more frequently in the combination arm (82%) than in the PHP-alone arm (41%); p=0.0006. The rate in the combination arm was similar to that reported in the FOCUS trial (81%). The most common grade 3/4 events were thrombocytopenia (34% vs 14%), leukopenia (26% vs 14%), γ-glutamyl transferase increase (18% vs 8%), and anemia (13% vs 3%). Most events were self-limiting or manageable with standard supportive care; no new safety signals were identified. One treatment-related death (immune-related triple M syndrome) occurred in the combination arm.

Overall, the authors conclude that the combination of PHP with ipilimumab and nivolumab offers a promising new approach for

patients with metastatic uveal melanoma.

About Delcath Systems, Inc., HEPZATO KIT, and CHEMOSAT

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary products, HEPZATO KIT (HEPZATO (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT Hepatic Delivery System (HDS) for Melphalan percutaneous hepatic perfusion (PHP), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary HDS. The HDS is used to isolate the hepatic venous blood from the systemic circulation while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers of the liver.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by Delcath or on its behalf. This press release contains forward-looking statements, including statements regarding the possible synergy seen in the successful Phase 2 CHOPIN Trial being transferable to other cancers with liver-dominant disease; statements regarding the potential of CHEMOSAT Hepatic Delivery System and HEPZATO KIT to improve outcomes for patients with metastatic uveal melanoma and other cancers with liver-dominant disease; statements regarding the potential to drive increased adoption of HEPZATO KIT; statements regarding Delcath's commitment to raising awareness of the innovative approach taken in the CHOPIN Trial, and accelerating the referral of patients to treatment sites; and statements regarding Delcath's continued growth and leadership in liver-directed oncology, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; contributions to adjusted EBITDA; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, 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.

This release contains forward-looking statements, including statements regarding the expected release of clinical trial results, which are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, delays in the presentation of the data, or other unforeseen issues relating to the release of the clinical trial results. For a detailed discussion of these and other risks, please refer to Delcath's filings with the SEC.

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