Delcath®

Corporate Presentation

NASDAQ: DCTH

March 2024

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Forward-Looking Statement

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This presentation contains forward-looking statements, 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 ability to successfully commercialize the HEPZATO KIT; 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 Delcath and third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for commercialized product; the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT; the timing and results of the Company's clinical trials; our determination whether to continue a clinical trial program or to focus on other alternative indications; the impact of the COVID-19 pandemic or other pandemics on the completion of our clinical trials; the impact of the presentations at major medical conferences and future clinical results consistent with the data presented; uncertainties relating to the timing and results of research and development projects; 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.

Delcath Investment Summary

HEPZATO KIT

- FDA approval for mUM* 8/14/23
- 1Q 2024 US Launch

Commercial Opportunity

- Ultra orphan pricing
- J-Code active April 1
- Focused call points
- US mUM TAM ~$600M

High Penetration

- Included in NCCN Guidelines
- First and only FDA approved whole-liver directed therapy

Experienced Management Team

- Expertise in commercializing high value, specialty products
- TheraSphere (BSX) veterans

Significant upside beyond mUM

- Strong efficacy signals in multiple other tumor types
- Unique interventional oncology asset

Multiple 2024 Catalysts

- Launch
- Site Activation and revenue build
- CHOPIN enrollment completion
- Initiate trials in other indications

* metastatic Uveal Melanoma (mUM)

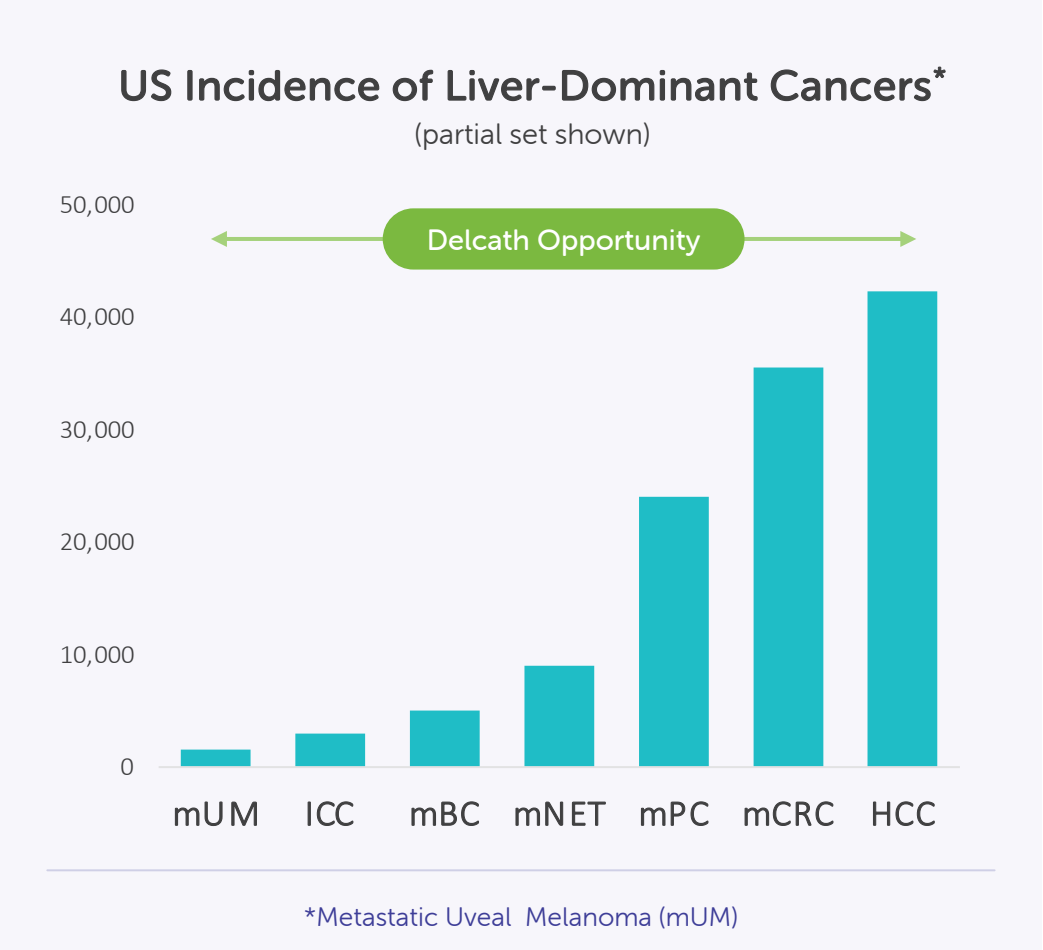
HIGH UNMET NEED:

Liver-Dominant Cancers

Liver-Dominant Cancers: High Incidence with High Unmet Medical Need

Up to **80%** **of patients with liver metastases are not amenable to surgical resection**
largely due to extensive tumor burden[1]

- Limited Overall Survival - Unresectable Liver Cancer
- Liver: Common Site of Metastases
  - Often the life-limiting organ
- Limited Effective Systemic Treatments
  - Systemic Therapies: low efficacy
  - Immuno-oncology agents become less effective in the presence of metastases



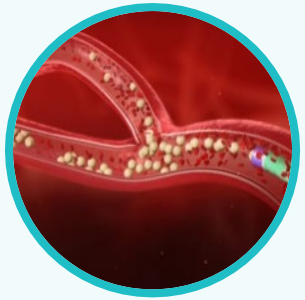
[1] Reddy S, et al. Isolated hepatic perfusion for patients with liver metastases, Ther Adv Med Oncol. 2014 Jul; 6(4): 180-194.

Current Liver-Directed Therapies

MAJORITY OF TREATMENT

Trans Arterial Chemo Embolization (TACE)[2]

- Beads obstruct blood flow to tumor and elute chemo
- 50-60k treatments and rising per year in US



SIRT (Y90)[3]

- Radioactive beads delivered into a portion of the liver
- 10-15k treatments and rising per year in US

Limitations

- Tumors recur and retreatment options limited due to damage to vasculature (TACE) and hepatotoxicity (Y90)
- Diffuse disease cannot be treated with a tumor-by-tumor modality (TACE) and bilobar treatment is hepatotoxic (Y90)
- Many tumors not imageable and micro-metastases are common, neither TACE or Y90 can treat the entire liver
- Neither approved for the treatment of mUM and lacking substantial high quality data set to support usage

[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.
[3] Lane AM, Kim IK, Gragoudas ES. Survival Rates in Patients After Treatment for Metastasis From Uveal Melanoma. JAMA Ophthalmol. 2018 Sep 1;136(9):981- 986.

HEPZATO KIT™

(melphalan) for Injection/ Hepatic Delivery System (HDS)

HEPZATO KIT™
(melphalan) for Injection/
Hepatic Delivery System (HDS)

Percutaneous Hepatic Perfusion (PHP)

Effective, Safe & Repeatable Liver-focused Disease Control

1. Isolation

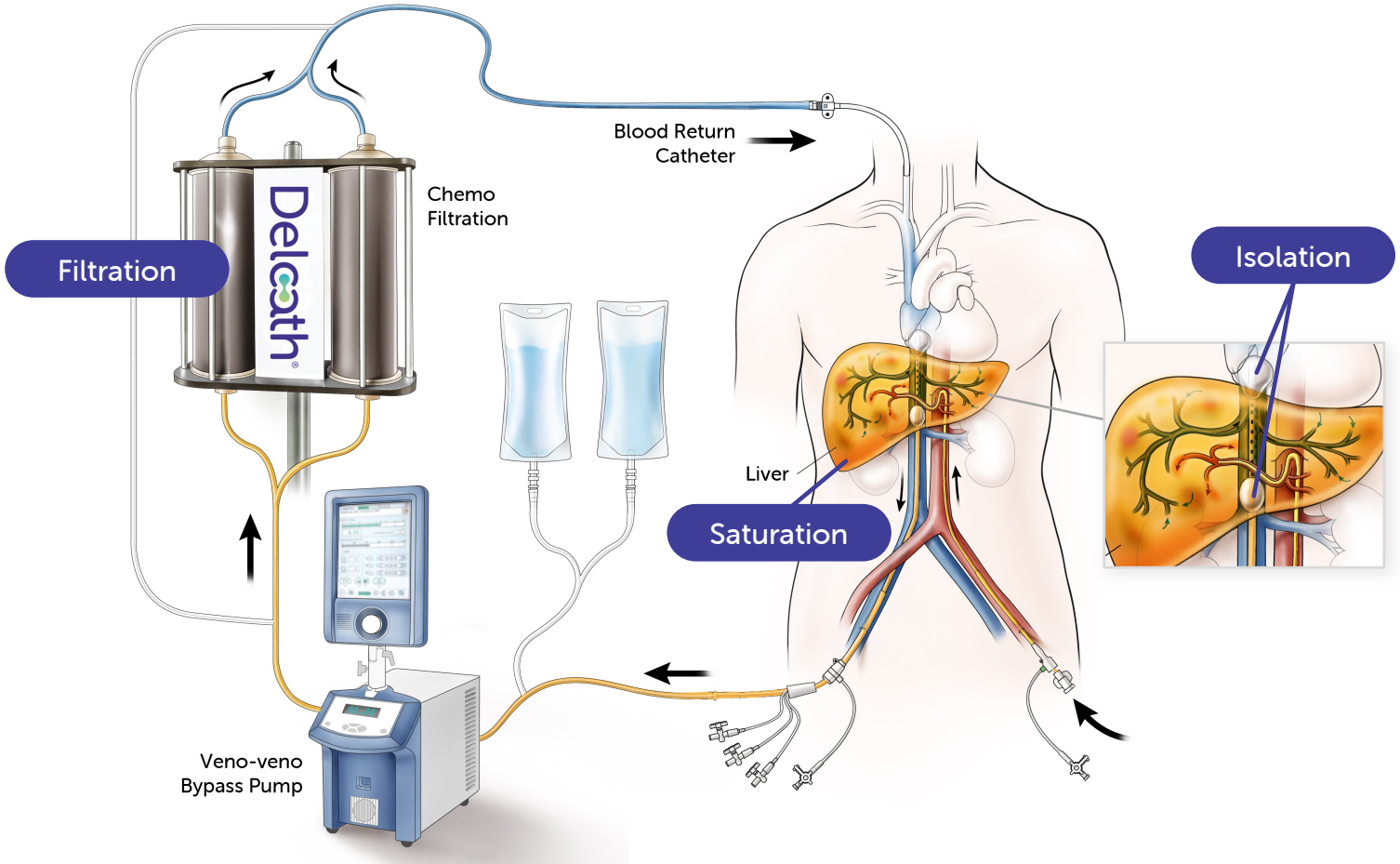
Hepatic venous flow is isolated, enabling >6X greater local concentration of chemo

2. Saturation

Melphalan (chemo) treats micro and macro lesions simultaneously regardless of location in the liver

3. Filtration

Proprietary filters remove greater than 85% of chemo from the body[4]



[4] Heppt, M, et al. Combined immune checkpoint blockade for metastatic uveal melanoma: a retrospective, multi-center study. J Immunotherap Cancer. 2019 Nov 13;7(1):299.

Indication Statement

HEPZATO KIT (melphalan) for Injection/Hepatic Delivery System

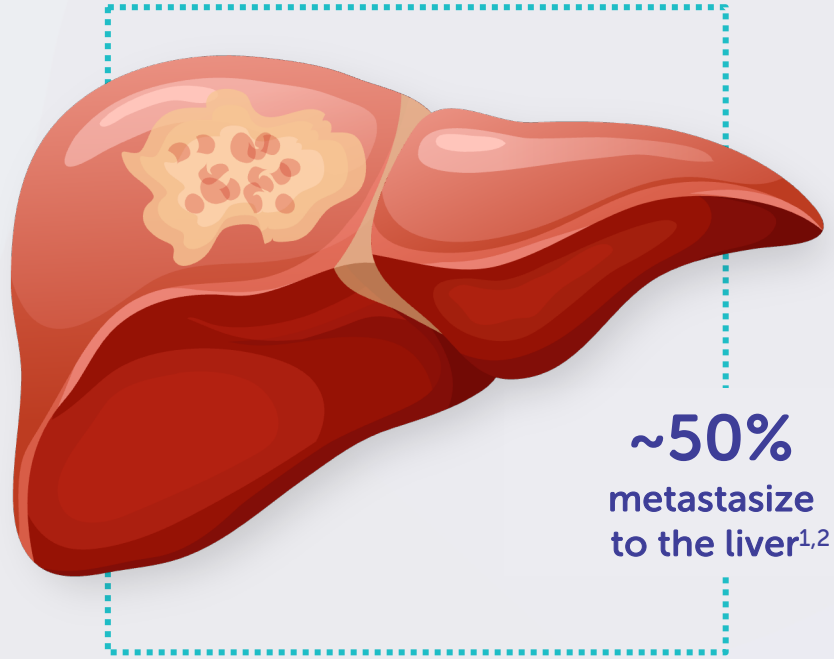
HEPZATO KIT is indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

- Indicated Patient Population Includes:
  - No HLA genotype restrictions
  - Treatment naïve and previously treated patients

Metastatic Uveal Melanoma (mUM)

mUM: Beachhead Market Opportunity

- ~2,000 newly diagnosed cases of primary uveal melanoma per year in the US[2]
- 50% metastasize with the liver involved in >90% of cases of metastatic disease[5,6] (1,000 mUM patients)[2,3]
- In 50% of mUM patients, the liver is the only site of metastasis[5,6]
- Most patients with mUM die from liver failure[6]
  - 1-year OS rate of patients with metastatic disease in the liver is 13%
  - Median survival ranging from 4 to 15 months[2,7]

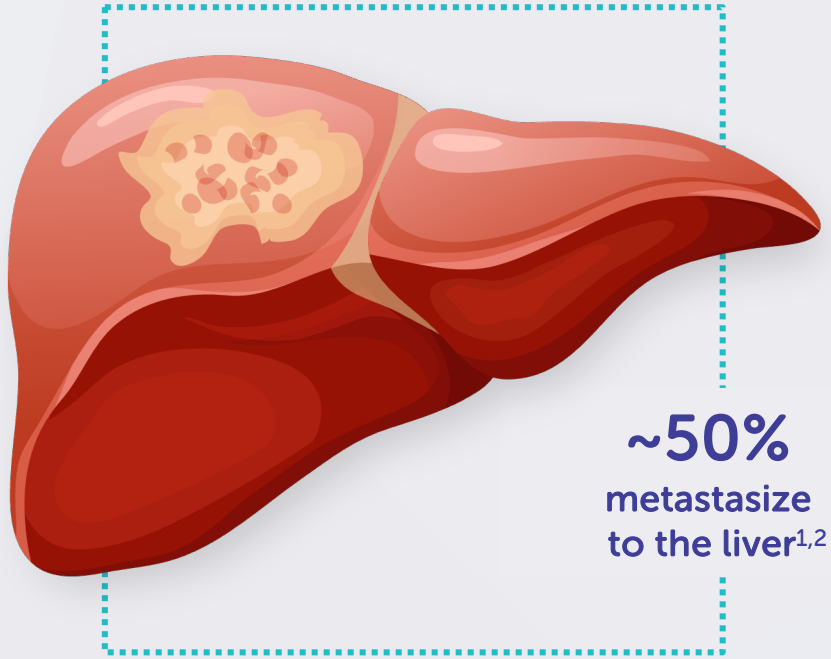


~50%
metastasize to the liver[1,2]

[1] Reddy S, et al. Isolated hepatic perfusion for patients with liver metastases, Ther Adv Med Oncol. 2014 Jul; 6(4): 180-194.
[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.
[3] Lane AM, Kim IK, Gragoudas ES. Survival Rates in Patients After Treatment for Metastasis From Uveal Melanoma. JAMA Ophthalmol. 2018 Sep 1;136(9):981- 986.
[5] Krantz BA, et al. Uveal Melanoma: Epidemiology, Etiology, and Treatment of Primary Disease. Clin Ophthalmol. 2017;11:279-289.
[6] Eschelman DJ et al. Transhepatic Therapies for Metastatic Uveal Melanoma. Semin Intervent Radiol. 2013;30(1):39-48.
[7] Carvajal RD, et al. Metastatic Disease from Uveal Melanoma: Treatment Options and Future Prospects. Br J Ophthalmol. 2017;101(1):38-44.

mUM: Beachhead Market Opportunity

- **Liver-directed treatment achieves better efficacy** compared to systemic therapy[8]
- **55%** of patients have **no approved systemic treatment** option
- Most patients treated with **multiple lines of therapy**



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[2] Xu L, T, Funchain P, F, Bena J, F, Li M, Tarhini A, Berber E, Singh A, D: Uveal Melanoma Metastatic to the Liver: Treatment Trends and Outcomes. Ocul Oncol Pathol 2019;5:323-332. doi: 10.1159/000495113.
[8] Olofsson BR, et al. Isolated Hepatic Perfusion With Melphalan for Patients With Isolated Uveal Melanoma Liver Metastases: A Multicenter, Randomized, Open-Label, Phase III Trial (the SCANDIUM Trial). J Clin Oncol. 2023 Jun 1;41(16):3042-3050

Diffuse/Miliary Metastatic Pattern in mUM

Diffuse Disease is Difficult to Treat with Other Liver Directed Options

- Solitary **liver lesions** are often treated with **surgery or ablation**.
- True nature of the disease may **only be seen upon visual confirmation**.
- Radiographically, metastatic Uveal Melanoma can **initially present** only as **focal lesions**.
- Traditional **liver-directed therapy** mechanism of action is **not optimal** if a whole liver treatment is needed.
- Whole organ therapy delivers **medication to a specific organ** then filters out the medication to **minimize systemic exposure**.

Actual patient sent for a liver resection based upon radiographic diagnosis*

* Data on File

Patient Journey

Initial Screening

Initial diagnosis & treatment
- Enucleation
- Radiation
- Photodynamic therapy

  - **Ophthalmology**
  - **Optometrists**
  - **Eye Specialist**

~2,000 patients

- **Ophthalmologist**
- **Ocular Oncologist**

MILESTONE
Surveillance Decision

Screening frequency dependent on risk level
- Higher risk patients (50%) are screened at a high frequency
- Lower risk patients (50%) are screened at a lower frequency

Gene expression profiling may occur

- **Ophthalmologist/ Ocular Oncologist** Surveillance

- **Medical Oncologist** Surveillance at Academic Center

- **Medical Oncologist** Surveillance at Nonacademic Center

MILESTONE
Metastases Detected

Treatment Decision

- **Surgical Oncologist** Surgical Resection

- **Interventional Radiologist** Liver-directed therapy

- **Medical Oncologist** Systemic Therapy

~1,000 patients

HEPZATO KIT™
(melphalan) for Injection/ Hepatic Delivery System (HDS)

Most patients receive both systemic and liver-directed therapies

~800 patients eligible

Pre-Metastatic | 3-5 years

Post-Metastatic

FOCUS

U.S. Registration Trial for the
Treatment of Patients with mUM

Summary of Efficacy Results[9]

Endpoints	HEPZATO KIT (N=91)
ORR, n	33 (36.3%)
DOR, Median in months	14.0
DCR, n	67 (73.6%)
PFS, Median in months	9.0
OS, Median in months	20.53

- Full analysis with **final data cut pending publication**
- HEPZATO Tx **every 6-8 weeks** up to a maximum of **6 cycles**
- Prescribing Information includes **ORR, DOR** and **response categories**
- Trial powered to show an **ORR advantage over a meta-analysis of Best Alternative Care**
  - Checkpoint inhibitors, chemotherapy, other liver-directed therapy
- Lower bound of **FOCUS ORR (26.4%) is significantly higher** than the upper bound of the meta-analysis (8.3%)

[9] DOI: 10.1200/JCO.2022.40.16_suppl.9510 Journal of Clinical Oncology 40, no. 16_suppl (June 01, 2022) 9510-9510.

Published mUM Prospective and Retrospective Studies*

Clinical Study/Publication	Study Type	Treatment	N	Median OS (months)	1 year OS	Median PFS (months)
FOCUS	**Single-Arm**	**HEPZATO**	**91[AL]**	**20.53**	**80%**	**9.03**
Khoja et al 2019[10]	Meta-Analysis	systemic and liver-directed therapies	912	10.2	NA	3.3
Rantala et al 2019[11]	Meta-Analysis	systemic and liver-directed therapies	2,494	12.84	NA	NA
Piulats et al 2021[12]	Single-Arm	ipi plus nivo	52[TN]	12.7	NA	3.0
Heppt et al 2019[13]	Single-Arm	ipi plus (pembro or nivo)	64[AL]	16.1	NA	3.0
Nathan et al 2021[14]	Randomized	tebentafusp	252[TN]	21.7	73%	3.3
		control	126[TN]	16	59%	2.9

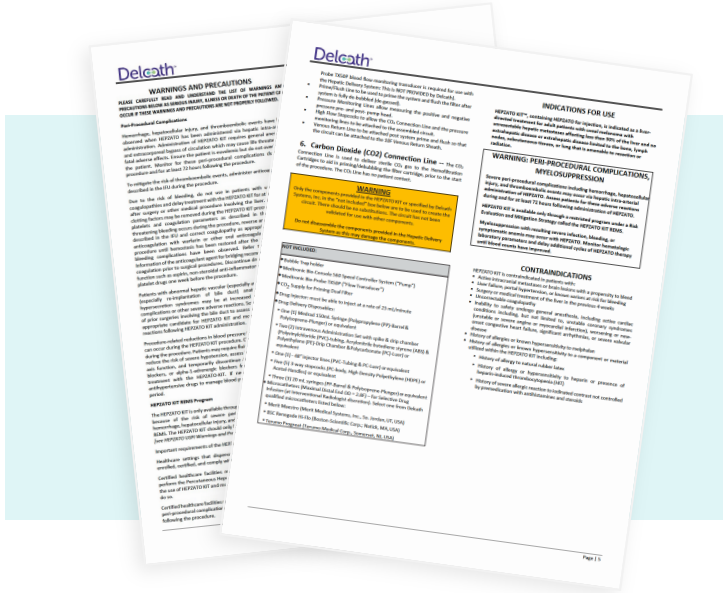
TN = Treatment Naïve, AL = Any Line

Ipi = ipilimUMab, nivo = nivolumab, pembro = pemUMab

*Studies from 2019 or later with >50 patients

[10] Khoja L, et al. Meta-analysis in metastatic uveal melanoma to determine progression free and overall survival benchmarks: an international rare cancers initiative (IRCI) ocular melanoma study. Ann Oncol 2019 Aug 1, 30(8): 1370-1380.
[11] Ranjala, E, et al. Overall survival after treatment for metastatic uveal melanoma: a systematic review and meta-analysis. Melanoma Res. 2019 Dec; 29(6): 561–568
[12] Piulats, J, et al. Nivolumab Plus Ipilimumab for Treatment-Naïve Metastatic Uveal Melanoma: An Open-Label, Multicenter, Phase II Trial by the Spanish Multidisciplinary Melanoma Group (GEM-1402). Journal of Clinical Oncology 39, no. 6 (February 20, 2021) 586-598.
[13] Heppt, M, et al. Combined immune checkpoint blockade for metastatic uveal melanoma: a retrospective, multi-center study. J Immunotherapy Cancer. 2019 Nov 13;7(1):299.
[14] Nathan, P, et al. Overall Survival Benefit with Tebentafusp in Metastatic Uveal Melanoma. N Engl J Med 2021; 385:1196-1206

Adverse Events



Adverse reactions are described further in the HEPZATO KIT PI.

- Most hematological side effects result from melphalan
- Side effect profile similar to standard melphalan use

	Adverse Reactions Related to Study Treatment Occurring in ≥10% of Patients (N=95)	
	ALL GRADES (%)	GRADES 3 OR 4 (%)
Thrombocytopenia*	64	55
Leukopenia*	44	34
Anemia*	61	33
Neutropenia*	35	29
International normalized ratio increased	29	8
Activated partial thromboplastin time prolonged	26	8
Aspartate aminotransferase increased	27	3
Hypocalcemia	12	3
Blood bilirubin increased	11	3
Alanine aminotransferase increased	31	2
Blood alkaline phosphatase increased	25	2
Troponin I increased	12	2
Abdominal pain upper	18	1
Dyspnea	11	1
Nausea	47	0
Fatigue	43	0
Vomiting	27	0
Contusion	16	0
Asthenia	13	0
Back pain	13	0
Decreased appetite	13	0
Abdominal pain	12	0
Lethargy	12	0
Groin pain	11	0
Headache	11	0

Anemia includes anemia, febrile bone marrow aplasia, hemoglobin decreased, normochromic normocytic anemia, red blood cell count decreased. Leukopenia includes leukopenia, lymphocyte count decreased, lymphopenia, and white blood cell count decreased. Neutropenia includes neutropenia and neutrophil count decreased. Thrombocytopenia includes thrombocytopenia and platelet count decrease.

HEPZATO KIT:

Commercialization

Delivering an Innovative Treatment with a Well-Trained Team

Treatment with HEPZATO KIT involves training and a team approach. The team members below complete a preceptorship and proctorship as well as a risk evaluation and mitigation strategy (REMS) training.

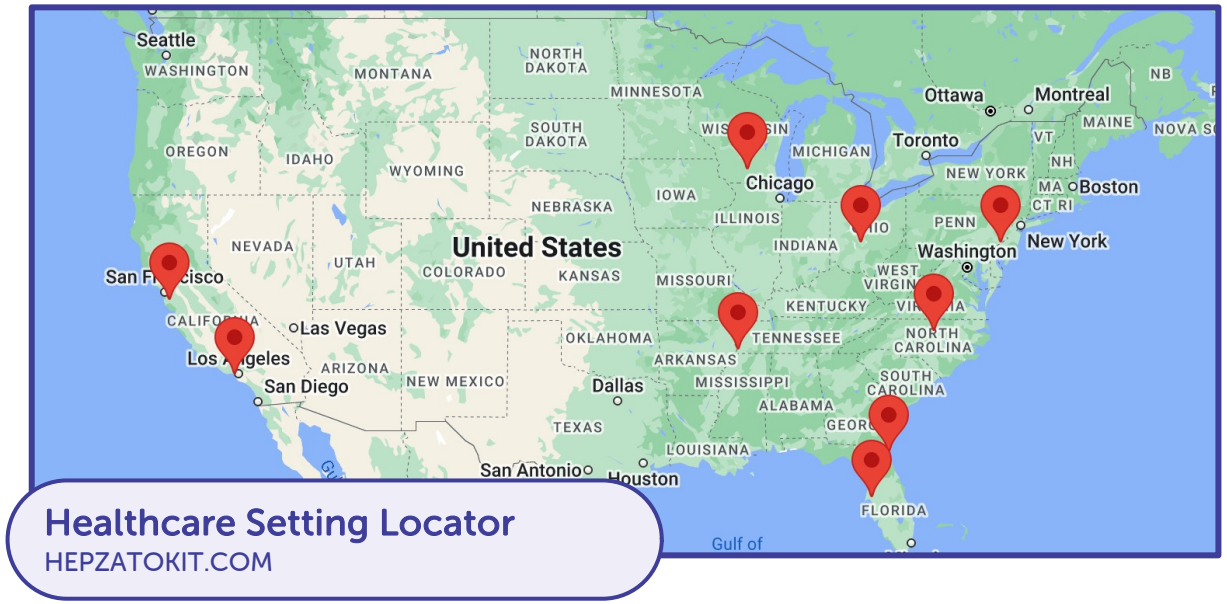
Interventional radiologist leads and performs the vascular interventional procedure

Perfusionist establishes, monitors, and controls the extracorporeal pump and veno-venous bypass circuit

Anesthesiologist manages sedation, analgesia, and respiratory and cardiovascular support

All REMS materials are available at www.HEPZATOKITREMS.com or by calling the REMS Coordinating Center at 1-833-632-0457.

Sites Accepting Patient Referrals*

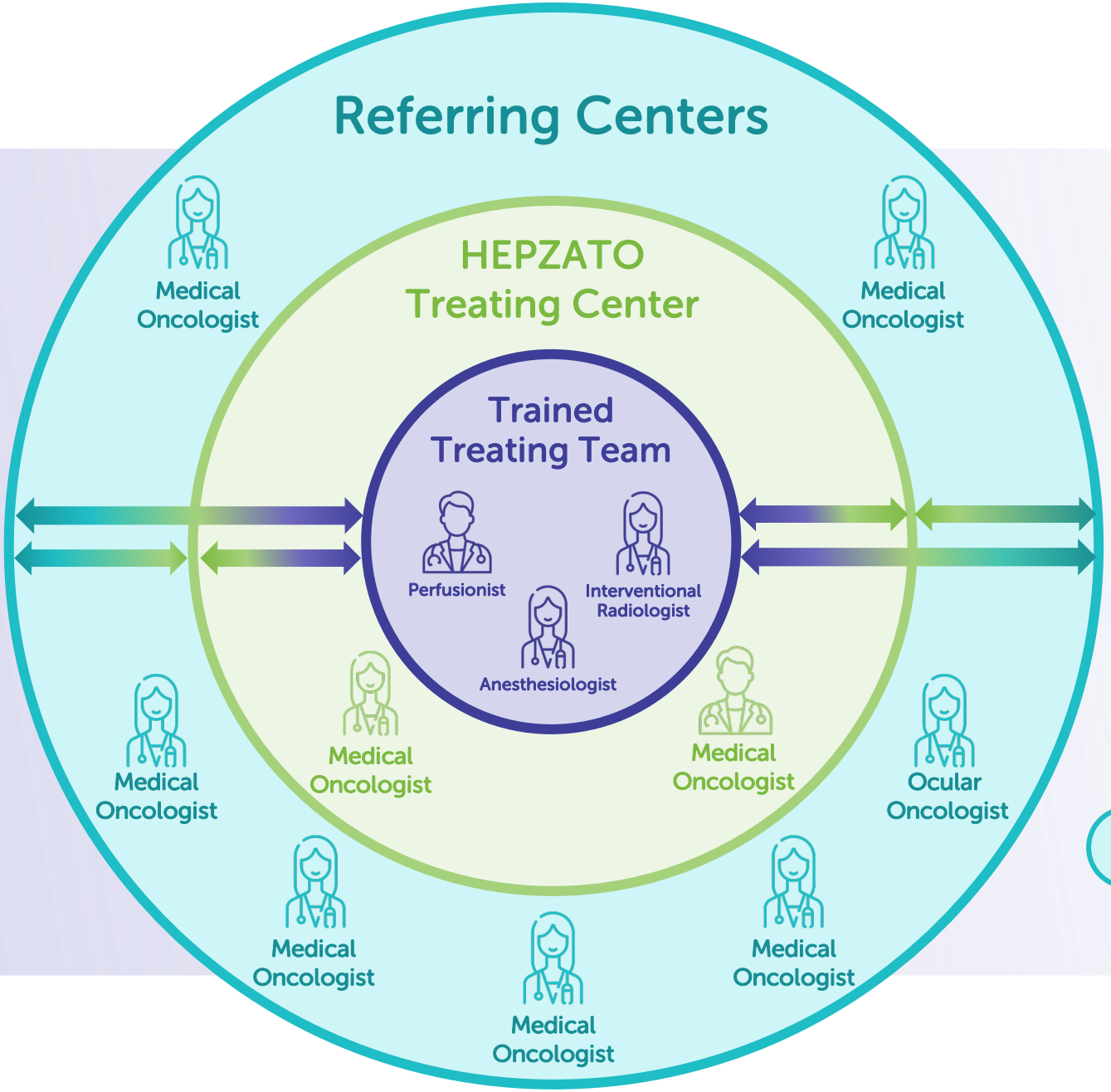


Healthcare Setting Locator
HEPZATOKIT.COM

- Duke Cancer Institute, Durham, NC
- Mayo Clinic, Jacksonville, FL
- Moffitt Cancer Center, Tampa, FL
- Ohio State Univ., Columbus, OH
- Stanford Health Care, Stanford, CA
- Thomas Jefferson, Philadelphia, PA
- UCLA Health, Santa Monica, CA
- University of Tennessee, Memphis, TN
- University of Wisconsin, Madison, WI

* As of 3/26/24

- First commercial use of HEPZATO KIT on January 12 at Moffitt
- ~9 sites are accepting referrals and are on the Healthcare Setting Locator
- Expect ~4 sites to have conducted their 1st commercial treatment by end of Q1
- Active conversations ongoing with >15 other sites

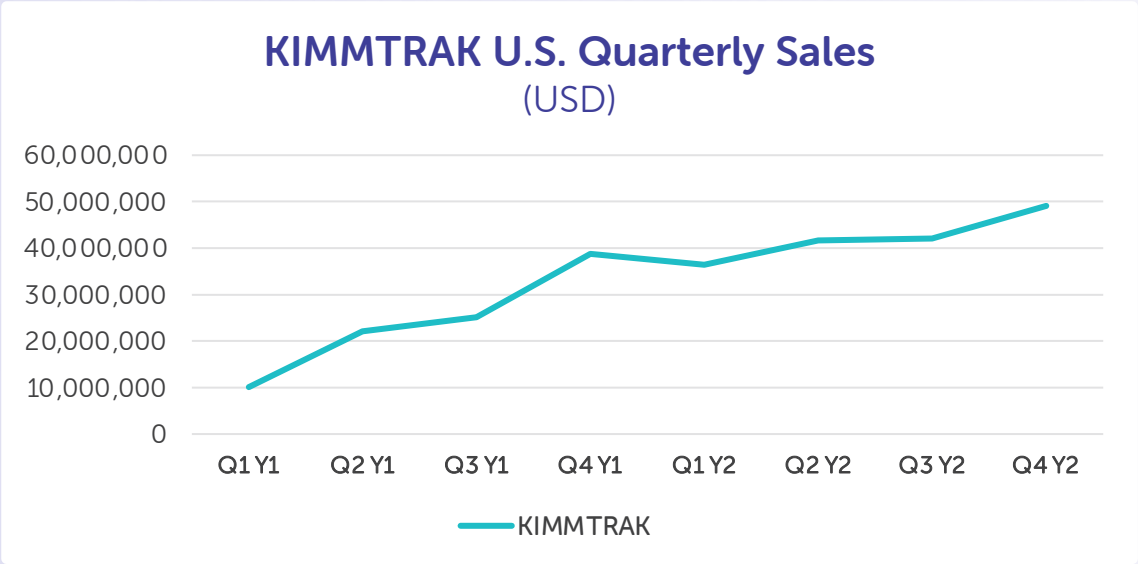


Specialized, Targeted Sales Teams

Three Complementary Representatives:

- Clinical Specialists
- Liver-Directed Therapy Representatives
- Oncology Managers

Demonstrated Demand for FDA Approved Treatment in mUM



KIMMTRAK

- $49.1 million in Q4 2023 US sales ($196M annualized revenue)
- Captured an estimated 40% share of eligible patients within 12 months
- Approximately 360* patients are eligible for KIMMTRAK
- Only 45%* of mUM patients are eligible for treatment due to HLA restriction

HEPZATO KIT: FDA Approved August 14, 2023 to Treat Patients with Liver-Dominant mUM

- Approximately 800 patients potentially eligible for treatment
- HEPZATO has no HLA genotype restrictions
- Patients often receive both systemic and liver-directed treatment
- Only FDA approved drug for 100% of all mUM patients, with appropriate liver involvement

*Due to HLA genotype restrictions

HEPZATO KIT:

Reimbursement & Pricing

Reimbursement

Medicare Patients

- J-Code assigned and active April 1, 2024
- Majority of patients will be outpatient
  - Drug directly covered by Medicare as pass through

Private Payer Patients

- Follow Medicare guidelines
  - For rare disease
  - Patients to be treated as outpatients
- Medical Prior-Authorization of patients likely required
  - Delcath has engaged a hub service to assist with benefit verification and navigation
- Centers of Excellence (Prospective Payment System (PPS) exempt and NCI designated Cancer Centers) have the leverage to negotiate favorable rates and reimbursement terms
  - ~50% of target sites are PPS exempt or NCI Cancer Centers

PHP is Already Part of Current NCCN Guidelines for mUM

NCCN Guidelines Version 1.2023
Melanoma: Uveal

Distant Metastatic Disease

WORKUP

- Biopsy if clinically appropriate[99]
- Imaging[ii] for baseline staging and to evaluate specific signs and symptoms
- HLA-A*02:01 testing
- Consider LFTs, including lactate dehydrogenase (LDH)[ll]
- Consider alkaline phosphatase[ll]

TREATMENT OF METASTATIC DISEASE

Clinical Trial (preferred)
OR
Consider on or more of the following:

- Systemic therapies[mm]
- Liver-directed therapies
  - Regional isolation perfusion of the liver
  - Embolization (chemotherapy, radiation,[n] immunotherapy)
  - Ablative procedures (thermal ablation, chryotherapy)
    Consider resection and/or RT (photon beam or SRS)[n] for limited or symptomatic disease of the liver[ll]
- Best supportive/palliative care

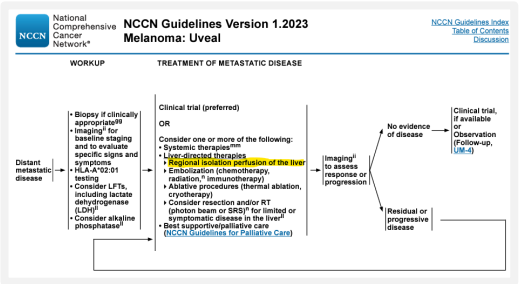
Imaging[ii] to assess response or progression

- **No evidence of disease** → **Clinical trial, if available or Observation (Follow-up, UM-4)**
- **Residual or progressive disease** → (return to TREATMENT OF METASTATIC DISEASE)

SOURCE: National Comprehensive Cancer Network®

Regional Isolation Perfusion

Methods include isolated hepatic infusion (IHP), percutaneous hepatic perfusion (PHP), HAI, and embolization techniques. **PHP is a simpler, less invasive alternative to IHP that can be repeated**. It uses a double-balloon catheter inserted into the inferior vena cava to isolate hepatic venous blood that is then filtered extracorporeally.



Components of Hospital Reimbursement

Assuming Outpatient Pass Through Status with J-Code

HEALTHCARE FACILITY FEE

- The existing CPT codes should capture all steps of the procedure
- Believe the existing codes will provide payment competitive with other interventional procedures

"PHYSICIAN" PAYMENT

- MDs primarily on salary but physician payments and associated RVUs are still relevant
- The existing CPT codes should capture all steps of the procedure
- Believe the existing codes will provide payment competitive with other interventional procedures

DRUG

- ASP+6% (CMS)
- Likely similar for commercial payers

CPT Code mapping complete

No meaningful impact on treatment decisions

HEPZATO KIT Pricing

Consistent with Only Other Approved mUM Therapy

At First Assessment (first time to discontinue treatment because of progression)			
DRUG	**DOSE COST***	**TREATMENTS #****	**TOTAL COST**
KIMMTRAK	$19,289	24 weeks	$462,936
HEPZATO	$182,500	2 kits	$365,000

Mean HEPZATO treatment vs. mean treatment duration of KIMMTRAK (per pivotal trials)			
DRUG	**DOSE COST***	**MEAN TREATMENTS #*****	**TOTAL COST**
KIMMTRAK	$19,289	41 weeks	$790,849
HEPZATO	$182,500	4.1 kits	$748,250

*Dose Cost ASP calculated using 7/2023 CMS payment allowance limit
** Minimum treatments prior to determining progression based on trial protocols
*** Mean from published phase 3 trials

NEXT STEPS:

Future Indications

Clinical Rationale for Broad Development Effort

Melphalan has demonstrated clinical activity in multiple tumor types

Promising ORR, DCR and PFS signals seen across multiple tumor types with CHEMOSAT in Europe and in earlier studies with IHP

In many solid tumor patients, liver metastases are often life limiting

HEPZATO is the only liver-directed treatment that can repeatedly treat the whole liver

Potential for significant improvement in survival

Converting unresectable liver metastases into resectable metastases and adjuvant usage to prevent recurrence

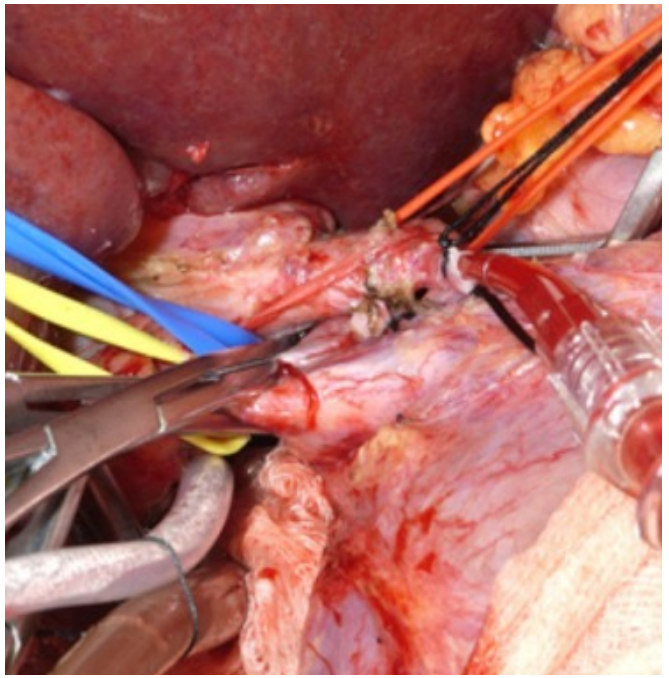
Potential for sequential usage with Immune-Oncology (I/O) agents

Liver metastases reduce I/O therapy efficacy due to the tumor microenvironment inducing immune tolerance, HEPZATO may reduce this effect

Strong Correlation of IHP and PHP Efficacy in mUM Patients

IHP activity in CRC and NET

Meta-analysis of 8 mUM clinical studies [15]		
Endpoint	**IHP (%)**	**PHP (%)**
mOS	17.1	17.3
mPFS	7.2	9.6
hPFS	10	9.5
Complications	39.1	23.8
Mortality	5.5	1.8



IHP / Melphalan in mCRC	
Van Iersel[16]	N=154 ORR 50% mPFS 7.4 months mOS 24.8 months
Alexander[17]	N=120 ORR 61% mOS 17.4 months 2-year survival 34%

IHP in mNET	
Grover[18]	ORR 50% DOR 15 months mhPFS 7 months mOS 48 months

IHP, or Intrahepatic Perfusion, is an invasive surgical technique for delivering high doses of chemotherapy to the liver; procedure related mortality and morbidity prevented common usage. **PHP is a minimally invasive, safer procedure** which accomplishes the same goals as IHP and **can be performed up to 6 times**.

[15] Bethlehem MS et al. Meta-Analysis of Isolated Hepatic Perfusion and Percutaneous Hepatic Perfusion as a Treatment for Uveal Melanoma Liver Metastases. Cancers (Basel). 2021 Sep 21;13(18):4726.
[16] Van Iersel LB, Gelderblom H, Vahrmeijer AL, et al. Isolated hepatic melphalan perfusion of colorectal liver metastases: outcome and prognostic factors in 154 patients. Ann Oncol. 2008;19:1127–34Grover A et al. Isolated Hepatic Perfusion with 200 mg Melphalan for Advanced Noncolorectal Liver Metastases. Surgery. (2005). 136. 1176-82.
[17] Alexander HR Jr, Bartlett DL, Libutti SK, et al. Analysis of factors associated with outcome in patients undergoing isolated hepatic perfusion for unresectable liver metastases from colorectal center. Ann Surg Oncol. 2009;16:1852–9
[18] Grover AC, Libutti SK, Pingpank JF, Helsabeck C, Beresnev T, Alexander HR. Isolated hepatic perfusion for the treatment of patients with advanced liver metastases from pancreatic and gastrointestinal neuroendocrine neoplasms. Surgery. 2004;136(6):1176-1182. doi:https://doi.org/10.1016/j.surg.2004.06.044

Rationale for Combining HEPZATO with IO Therapy

Liver Metastases Suppress IO Therapy Efficacy

nature medicine

Article | Published: 04 January 2021

Liver metastasis restrains immunotherapy efficacy via macrophage-mediated T cell elimination

Science Immunology

SCIENCE IMMUNOLOGY · 30 Oct 2020 · Vol 5, Issue 52 · DOI: 10.1126/sciimmunol.aba0759

Regulatory T cell control of systemic immunity and immunotherapy response in liver metastasis

HBSN HEPATOBILIARY SURGERY AND NUTRITION

Hepatobiliary Surg Nutr. 2021 Aug; 10(4): 526–529.
doi: 10.21037/hbsn-21-215

PMCID: PMC8351020
PMID: 34430535

Liver metastases "siphon" off immunotherapy response

frontiers in Oncology

Front Oncol. 2021; 11: 728018.
Published online 2021 Aug 23. doi: 10.3389/fonc.2021.728018

PMCID: PMC8419351
PMID: 34497771

From Immunogenic Cell Death to Immunogenic Modulation: Select Chemotherapy Regimens Induce a Spectrum of Immune-Enhancing Activities in the Tumor Microenvironment

HEPATOLOGY AASLD

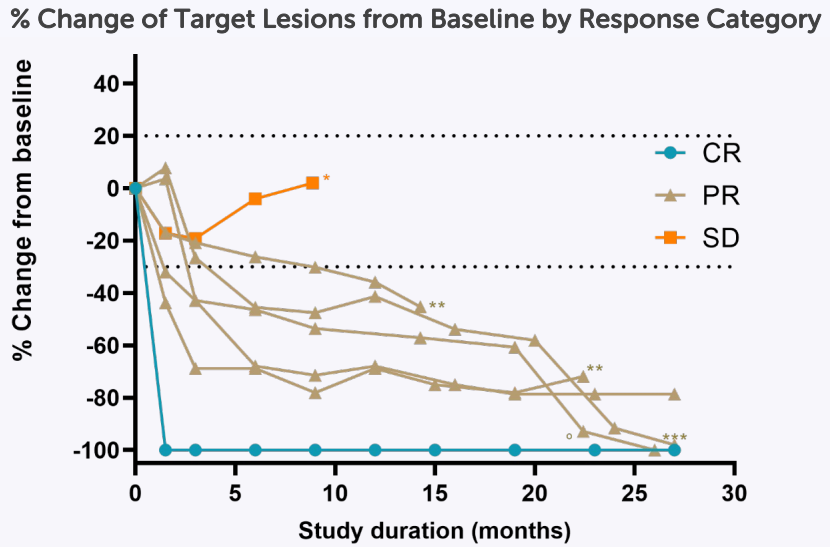
ORIGINAL ARTICLE

Enhancing the therapeutic efficacy of programmed death ligand 1 antibody for metastasized liver cancer by overcoming hepatic immunotolerance in mice

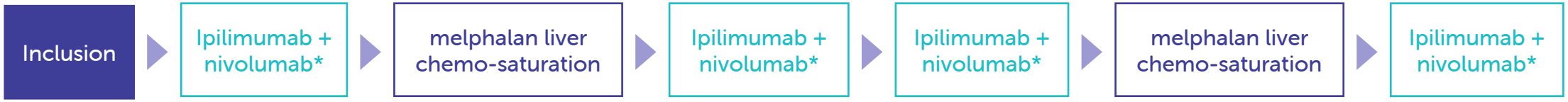
First published: 03 December 2021 | https://doi.org/10.1002/hep.32266 | Citations: 2

Encouraging Signal of Efficacy for PHP and I/O Drug Combination

From Phase 1b Part of the Chopin Trial



- N=7 in Phase 1b portion of the trial[19]
- RP2D: IPI 1mg/kg and NIVO 3mg/kg.
  Well tolerated, no DLTs or deaths.
- 1CR, 6 PR and 1 PD (85.7% ORR, 100% DCR) – meta-analysis of prior IO trials has shown ORR<<10%
- As of 11/15/22 the median follow-up was 29.1 months, the median PFS was 29.1 months, and the median duration of response was 27.1 months. All patients are still alive.
- 3 of 4 patients who subsequently experienced PD continued with treatment in the form of repeated Melphalan Chemosat treatments
- Ongoing randomized Phase 2 (control is Chemosat) has recruited 50% of N=76 patients and will provide an interim analysis at N=40 patients



*c1: 1+1mg/kg, c2: 1+3mg/kg

[19] Tong TML et al. Combining Melphalan Percutaneous Hepatic Perfusion with Ipilimumab Plus Nivolumab in Advanced Uveal Melanoma: First Safety and Efficacy Data from the Phase Ib Part of the Chopin Trial. Cardiovasc Intervent Radiol. 2023 Mar;46(3):350-359.

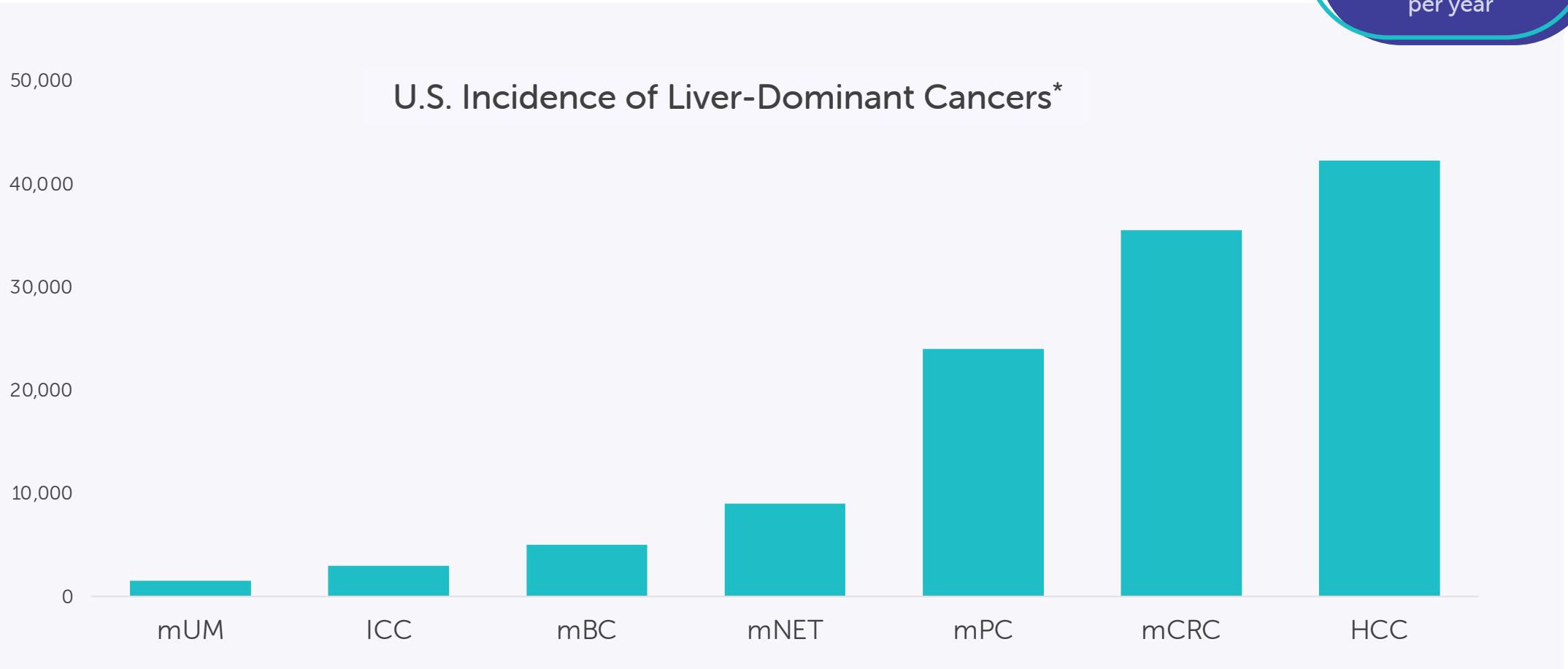
Market Expansion

Significant Upside

U.S. TAM

>$1B

per year



*Metastatic Uveal Melanoma (mUM)

HEPZATO KIT:

Financials and Team

Capital Structure and Share Information

Capitalization	DCTH (NASDAQ)
Shares Outstanding[a]	28.6M
Warrants Outstanding[b]	7.8M
Stock Options Granted	4.2M
Fully Diluted Shares	40.6M
52 Week Low - High[c]	$2.25 - $7.96
30d Average Daily Volume[d]	400k

Financial Metrics	12/31/2023
Cash, Cash Equivalents and Investments[e]	$32.5M
2023 Q4 Cash Burn[f]	$8.1M
Debt[g]	$9.8M

a. As of December 31, 2023; includes 22.8M of Common plus; 1.1M Preferred E & E-1, 0.8M of Preferred F-2; 2.4M of Preferred F-3; Conversion of convertible notes .5M; & 1.0M Pre-funded Warrants as converted. Does not include Tranche B Outstanding Warrants.

b. As of December 31, 2023; 3.6M warrants at a $10 exercise price and 4.2M Tranche B warrants for an aggregate exercise price $25 million exercisable until the earlier of 3/31/2026 or 21 days following recording at least $10 million in quarterly U.S. revenue

c. Used NASDAQ closing price information starting on January 1, 2023 – December 31, 2023

d. 30-day average calculated between December 1, 2023 to December 31, 2023

e. As of December 31, 2023; (10-K filing on March 26, 2024);

f. Q4 Net cash used in operating activities

g. Includes $5.0M of notes convertible at $11.98 per common share equivalent

Multi-Disciplinary, Experienced Leadership Team

Gerard Michel
CHIEF EXECUTIVE OFFICER

- 30+ yrs. pharma/medtech experience
- C-suite roles at Vericel Corp, Biodel, & NPS
- M.S. Microbiology, B.S. Biology & Geology from the Univ. of Rochester School of Medicine
- M.B.A. Simon School of Business & Leadership

Martha S. Rook, PhD
CHIEF OPERATING OFFICER

- 25+ yrs. molecular bio., process dev., manufacturing, supply chain and quality experience
- Senior roles at insitro, Sigilon Therapeutics, and MilliporeSigma
- Ph.D. Biochemistry from MIT, B.S. in chemistry from Texas A&M
- Postdoctoral studies at Harvard Medical School

BOARD OF DIRECTORS

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Steven Salamon	Director
Dr. Gil Aharon, Ph.D.	Director
Gerard Michel	CEO

Vojislav Vukovic, MD PhD
CHIEF MEDICAL OFFICER

- Oncology dev. exec, global clinical expertise
- Former CMO at Aileron, Taiho, Synta
- MD, Univ. of Sarajevo | MSc, PhD, Univ. of Toronto
- Published, AACR, ASCO, ASH, ESMO member

Kevin Muir
GENERAL MANAGER, INTERVENTIONAL ONCOLOGY

- 20+ yrs. medtech/bioTx sales & marketing experience
- Senior leadership roles at BTG, ClearFlow, Aragon Surgical, Kensey Nash Corporation, and Kyphon
- Field Artillery officer, U.S. Army
- B.S. in Management Systems Engineering, U.S. Military Academy at West Point

Sandra Pennell
SVP, FINANCE

- 20+ years' biotech financial oversight experience
- Manages global financial affairs, U.S. GAAP compliance
- Led finance at Invivyd
- VP at Vericel Corp
- MSc, Accountancy, Univ. of Illinois

Thank You

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