UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 3, 2023

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-16133**	**06-1245881**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1633 Broadway, Suite 22C, New York, New York 10019
(Address of principal executive offices) (Zip Code)

(212) 489-2100
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $.01 par value	DCTH	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On January 3, 2023, Delcath Systems, Inc. (the "Company") updated its corporate presentation. A copy of the slides used in the presentation are attached hereto as Exhibit 99.1. The furnishing of the attached corporate presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the slide titled "Forward Looking Statements" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Delcath Systems, Inc. corporate presentation dated January 3 2023
104	Cover Page Interactive File (the cover page tags embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: January 3, 2023

By: /s/ David Hoffman
Name: David Hoffman
Title: General Counsel, Chief Compliance Officer and Secretary

Exhibit 99.1

Delcath

Corporate Presentation

(NASDAQ: DCTH)

January 2023

Forward-looking Statements

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. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the timing and results of the Company's clinical trials, including without limitation the mOM and ICC clinical trial programs, as well as the receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial and the impact of the COVID-19 pandemic 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; 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 HEPZATO KIT/CHEMOSAT system and the potential of the HEPZATO KIT/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; approval of the current or future HEPZATO KIT/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 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; 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

Executive Summary

Delcath aims to be the leader in targeted, safe and highly-effective minimally-invasive treatments for patients with cancers of the liver.

UNMET NEED LIVER CANCER

Incidence US/EU
- >200K primary and metastatic liver tumors per year[1-14]

Current local/regional treatments
- Cannot treat the whole liver
- Targeted to visible and accessible tumors
- Limited in their ability to retreat

PERCUTANEOUS HEPATIC PERFUSION (PHP)

PHP drug-device platform
- Delivers high dose chemotherapy to the entire liver
- Limits systemic exposure
- Minimally invasive, repeatable and well-tolerated

US: HEPZATO KIT
EU: CHEMOSAT

COMPANY & CLINICAL PROGRAM

FOCUS pivotal trial
- Metastatic Ocular Melanoma (mOM)
- Primary endpoint met*
- NDA submission 1Q '22

Real World Evidence
- **>1k** commercial treatments in EU
- Multiple single center publications

POTENTIAL FDA APPROVAL: Q3 2023

LARGE MARKET OPPORTUNITY

Near-term (mOM)
- >$500 TAM in US and EU
- Unsurpassed 1 year survival data

Longer Term (CRC, ICC, Pancreatic, etc.)
- >>$1B TAM
- Investigator interest in more than 10 other tumor types

Liver-Dominant Cancers

High incidence with poor prognosis

Up to **80%**

Many patients with liver metastases are not amenable to surgical resection largely due to extensive tumor burden[15]

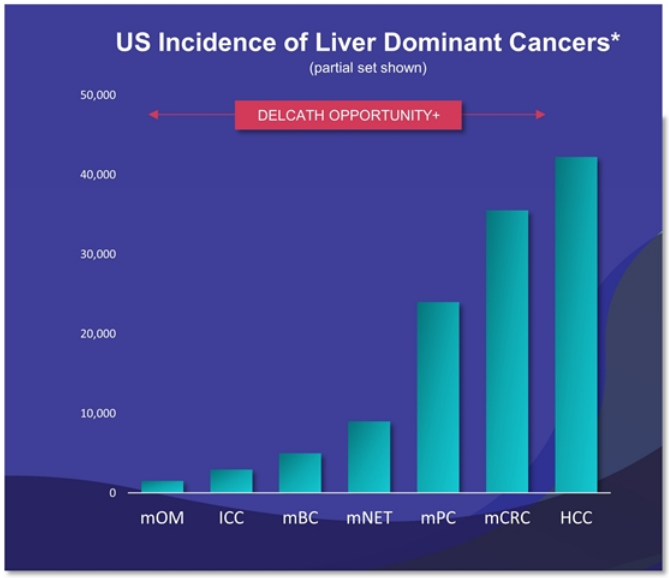
Liver: Common Site of Metastases

Limited Effective Systemic Treatments

- Systemic therapies - low efficacy
- Immuno-oncology agents - become less effective in the presence of metastases

Limited Overall Survival – Unresectable Liver Cancer

- Often the life-limiting organ



*Metastatic Ocular Melanoma (mOM)[1,2], Cholangiocarcinoma (ICC)[3,4], Liver-dominant Breast Cancer (mBC)[7-10], Metastatic Neuroendocrine Tumors (mNET)[6,7] Metastatic Pancreatic Cancer (mPC)[7,13], Metastatic Colorectal Cancer (mCRC)[11,12], Hepatocellular carcinoma (HCC)[15]

Limitations of Current Liver-Directed Therapies

Majority of Treatment

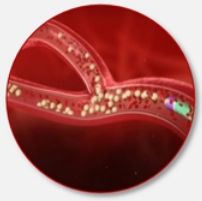
Trans Arterial Chemo Embolization (TACE)[17]

- Beads obstruct blood flow to tumor and elute chemo
- **50-60k treatments per year** in US (and growing)

⊗ Effective, but tumors recur & retreatment limited due to damaged vasculature

Y90[16]

- Radioactive beads delivered into the tumor
- **10-15k treatments per year** in US (and growing)

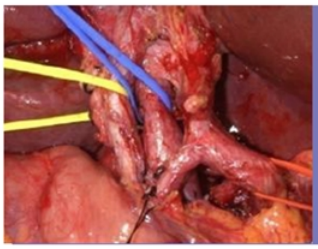


⊗ Diffuse disease: cannot be treated with a tumor-by-tumor modality

⊗ Many tumors are not imageable – micro-metastases are common

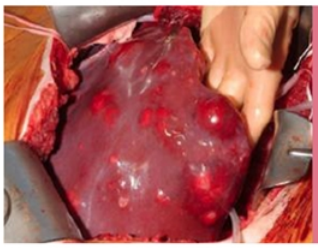
Isolated Hepatic Perfusion (IHP)

The pathway to developing Percutaneous Hepatic Perfusion



Benefits

- Temporarily isolates liver blood supply
- Delivers substantially higher concentrations of chemotherapy (Melphalan) with limited toxicity



Limitations

- High treatment related mortality (>5%)
- Not repeatable and few patients are eligible

HISTORY OF IHP[15]

- **1961** — Dr. Robert Ausman publishes 1st description of IHP technique
- **1975** — Stehlin demonstrates effects of Melphalan in regional perfusion
- **1984** — Isolated liver perfusion in advanced metastases of colorectal cancers studied.
- **1990s** — Phase I-II study of Isolated Hepatic Perfusion using Melphalan for patients with metastatic Ocular Melanoma.
- **1998** — National Cancer Institute conducts trial establishing IHP, using melphalan as a viable treatment option.
- **2000s** — IHP documented efficacy across multiple tumor types including mOM, CRC, and NET

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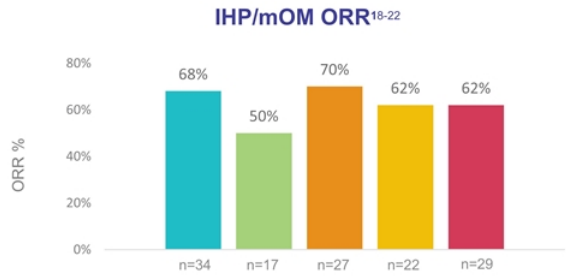
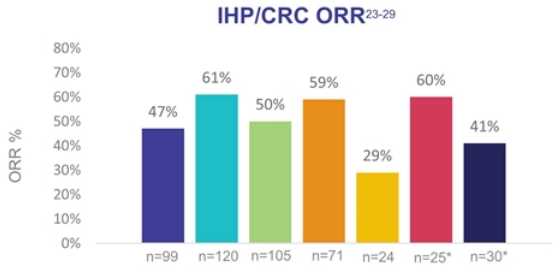
IHP Results in mOM Provided Rationale for PHP in mOM and Provides Rationale for CRC and Other Tumor Types





IHP Studies in other disease states

- Primary HCC and ICC utilizing IHP (melphalan +/- TNF alpha). ORR = 67% (N=13) with a median actuarial survival of 16.3 months.[30]
- Unresectable GEP-NET utilizing IHP (melphalan +/- TNF alpha). ORR = 50% (N=13) with a median actuarial survival of 48 months.[31]

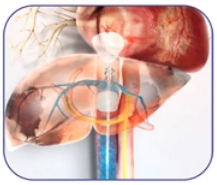
*Hepatic arterial infusion used adjunctively.

HEPZATO™ Kit: Percutaneous Hepatic Perfusion (PHP)

Repeatable, safe & effective liver-focused disease control

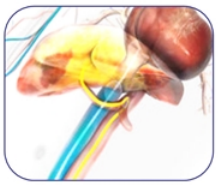
ISOLATION

Hepatic venous flow is isolated, enabling 12x increased dose



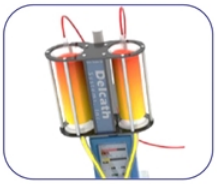
SATURATION

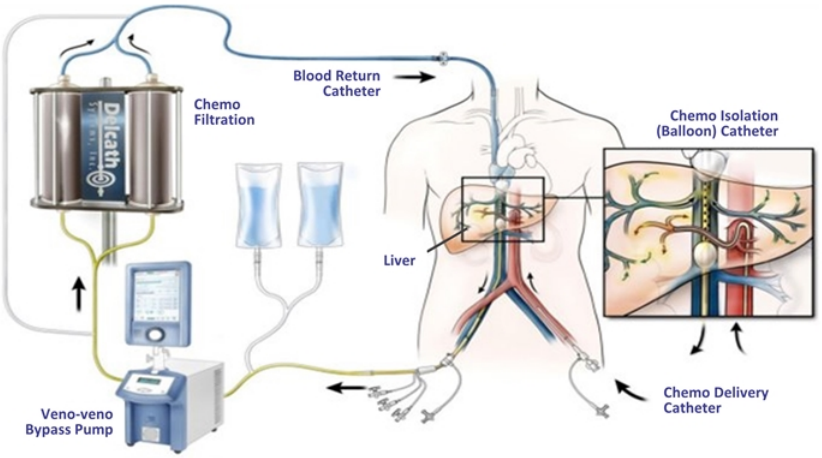
Melphalan (chemo) treats micro and macro lesions simultaneously



FILTRATION

Proprietary filters remove greater than 85% of chemo from the body[33]





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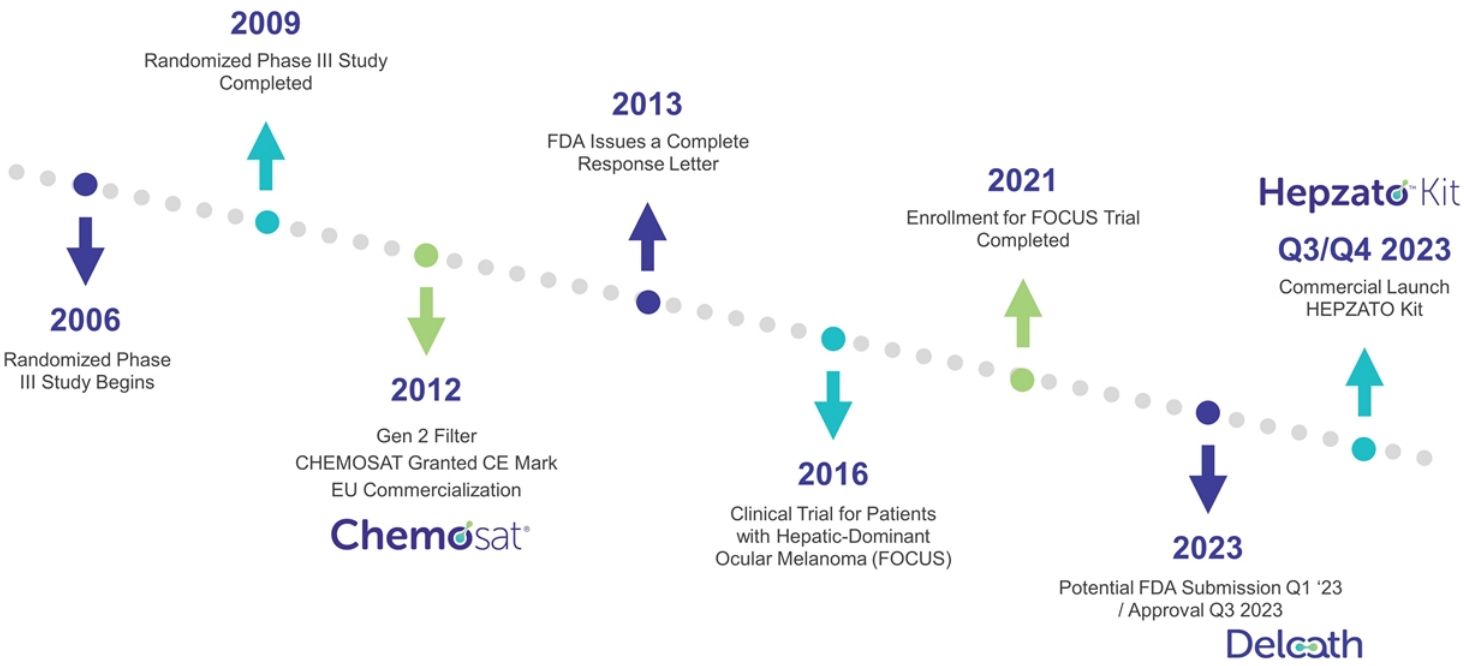
History of HEPZATO Kit Development



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mOM: Beachhead Market Opportunity

No FDA-approved treatment, no current standard of care

Unmet Need

- ~6,000 cases of ocular melanoma per year in the US/EU[12,34]
- 50% metastasize, 90% to the liver[2,35]
- Median survival up to 12 months.[36]

Low Risk Opportunity

- FOCUS pivotal trial has met primary endpoints to support approval in mOM[37]
- Significantly improved safety profile over Gen 1 filter technology
- Real world safety and efficacy demonstrated in EU

High Barrier to Entry

- EXCLUSIVE: Granted orphan indication status allows for extended exclusivity
- HEPZATO is a combination drug device regulated by CDER – no ANDA pathway
- Melphalan granted orphan indication

Favorable Commercial Economics

- Most commonly used systemic treatments (immuno-oncological agents) cost $250K - $1M annually
- 20 US treatment centers = ~80% patients

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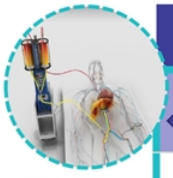
Competitive Landscape for mOM



	Minimally Invasive – Liver Directed			Infusion – Systemic	
	HEPZATO™	TACE[17]	Y90/SIRT[16]	Mono/Combo IO[38]	Tebentafusp[29*]
High Efficacy ORR %	36.3%**	<21%	<17%	5.5%	Up to 9%[25]
OS at 12 months (% surviving)	77%***	-	-	-	73%****
Repeatable (>3x)	✓	X / ✓	X	✓	✓
Preserves QoL	✓	✓	✓	X	✓
FDA Approved for mOM	Q2 2023	X	X	Melanoma	✓
Applicable to most mOM patients	✓	✓	✓	✓	X

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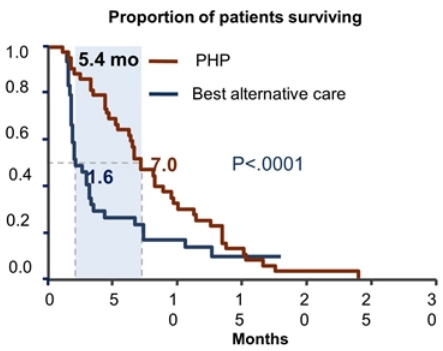
*HLA A+ patient indication only ** Treated Population 29-Apr-2022 data cut ***Post hoc analysis Treated Population, BAC OS 59%, HR 0.48 , 95% CI 0.22, 1.08, p-value = 0.075 based on 1-Jun-2022 data cut
****Control OS 59%, HR 0.51, 95% CI 0.37, 0.71, p-value <0.001

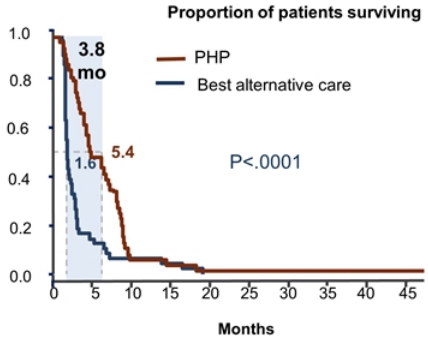
First Phase 3 RCT Results*

Hepatic Progression Free Survival (IRC Assessment)



Hazard Ratio (95% CI) = 0.39

Overall Progression Free Survival (INV Assessment)



Hazard Ratio (95% CI) = 0.42

Response Rates (ITT population)

Cohort	PHP (N=44)	BAC (N=49)	P-Value
hOR	36.4%	2.0%	<0.001
ORR	27.3%	4.1%	=0.003

Crossover design confounded overall survival analysis – most subjects in BAC arm [57.1%] crossed over to PHP arm

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*Mix of mOM and metastatic melanoma with >90% patients diagnosed with mOM - NDA 201848 Clinical Study Report dated 15 August 2012.

Safety Issues and Resulting Improvements

Safety Issue

Hematological toxicities led to 3 patient deaths

Adverse Event G3/4	Gen 1 Hughes 2016[28]	
	%	n
Anemia	62.9%	44
Neutropenia	85.7%	60
Thrombocytopenia	80.0%	56

Inappropriate patient selection and procedural issues led to 1 patient death and other AE's

- ~90% liver involvement causing tumor lysis syndrome

Improvement

Gen 2 Filter introduced in 2013

Adverse Event G3/4	Gen 2 Karydis 2018[33]		% Improvement Gen 1 → 2
	%	n	
Anemia	29.4%	15	**53%**
Neutropenia	31.3%	16	**64%**
Thrombocytopenia	31.3%	16	**61%**

- Protocol amendments were put in place for patient selection
- Training improved

FDA required these issues be addressed prior to the start of the FOCUS trial

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FOCUS Trial

2nd Registration Clinical Trial for Patients with mOM

FOCUS

- Multinational, multicenter, single-arm trial
- Efficacy Endpoints:
  - » Primary: Objective Response Rate (ORR) compared to meta-analysis of IO therapy
  - » Secondary: Duration of Response (DOR), Disease Control Rate (DCR), Overall Survival (OS), Progression Free Survival (PFS)
- 102 subjects enrolled, 91 completed treatments at 23 centers in the US and EU
- HEPZATO Tx every 6-8 weeks up to a maximum of 6 cycles
- Initially a RCT against Best Alternative Care (BAC)
  - » Subsequently modified with FDA agreement to single-arm trial
  - » FDA will view the comparisons with the 32 patient BAC arm as supportive exploratory analyses

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2020 –'21 Initial Approvals Using ORR in Single-Arm Oncology Trials

Two trials n=22 / 38	Single trial n=114	Single trial n=71	Single trial n=95	Single trial n=105	Single trial n=97	Single trial n=108
Danyelza (naxitamab-gqgk)	**Gavreto (pralsetinib)**	**Monjuvi (tafasitamab-cxix)**	**Tazverik (tazemetostat)**	**Zepzelca (lurbinectedin)**	**Tabrecta (capmatinib)**	**Trodelvy (sacituzumab)**
Accelerated	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**
Relapsed or refractory neuroblastoma **ORR** Study 1 = 45% **ORR** Study 2 = 34%	Metastatic *RET* NSCLC **ORR naïve** = 70% **ORR exp.** = 57%	Relapsed or refractory large B-cell lymphoma **ORR** = 39%	Lymphoma positive for EXH2 mutation **ORR mutant** = 69% **ORR** wild-type = 34%	Metastatic SMLC 2nd Line **ORR** = 35%	mNSCLC with mutation MET exon 14 skipping **ORR naive** = 68% **ORR exp.** = 41%	3rd Line Metastatic triple-negative BC **ORR** = 33.3%

Single trial n=50	Single trial N=43	Single trial n=107	Single trial n=31	Single trial n=101	Single trial n=114	Single trial n=209
Koselugo (selumetinib)	**Ayvakit (avapritinib)**	**Pemazyre (pemigatinib)**	**Fyarro (sirolimus)**	**Tivdak (tisotumab vedotin-tftv)**	**Exkivity (mobocertinib)**	**Jemperli (dostarlimab-gxly)**
Accelerated	**Standard**	**Accelerated**	**Standard**	**Accelerated**	**Accelerated**	**Accelerated**
Neurofibromatosis Type 1 **ORR** = 66%	mGIST with PDGFRA exon 18 mutation **ORR** = 84%	Previously treated ICC with FGFR2 fusion **ORR** = 36%	Malignant perivascular epithelioid cell tumor **ORR** = 39%	2nd Line cervical cancer **ORR** = 24%	mNSCLC with EGF exon 20 insertion mutations **ORR** = 28%	MMRD recurrent or advanced solid tumors – 2nd line **ORR** = 41.6%

Single trial n=61 for RCC*	Single trial n=108	Single trial n=124	Single trial n=81	Single trial n=71	Single trial n=112	Single trial n=152
Welireg (belzutifan)	**Truseltiq (infigratinib)**	**Lumakras (sotorasib)**	**Rybrevant (amivantamab-vmjw)**	**Jemperli (dostarlimab-gxly)**	**Libtayo (cemiplimab-rwlc)**	**Tepmetko (tepotinib)**
Standard	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**
von Hippel-Lindau disease +RCC, blastomas, or NET **ORR =** 49%	2nd Line ICC with a FGF 2 fusion **ORR =** 23%	KRAS G12C mutated mNSCLC **ORR =** 36%	mNSCLC with EGFR exon 20 insertion mutations **ORR =** 40%	MMRD endometrial cancer, 2nd Line. **ORR =** 42.3%	Metastatic BCC **ORR meta. =** 21% **ORR adv. =** 29%	mNSCLC w/ met exon 14 **ORR naïve =** 43% **ORR exp. =** 43%

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Focus Trial Success Criteria - Informed By FDA Interactions

Critical Single Arm Efficacy End Points*

- "Clinically Meaningful" ORR**
  - » Trial powered to show an advantage over immuno-oncology (IO) agents
  - » Upper bound at 95% Confidence Interval needed to exceed 8.3%
- "Clinically Meaningful" DOR***
  - » >6 months

Overall Risk Benefit Assessment

- Significantly improved safety relative to first pivotal trial
- Positive trends in exploratory BAC comparisons (ORR, DOR, DCR, PFS and OS)

Best Alternative Care (BAC) Arm	Enrolled N=42	Treated N=32
Dacarbazine	1	0
Ipilimumab	7	1
Pembrolizumab	8	6
TACE	26	25

* Per FDA and SAP ORR is the primary endpoint and per FDA primary analysis population will be treated patient population (SAP defined ITT as primary analysis population)

** FDA did not object to using a meta-analysis of checkpoint inhibitors "to provide support for a clinically meaningful ORR" (476 patients from 16 publications, 95% Confidence Interval for ORR of 3.6% - 8.3%)

*** FDA specified that DOR would be the critical secondary endpoint and requested that patients be followed for at least 6 months to assess durability of response

FOCUS Trial Analysis: Prespecified Endpoint Met*

ORR Advantage Coupled With Meaningful Duration of Response

ORR and DCR in the Treated Population

Efficacy Endpoint	PHP (n=91)	BAC (n=32)	*p* Value*
ORR, n (%)	33 (36.3)	4 (12.5)	0.0117
[95% CI]	[26.44 – 47.01]	[3.51 – 28.99]	
DCR, n (%)	67 (73.6)	12 (37.5)	0.0002
[95% CI]	[63.35 – 82.31]	[21.10 – 56.31]	

DCR, disease control rate; ORR, objective response rate.
*Chi-square test.

DOR in the Treated Population

	PHP (n=91)	BAC (n=32)
Median DOR, months	14	NC
[95% CI]	[8.31 – 17.74]	[6.93 – NC]
Patients with confirmed CR or PR	33 (7 CR, 26 PR)	4 (all PR)
Patients with subsequent PD, n (%)	16 (48.5)	1 (25.0)
Censored, n (%)	17 (51.5)	3 (75.0)

CR, complete response; DOR, duration of response; NC, not calculable; PD, progressive disease; PR, partial response.

26.44% >> 8.3% prespecified threshold**
Exploratory comparison versus BAC supportive

14 Month Duration of Response
7 Complete Responses

* 29-Apr-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

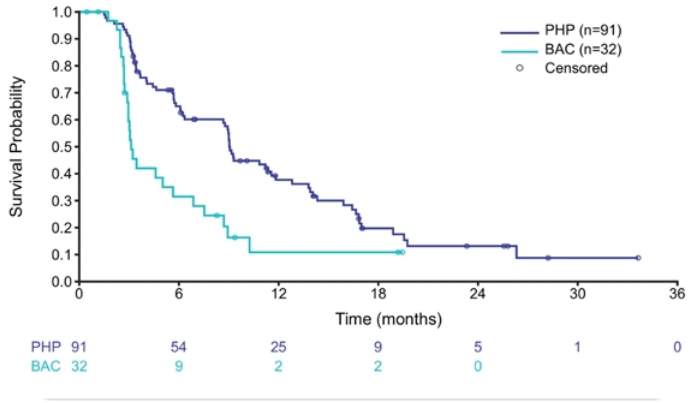
* * Meta-analysis of checkpoint inhibitors (476 patients,16 publications) calculated a 95% Confidence Interval for ORR of 3.6% - 8.3%"

PRELIMINARY DATA - SUBJECT TO CHANGE

Delcath

Progression Free Survival

Kaplan Meier Curves in Treated Populations*



Pre-Specified Exploratory Analyses*

Secondary Endpoint	PHP (n=91)	BAC (n=32)	*p* Value*
Median PFS, months	9.03	3.12	0.0003
[95% CI]	[6.34 – 11.56]	[2.89 – 5.65]	
PFS status, n (%) Events	67 (73.6)	25 (78.1)	
Censored	24 (26.4)	7 (21.9)	
Hazard ratio estimate	0.38		0.0001
[95% CI]	[0.232 – 0.628]		

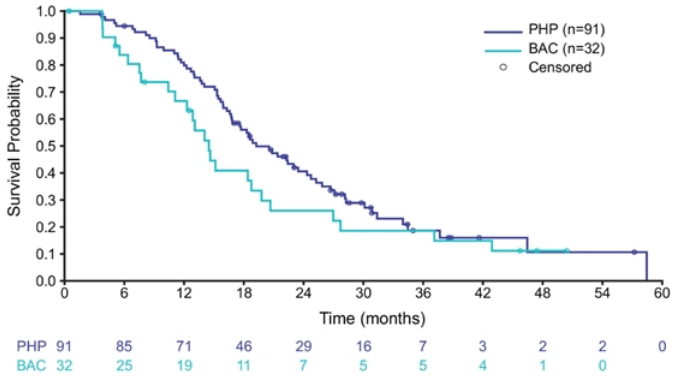
PFS, progression-free survival.

Exploratory comparison versus BAC supportive

* 29-Apr-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

Overall Survival

Kaplan Meier Curves in Treated Populations*



Pre-Specified Exploratory Analyses*

Secondary Endpoint	PHP (n=91)	BAC (n=32)	*p* Value*
Median OS, months	19.25	14.49	0.1479
[95% CI]	[16.72 – 24.35]	[11.10 – 19.78]	
OS status, n (%) Events	67 (73.6)	25 (78.1)	
Censored	24 (26.4)	7 (21.9)	
Hazard ratio estimate	0.700		0.1437
[95% CI]	[0.434 – 1.129]		

*Chi-square test.

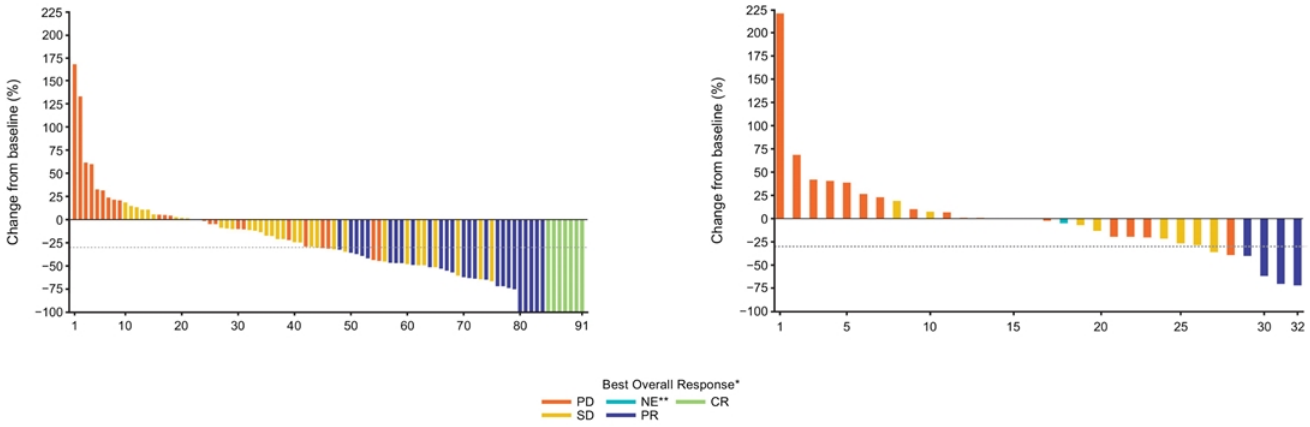
Exploratory comparison versus BAC supportive

** 29-Apr-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

Best Percent Change in Target Lesion Tumor Burden

PHP Patients (n=91)

BAC Patients (n=32)



CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; NE, not evaluable.

* Best Overall Response (BOR) is based on status of target, nontarget and new lesions, so a 30% or 100% reduction in target lesion tumor burden does not necessarily indicate BOR of PR or CR.

** Not evaluable target lesions are represented with a 0% change from baseline.

Hematological Toxicities - Comparison with Previous Trials*

Grade 3 or higher Adverse Events	Focus Trial (n=91)	Hughes 2016[28] (n=70)
Anemia	27 (29.7%)	44 (62.9%)
Thrombocytopenia	24 (26.4%)	56 (80.0%)
Neutropenia	18 (19.8%)	60 (85.7%)

Hematological AE's consistent with European experience

* Data cut 29-Apr-2022

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FOCUS Trial – Safety Comparison with Previous Trials*

Category	FOCUS Trial (N=91)	Pooled Analysis of Prior Studies (N=121)
Patients who Withdrew due to an AE or SAE	20 (22%)	46 (38%)
Patients who Required a Dose Reduction	12 (13.2%)	27 (22.3%)
Average Number of Cycles	4.1	2.8

Improvement in tolerability led to a larger number of treatments

* Data cut on 29-Apr-2022

Substantial Clinical Improvement for All Patients Over the Only Other FDA-Approved Therapy for mOM

- Hepzato Kit is available for 100% patients
  - Study includes treatment naïve; 2nd line and 3rd line patients

- Kimmtrak is for HLA-A*02:01+ patients only (45% of US patients qualify)
  - Study includes only treatment naïve patients

Treatment	PT	n	CR	PR	ORR	SD	DCR	PD	PFS	DOR	mOS	1yr OS
Hepzato Kit*	TN,2L,3L	102	7.7	28.6	36.3	37.4	73.6	25.3	9.03	14	19.3	77%
Kimmtrak[3]	TN	252	0	9	9	35	46	64	3.3	9.9	21.7	73%

CR-Complete Response, PR-Partial Response, ORR-Overall Response Rate, SD-Stable Disease, DCR-Disease Control Rate, PD-Progressive Disease, PFS-Progression Free Survival, DOR-Duration of Response, mOS-Median Overall Survival

* Data cut on 29-Apr-2022

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mOM Beachhead Market Strategy

BEACHHEAD MARKET | mOM | LIVER DISEASE

SIGNIFICANT REVENUE OPPORTUNITY:

- Oncologists* believe ~80% of mOM patients would be HEPZATO candidates - ~800 patients
- Considered a significant advancement
- Payer & hospital finance stakeholders suggest pricing expectations in the range of IO agents
- Tebentafusp is priced at an estimated ~$400K to $1M per patient** and generated $20M in US revenue if the 1st full quarter post launch
- May be positioned as a first-line treatment due to limited efficacy of available therapies.

US TAM

>$400M

per year

*Source: Boston Health Associates primary research n=13 physicians, ** $400K consensus estimates from Immunocore's covering analysts assuming treatment until progression, $1M annualized cost assuming treatment through progression

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Specialized, Targeted Sales Team

Leveraging EAP and Longitudinal Data

EAP (FDA Approved) – Up to 8 Sites

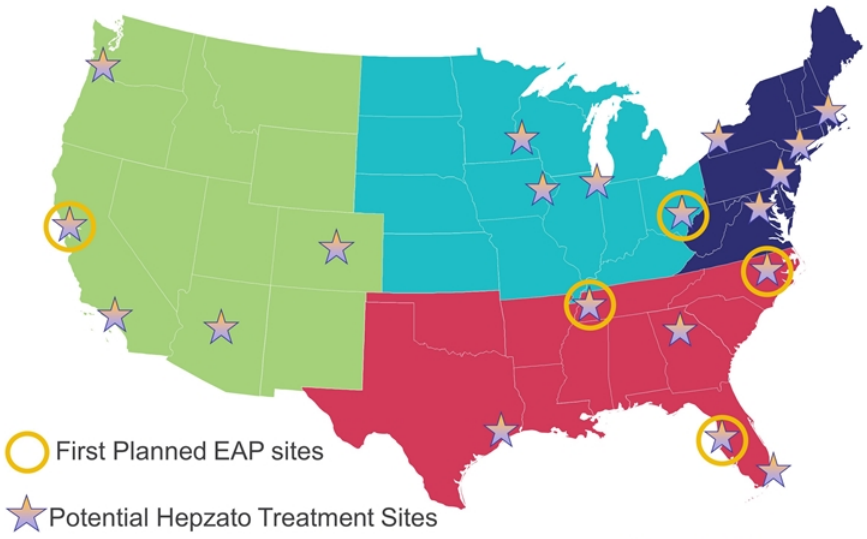
- Provide immediate access to patients
- First Commercial Sites
- Train new medical teams to use Hepzato after launch

Regional Based Sales Team

- Experienced, Oncology focused
- Upon launch, placed in key geographies
- Supplement with Clinical Support Specialist

Leverage Longitudinal Data

- Partnered with data provider to access patient level longitudinal data with 3-week refresh
- Accurately map and quantify surveillance, referral and treatment patterns at the patient and MD level



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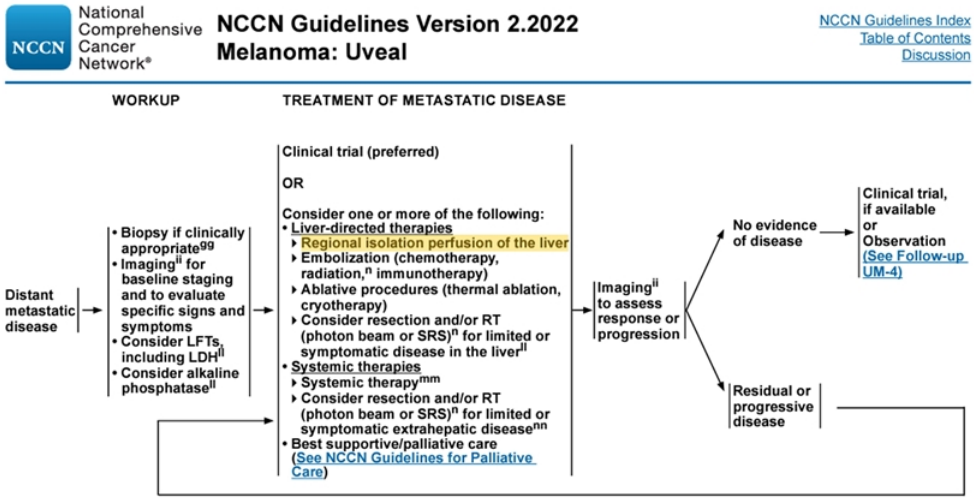
Reimbursement

HEPZATO will be billed as a drug with a J-Code

- Medicare Patients
  - Initially a C-Code
  - Majority of patients will be outpatient (2 midnight rule) with the drug directly covered by Medicare
  - For patients which become inpatient patients split billing (inpatient / outpatient) allows the drug to still be directly billed (e.g., not paid under a DRG)
- Private Payer Patients
  - Private Payers for rare disease generally follow Medicare guidelines and we expect these patients to be treated as outpatients
  - Prior-Authorization of patients might be needed, we are planning to contract out a hub service
  - Centers of Excellence (PPS exempt and NCI designated Cancer Centers) have the leverage to negotiate favorable rates and reimbursement terms (our target sites are all either PPS exempt or NCI Cancer Centers)

PHP Is ALREADY Part of Current NCCN Guidelines for mOM



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.

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Components of Hospital Reimbursement

Assuming Outpatient Pass Through Status with C Code

Drug

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

Healthcare Facility Fee

- Highly variable based on coding – we do not "map" to any existing code
- Using existing codes is advised and should provide the hospital adequate payment

"Physician" payment

- Actually goes to hospital but still matters to MD
- Highly variable based on coding – we do not "map" to any existing code
- Using existing codes is advised and should provide the hospital adequate payment

CPT Code mapping underway – while important, it will not have a meaningful impact on drug pricing decision

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Hepzato vs. Kimmtrak Cost of Treatment Comparisons

At First Assessment (first time to discontinue treatment because of progression)			
Drug	Dose Cost	Treatments #	Total cost
Kimmtrak	$20,261	24	$486,264
Hepzato	t.b.d.	2	t.b.d.

Mean Hepzato treatment vs. mean treatment duration of Kimmtrak			
Drug	Dose Cost	Mean Treatments #	Total cost
Kimmtrak	$20,261	41	$830,701
Hepzato	t.b.d.	4.1	t.b.d.

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EU – Broad Reimbursement Pending Focus Trial Data, But Strong Interest Across Multiple Indications

- CE Marked - available in ~23 centers in 4 countries
- Delcath resumed direct sales on 3/1/22

- NICE (UK) upgraded status from "Research" to "Special Status"
- German reimbursement based on annual hospital special request ("ZE" process)

- Strong interest to fuel additional indications driven by HCP's

- 1,343 commercial Chemosat kits shipped to the EU
- Queensbury facility has been inspected 21 times by the Notified Bodies LRQA and BSI, Health Authorities FDA and ANVISA

CHEMOSAT Used In 13 Tumor Types

~70%: Metastatic Ocular Melanoma (mOM)

Other Types Treated:

- Intrahepatic Cholangiocarcinoma (ICC)
- Hepatocellular Carcinoma (HCC)
- Metastatic Colorectal Cancer (mCRC)
- Metastatic Breast (mBreast)
- Pancreatic
- Metastatic Neuroendocrine Tumors (mNET)
- Metastatic Cutaneous Melanoma (mCM)

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IO Combination Therapy Likely – Ongoing CHOPIN Trial

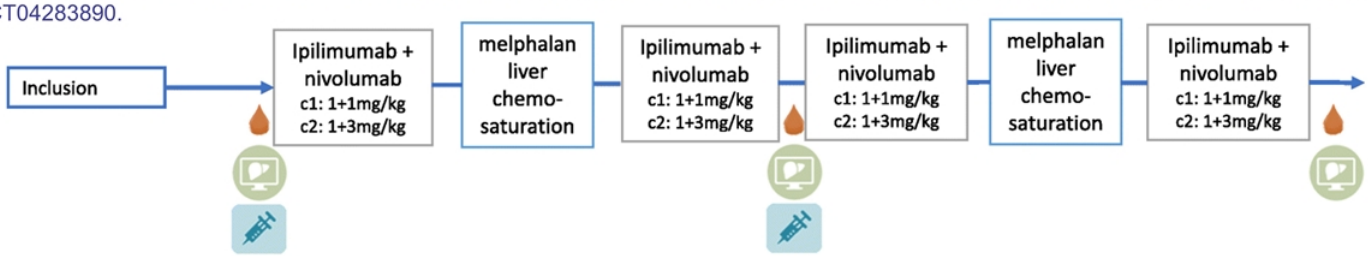
Safety and efficacy of combined melphalan percutaneous hepatic perfusion (M-PHP) and ipilimumab plus nivolumab (IPI+NIVO) in metastasized uveal melanoma (mUM): First results of the phase Ib part of the CHOPIN trial.

Abstract Number: 9560 (2022 ASCO)

Thaïs M.L. Tong Leiden University Medical Center, Department of Medical Oncology/Radiology, Leiden, Netherlands

Results: 7 pts were included (4 male, median age 63.6 years (range 50-74)). Both cohorts were tolerated with no dose-limiting toxicities or deaths. Grade III/IV adverse events (AE) were observed in 2/3 pts in cohort 1 and in 3/4 pts in cohort 2 consisting of SIRS, febrile neutropenia, cholecystitis, neutropenia, thrombopenia, leukopenia, increased transaminases and fever. Grade I/II immune-related AEs occurred in all pts (myositis, hypothyroidism, hepatitis and dermatitis). BOR was 1 complete response, 5 partial responses and 1 stable disease accounting for an **objective response rate (ORR) of 85.7%.** At a median FU time of 20.2 months, 4 pts have an ongoing response. **Currently the median PFS is 22.4 months, and all pts are still alive.**

Conclusions: Combining M-PHP with IPI+NIVO is safe at a dosing of IPI 1 mg/kg and NIVO 3 mg/kg and very promising ORR, PFS and OS have been observed. The randomized phase II part comparing M-PHP versus M-PHP+IPI+NIVO is currently recruiting. Clinical trial information: NCT04283890.



The Local Hepatic Myeloablative Effect May Improve IO Efficacy

nature medicine

Article | Published: 04 January 2021

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

Nat Med. 2021 Jan; 27(1): 152–164. PMID: 33398162
Published online 2021 Jan 4. doi: 10.1038/s41591-020-1131-x

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

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

frontiers in Oncology

Front Oncol. 2021; 11: 728018. PMCID: PMC8419
Published online 2021 Aug 23. doi: 10.3389/fonc.2021.728018 PMID: 34497

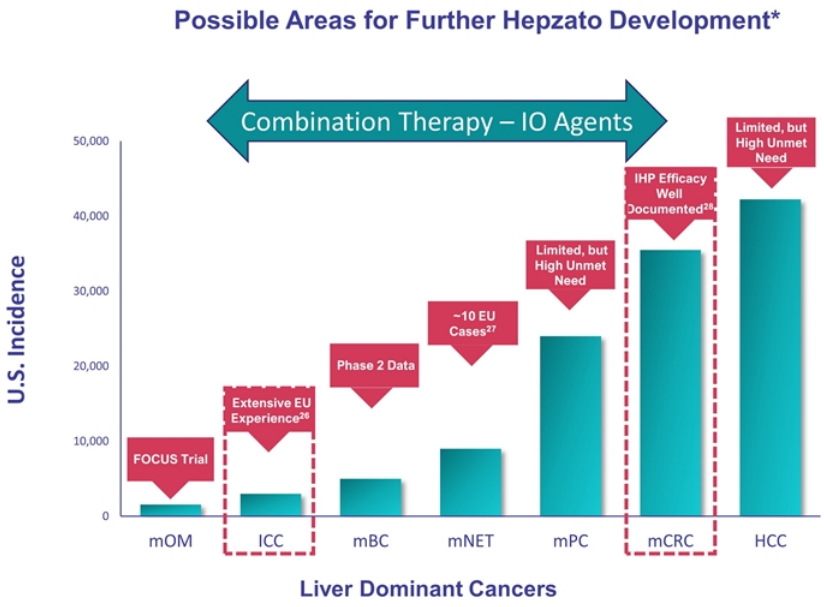
From Immunogenic Cell Death to Immunogenic Modulation: Select Chemotherapy Regimens Induce a Spectrum of Immune-Enhancing Activities in the Tumor Microenvironment

HBSN HEPATOBILIARY SURGERY AND NUTRITION

Hepatobiliary Surg Nutr. 2021 Aug; 10(4): 526–529. PMCID: PMC8351020
doi: 10.21037/hbsn-21-215 PMID: 34430535

Liver metastases "siphon" off immunotherapy response

Market Expansion: Significant Investigator Interest



US TAM

>$1B

Per Year

*Metastatic Ocular Melanoma (mOM)[1,2], Cholangiocarcinoma (ICC)[3,4], Liver-dominant Breast Cancer (mBC)[7-10], Metastatic Neuroendocrine Tumors (mNET)[6,7] Metastatic Pancreatic Cancer (mPC)[7,13], Metastatic Colorectal Cancer (mCRC)[11,12], Hepatocellular carcinoma (HCC)[15]

Clinical Rationale for Broad Development Effort

"Broad-spectrum" alkylating agent given at 12X normal systemic doses	• Promising ORR and DCR signals seen across multiple tumor types in Europe and in earlier studies with IHP
Liver mets are often life limiting and reduce I/O efficacy	• When the liver is the life limiting organ, systemic chemotherapy can be paused and HEPZATO added to prolong survival • Early data supports that combination with I/O agents is safe and effective
PHP treats the entire liver and is not dependent on tumor location	• For patients at high risk of liver mets based on tumor characteristics or ctDNA, adjuvant therapy is logical

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FOCUS Study – Upcoming News Flow

Capital Structure and Share Information

Share Listing - Current	DCTH (NASDAQ)
Shares Outstanding[1]	10.58M
Cash and Cash Equivalents[2]	$14.0M
Warrants Outstanding[3]	3.61M
Stock Options Granted	2.2M
2022 Q3 Cash Burn (YTD)[4]	$17.6M
Debt[5]	$17.6M
52 week Low – High[6]	$2.34 - $11.95
30d Average Daily Volume[7]	57,503

[1] As of September 30, 2022; includes 8.6M of Common plus 1.1M, Preferred E & E-1 & 0.9M Pre-funded Warrants as converted
[2] As of September 30, 2022; (10-Q filing on November 8, 2022) Includes $4.2M of restricted cash
[3] As of September 30, 2022; Warrants at a $10 exercise price
[4] Q3 Net cash used in operating activities
[5] Includes $5.0M of notes convertible at $11.98 per common share equivalent,
[6] Used NASDAQ price information starting on November 8, 2021- November 4, 2022
[7] 30-day average calculated between September 26, 2022- November 4, 2022

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

JOHN PURPURA
Chief Operating Officer

- Past VP and Exec Director roles of Reg. Affairs for Bracco Diagnostics
- Held senior roles Sanofi-Aventis, Bolar Pharma, Luitpold Pharma & Eon Labs
- M.S. Mgmnt. & Policy and B.S. Chemistry and Biology at the State University of NY at Stony Brook

JOHNNY JOHN, MD
SVP Clinical Development & Medical Affairs

- 15+ yrs. experience in oncology drug development and clinical trials
- 11 years of personal clinical practice
- Received M.D. from Mangalore University, India; post-grad training at the University of IL

KEVIN MUIR
VP, Commercial Operations

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

BOARD OF DIRECTORS	
Dr. Roger G. Stoll, Ph.D.	Chairman
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Steven Salamon	Director
Dr. Gil Aharon, Ph.D.	Director
Gerard Michel	CEO

Delcath: A Unique Opportunity

- Novel platform in interventional oncology
- Multiple near-term catalysts (Final data and NDA filing, new indications)
- Safety and efficacy supported by multiple trials and commercial usage
- Initial orphan indication allows for targeted marketing effort and rapid uptake
- Platform has potential utility in multiple indications

THANK YOU

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