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): December 2, 2021

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 December 2, 2021, Delcath Systems, Inc. (the "Company") is planning to hold an Investor Update Meeting from 10:00 am EST – 1:30 pm EST which includes the slides attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01. Other Events.

On December 2, 2021, the Company issued a press release announcing clinical trial data. The full text of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Delcath Corporate Presentation for Investor Update Meeting to be held December 2, 2021.
99.2	Press Release issued on December 2, 2021 by Delcath Systems, Inc. announcing clinical trial data.
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: December 2, 2021

By: /s/ Gerard Michel
Name: Gerard Michel
Title: Chief Executive Officer

Exhibit 99.

Delcath

Corporate Presentation

(NASDAQ: DCTH)

December 2021

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[2-14,29]

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 mid '22

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

ANTICIPATED FDA APPROVAL: Q4 2022

LARGE MARKET OPPORTUNITY

Near-term (mOM)
- >$300M TAM in US and EU
- No effective standard of care

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

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Metastatic Ocular Melanoma (mOM)[2,3], Cholangiocarcinoma (ICC)[4,5], Liver-dominant Breast Cancer (mBC)[8-11], Metastatic Neuroendocrine Tumors (mNET)[6,7], Metastatic Pancreatic Cancer (mPC)[8,16], Metastatic Colorectal Cancer (mCRC)[12,13], Hepatocellular carcinoma (HCC)[29]

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[1]

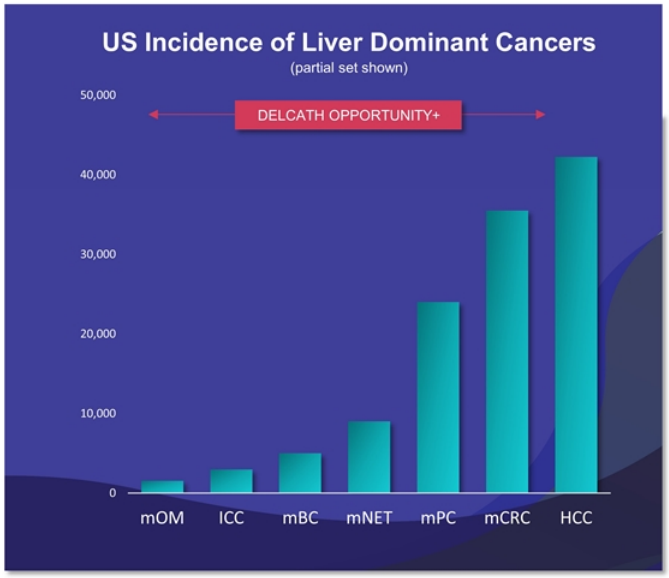
Liver: Common Site of Metastases

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



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Metastatic Ocular Melanoma (mOM)[2,3], Cholangiocarcinoma (ICC)[4,5], Liver-dominant Breast Cancer (mBC)[8-11], Metastatic Neuroendocrine Tumors (mNET)[6,7], Metastatic Pancreatic Cancer (mPC)[8,16], Metastatic Colorectal Cancer (mCRC)[12,13], Hepatocellular carcinoma (HCC)[29]

Limitations of Current Liver-Directed Therapies

Majority of Treatment

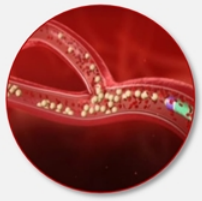
Trans Arterial Chemo Embolization (TACE)

- 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

- 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

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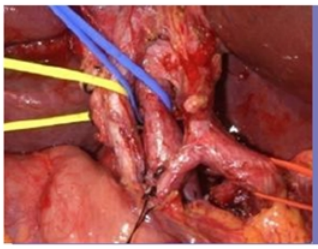
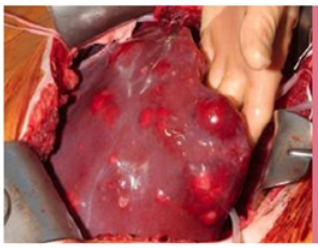
Isolated Hepatic Perfusion (IHP)

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[1]

- **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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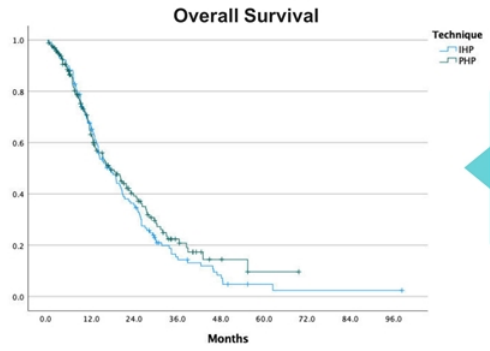
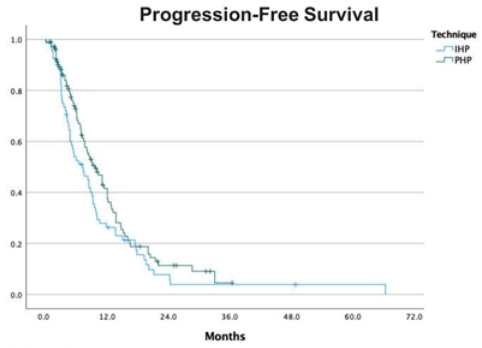
PHP Advances IHP Clinical Benefits



Comparable OS & PFS Between Techniques[30]

cancers



Meta-Analysis of Isolated Hepatic Perfusion and Percutaneous Hepatic Perfusion as a Treatment for Uveal Melanoma Liver Metastases

"There was no difference in overall survival (OS) or progression-free survival (PFS) between IHP and PHP for patients with uveal melanoma liver metastases, but patients have **significantly less** of a **risk for complications and mortality following PHP**."

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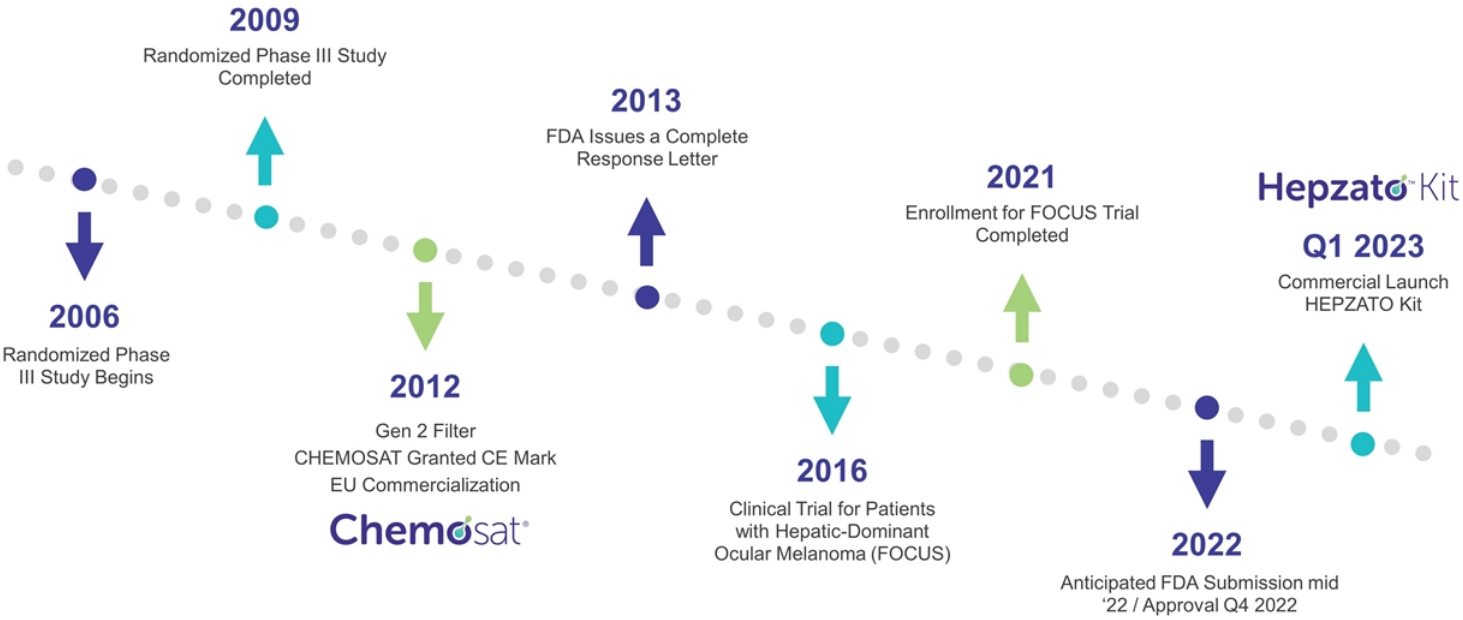
History of HEPZATO Kit Development

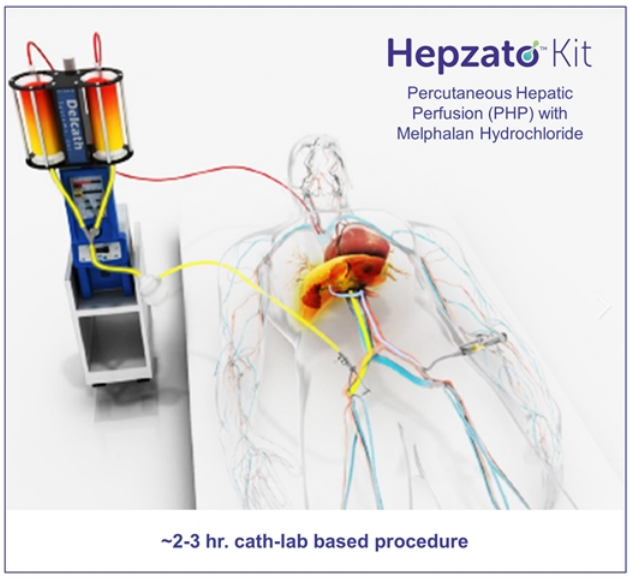


HEPZATO™ Kit: Percutaneous Hepatic Perfusion (PHP)

Repeatable, safe & effective liver-focused disease control

Next-Generation, Minimally-Invasive Liver-Directed Treatment

The only minimally invasive cancer treatment that isolates the liver from systemic circulation, allowing for repeated delivery of high-dose chemo to the entire liver while limiting systemic side effects.



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Three Steps. Targeted Treatment.

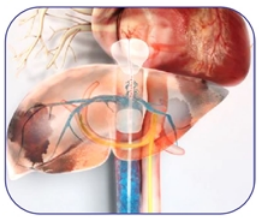
Hepzato™ Kit

Novel, whole-organ treatment that provides targeted, high-dose liver chemo while minimizing systemic exposure.

1

ISOLATION

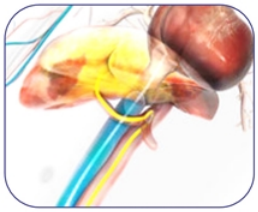
Hepatic venous flow is isolated, enabling 12x increased dose



2

SATURATION

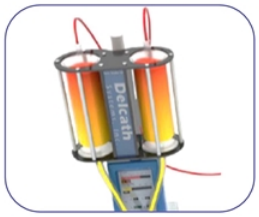
Melphalan (chemo) treats micro and macro lesions simultaneously



3

FILTRATION

Proprietary filters remove greater than 85% of chemo from the body[1]*



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*In vitro model - Data on file

1. de Leede E., et al. Cardiovascular Intervent Radiol. 2017 Aug;40(8):1196-1205.

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[13,17]
- 50% metastasize, 90% to the liver[3,14]
- Median survival up to 12 months.[15]

Low Risk Opportunity

- FOCUS pivotal trial has met primary endpoints to support approval in mOM[19]
- 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

- Payer/hospital financial stakeholder interviews suggest expected pricing is on par with immuno-oncological agents ~$250k annually
- 20 US treatment centers = ~80% patients

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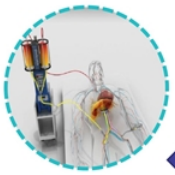
Competitive Landscape for mOM

HEPZATO™ is the only highly-effective, targeted mOM treatment that enables repeat treatments while optimizing QoL



	Minimally Invasive – Liver Directed			Infusion – Systemic	
	HEPZATO™	TACE[23]	Y90/SIRT[21]	Mono/Combo IO[24]	Tebentafusp[22*]
High Efficacy ORR %	31.4%	<21%	<17%	5.5%	Up to 9%[25]
OS at 12 months (% surviving)	75%**	-	-	-	73%***
Repeatable (>3x)	✓	X / ✓	X	✓	✓
Preserves QoL	✓	✓	✓	X	✓
FDA Approved for mOM	Q4 2022	X	X	Melanoma	Pending
Applicable to most mOM patients	✓	✓	✓	✓	X

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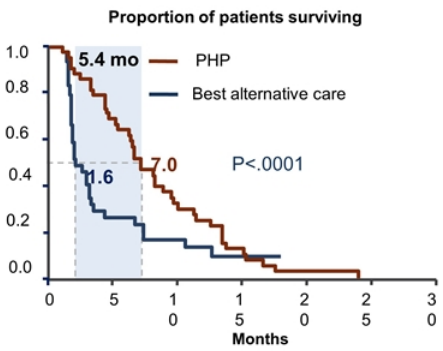
*HLA A+ patient indication only **mITT, BAC OS 47%, HR 0.37 , 95% CI 0.17, 0.79, p-value 0.01
***Control OS 59%, HR 0.51, 95% CI 0.37, 0.71, p-value <0.001

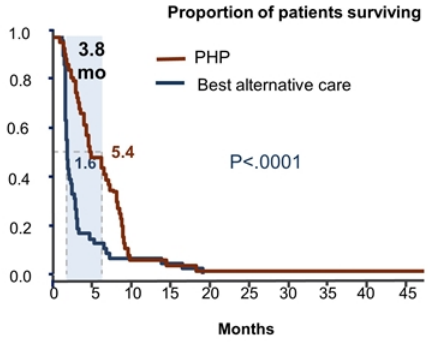
First Phase 3 RCT Results*

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

*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[20]	
	%	n
Anemia	62.9%	44
Neutropenia	85.7%	60
Thrombocytopenia	80.0%	56

Improvement

Gen 2 Filter introduced in 2013

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

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

- ~90% liver involvement causing tumor lysis syndrome

- 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

OVERVIEW:

- Multinational, multicenter, single-arm trial
- Endpoints:
  - » Primary: Objective Response Rate compared to historic control
  - » Secondary: Duration of response, disease control rate, overall survival, progression free survival, safety, PK, QoL
- 102 subjects enrolled, 91 completed treatments at 30 centers in the US and EU
- HEPZATO Tx every 6-8 weeks up to a maximum of 6 cycles

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FOCUS Trial Analysis: Prespecified Endpoint Met

Intent to Treat:

Primary Effectiveness Endpoint[19]	PHP (N=91 treated + 11 untreated)	95% CI*
Objective Response Rate	**31.4%**	**[22.55-41.31]**

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

Lower bound 22.55% far exceeds 8.3% upper bound prespecified threshold.

PRELIMINARY DATA - SUBJECT TO CHANGE

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Hematological Toxicities - Comparison with Previous Trials

Grade 3 or higher Adverse Events	Focus Trial (n=91)	Hughes 2016 (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

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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

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Recent Initial Approvals Using ORR in Single-Arm Oncology Trials

Single trial n=50								
Danyelza (naxitamab-gqgk)	**Gavreto (pralsetinib)**	**Monjuvi (tafasitamab-cxix)**	**Tazverik (tazemetostat)**	**Zepzelca (lurbinectedin)**	**Tabrecta (capmatinib)**	**Trodelvy (sacituzumab)**	**Pemazyre (pemigatinib)**	**Koselugo (selumetinib)**
Accelerated	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**	**Accelerated**
Relapsed or refractory neuroblastoma in bone or marrow post response or stable disease to prior therapy	Metastatic *RET* fusion-positive NSCLC	Relapsed or refractory diffuse large B-cell lymphoma	Relapsed or refractory follicular lymphoma positive for EXH2 mutation	Metastatic SMLC with progression on or after platinum chemotherapy	Metastatic NSCLC with mutation MET exon 14 skipping	Metastatic triple-negative breast cancer after at least 2 prior metastatic disease therapies	Previously treated metastatic cholangiocarcinoma with FGFR2 fusion	Neurofibromatosis Type 1 with inoperable plexiform neurofibromas

Single trial N=43				Pooled subgroup analysis n=51 | 3 single arm trials				Pooled subgroup analysis n=72 | 2 single arm trials
Ayvakit (avapritinib)	**Enhertu (famtrastuzmab deruxtecan)**	**Padcev (enfortumab vedotin)**	**Brukinsa (zanubrutinib)**	**Rozlytrek (entrectinib)**	**Xpovio (selinexor)**	**Balversa (erdafinitib)**	**Vitrakvi (larotrectinib)**	**Libtayo (cemiplimab-rwlc)**
Standard	**Accelerated**	**Accelerated**	**Accelerated**	**Standard**	**Accelerated**	**Accelerated**	**Accelerated**	**Standard**
Unresectable or metastatic gastrointestinal stromal tumor with PDGFRA exon 18 mutation	Unresectable or metastatic HER2+ breast with two or more prior anti HER2 regimens in metastatic setting	Metastatic urothelial cancer with previously received PD-1 or PD-L1 and platinum chemotherapy	Mantle cell lymphoma with at least one prior therapy	Metastatic NSCLC that is *ROSI+*	Relapsed or refractory multiple myeloma with at least 4 prior therapies	Metastatic unrothial carcinoma with susceptible FGFR 3(2) alterations	Solid tumors with neurotrophic receptor tyrosine kinase fusion	Metastatic squamous cell carcinoma

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Supportive Evidence: Comparison Versus BAC

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

Amended Study

- FOCUS was initially a RCT against Best Alternative Care (BAC)
- Due to enrollment challenges as a result of known limited efficacy of BAC control arm and availability of treatment with PHP (CHEMOSAT), FDA agreed to amend it to single-arm, non-RCT

FOCUS Trial – Exploratory Analyses vs BAC

Statistically Significant ORR and DCR Advantage vs. BAC

Intent to Treat:

Efficacy Endpoint	PHP (N=102)	BAC (N=42)	P-Value*
Objective Response Rate - Primary	32 (31.4%)	4 (9.5%)	0.0059
95% CI	[22.55 - 41.31]	[2.66 - 22.62]	
Disease Control Rate	67 (65.7%)	12 (28.6%)	<0.0001
95% CI	[55.63 - 74.81]	[15.72 - 44.58]	

Modified Intent to Treat**:

Efficacy Endpoint	PHP (N=91)	BAC (N=32)	P-Value*
Objective Response Rate	32 (35.2%)	4 (12.5%)	0.0154
95% CI	[25.44 – 45.88]	[3.51 – 28.99]	
Disease Control Rate	67 (73.6%)	12 (37.5%)	0.0002
95% CI	[63.35 - 82.31]	[21.10 - 56.31]	

*Chi-square
** mITT Population – any patient who received at least one study treatment

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FOCUS Trial – Exploratory Analyses vs BAC

ORR Advantage Coupled With Meaningful Duration of Response

	mITT Population	
	PHP (N=91)	BAC (N=32)
Duration of Response (DOR, median)	14.00 mos.	NC
95% CI	[8.54 - NC]	[6.93 - NC]
Patients with Confirmed CR or PR	32	4
Patients with Subsequent PD	14 (43.7%)	1 (25.0%)
Censored	18 (56.3%)	3 (75.0%)

FOCUS Trial - Exploratory Analyses vs BAC

PHP Progression-Free Survival ~3X that of BAC[19]

Secondary Endpoint		PHP (N=91)*	BAC (N=32)*	P-Value*
Median Progression-Free Survival		9.03 mos.	3.12 mos.	0.0007
	95% CI	[6.34 - 11.56]	[2.89 - 5.65]	
PFS Status	Events	64 (70.3%)	25 (78.1%)	
	Censored	27 (29.7%)	7 (21.9%)	
Hazard Ratio Estimate		0.39		0.0002
	95% CI	[0.237 - 0.643]		

* Treated patients only, per the protocol untreated patients were not followed

Focus Trial Results – 12 Month Survival*

Intent to Treat:

Secondary Endpoint	PHP (N=102)	BAC (N=42)
% Surviving at 12 months	68%	36%
Hazard Ratio**	0.42	
95% CI	0.20 - 0.88	
p-value	0.0215	

Modified Intent to Treat***:

Secondary Endpoint	PHP (N=91)	BAC (N=32)
% Surviving at 12 months	75%	47%
Hazard Ratio*	0.37	
95% CI	0.17, 0.79	
p-value	0.010	

* Post Hoc analysis
** Log Rank Test
*** mITT Population – any patient who received at least one study treatment

Focus Trial Results – Overall Survival

Data still maturing
PHP enrollment ended in May 2020, BAC in 2018
OS will be analyzed 24 months post last patient last treatment

Intent to Treat:

Secondary Endpoint		PHP (N=102)*	BAC (N=42)*	P-Value*
Overall Survival (OS, Median)		19.25 mos.	14.06 mos.	0.2021
	95% CI	[16.30 – 24.35]	[9.99 – 19.78]	
OS Status	Events	66 (64.7%)	23 (54.8%)	
	Censored	36 (35.3%)	19 (45.2%)	
Hazard Ratio Estimate		0.739		0.2308
	95% CI	[0.451 – 1.212]		

Modified Intent to Treat**:

Secondary Endpoint		PHP (N=91)*	BAC (N=32)*	P-Value*
Overall Survival (OS, Median)		20.53 mos.	14.06 mos.	0.1626
	95% CI	[16.59 – 24.53]	[9.99 – 19.78]	
OS Status	Events	64 (70.3%)	23 (71.9%)	
	Censored	27 (29.7%)	9 (28.1%)	
Hazard Ratio Estimate		0.708		0.1725
	95% CI	[0.431 – 1.163]		

*Chi-square
** mITT Population – any patient who received at least one study treatment

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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 over other therapies
- Payer & hospital finance stakeholders suggest pricing expectations in the range of IO agents - ~$256k per yr.
- May be positioned as a first-line treatment due to limited efficacy of available therapies.

US TAM

>$200M

per year

*Source: Boston Health Associates primary research n=13 physicians

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Experienced Interventional Oncology Leadership

- Kevin Muir-VP Commercial
  - Formerly Head of Sales for US Therasphere Y90 (BTG/Boston Scientific)
  - Led sales revenue growth from $60M to $220M
  - Built sales team to focus on all members of the MDT

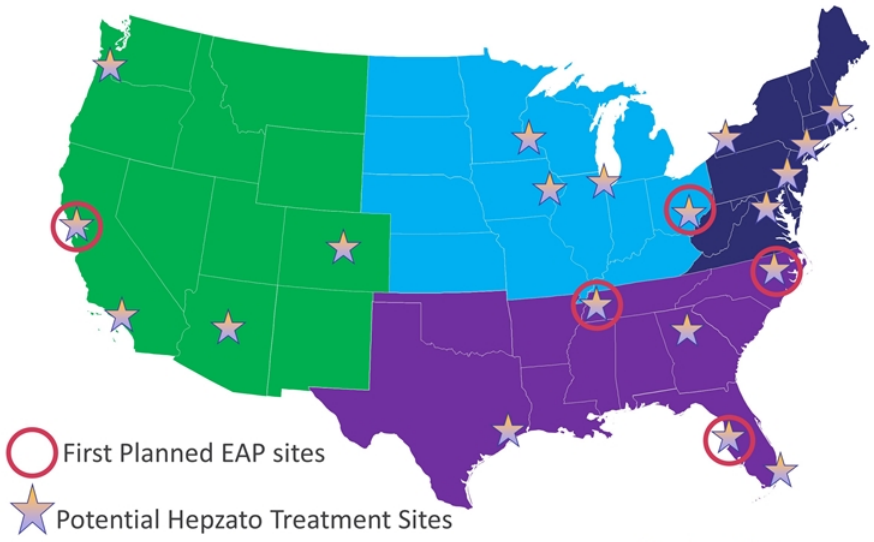
- Michael Ujhelyi - US Medical Director
  - Formerly Head of Medical Affairs US Therasphere (BTG/Boston Scientific)
  - Built Medical Science Liaison Team
  - Responsible for Clinical Trial recruitment and IISs and IITs

Specialized, Targeted Sales Team Will Leverage Expanded Access Protocol (EAP) and Longitudinal Data

EAP (FDA Approved)
- 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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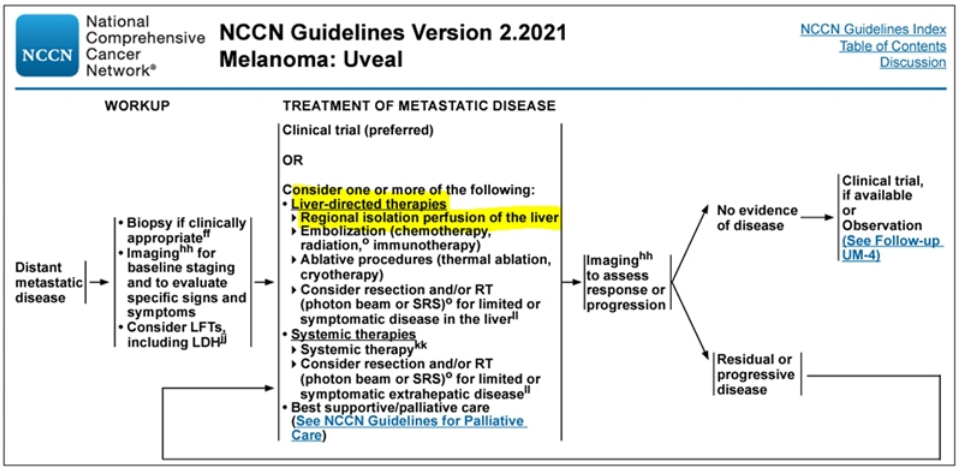
PHP Is Likely Part of Current NCCN Guidelines for mOM

"Regional Isolation Perfusion of the Liver"

PHP- Percutaneous Hepatic Perfusion



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Reimbursement

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

- Medicare Patients
  - 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)

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

- CE Marked - available in ~23 centers in 4 countries
- Currently distributed by MEDAC Pharma
- MEDAC has been notified of our intent to terminate – discussions ongoing

- 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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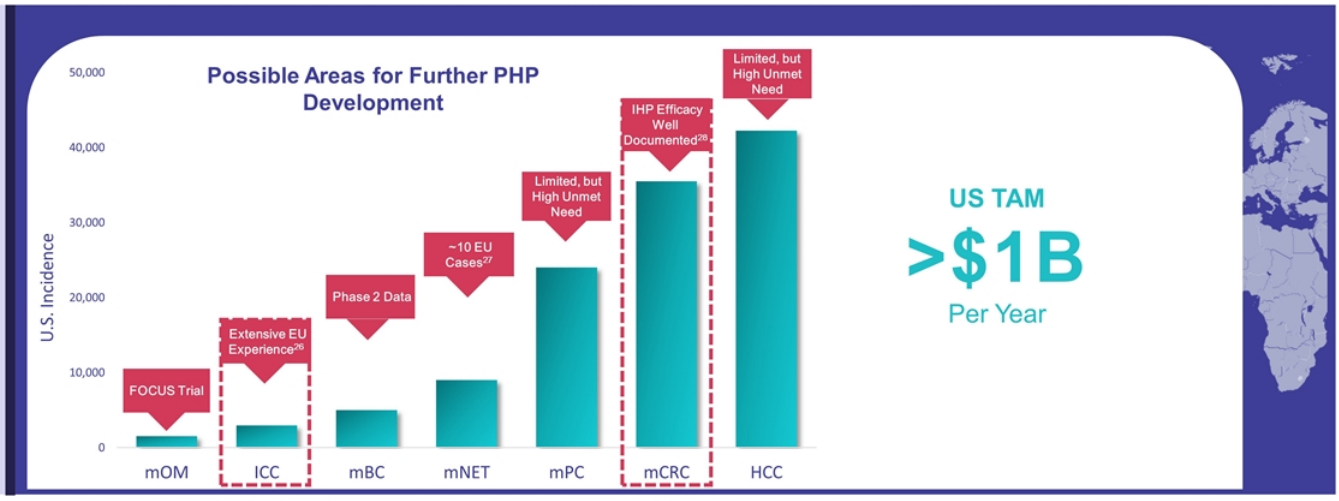
Market Expansion: Liver Disease

BEACHHEAD MARKET | mOM

LIVER DISEASE



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Metastatic Ocular Melanoma (mOM)[2,3], Cholangiocarcinoma (ICC)[4,5], Liver-dominant Breast Cancer (mBC)[8-11], Metastatic Neuroendocrine Tumors (mNET)[6,7], Metastatic Pancreatic Cancer (mPC)[8,16], Metastatic Colorectal Cancer (mCRC)[12,13], Hepatocellular carcinoma (HCC)[29]

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
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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Near Term HEPZATO Development Plan

	Ongoing	2022 Trial Starts	2023+
Pan Tumor		I/O Combination	
Other		LD Pancreatic NET	LD Breast and/or Pancreatic
ICC		2nd Line	
CRC		LD 2nd Line Additive Stage IV Post Resection ctDNA+ Hepatic ctDNA Liver MRD Dx	Stage II/III Post Resection LD MRD
OM	I/O Combination FOCUS	No Radiological Disease - ctDNA+	

Ongoing | Investigator Interest Confirmed | Pending | Multi-Center Sponsored | Investigator Initiated

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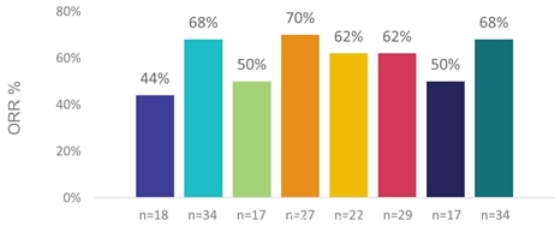
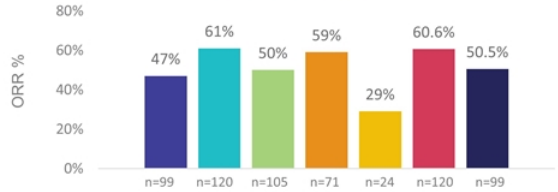
Liver Dominant CRC IHP Results Provide Strong Rationale for CRC PHP Trials

mOM Results Similar Between IHP and PHP

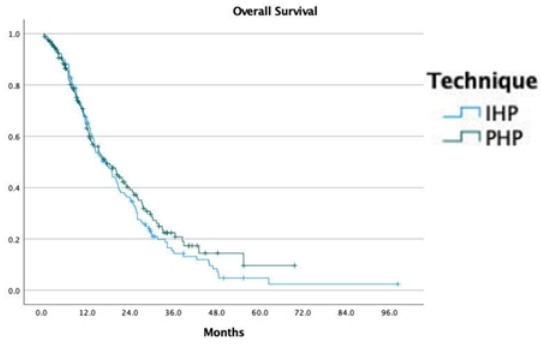
IHP/mOM ORR[31-38]



IHP/CRC ORR[43-49]



mOM Overall Survival



Pending Future Investigation

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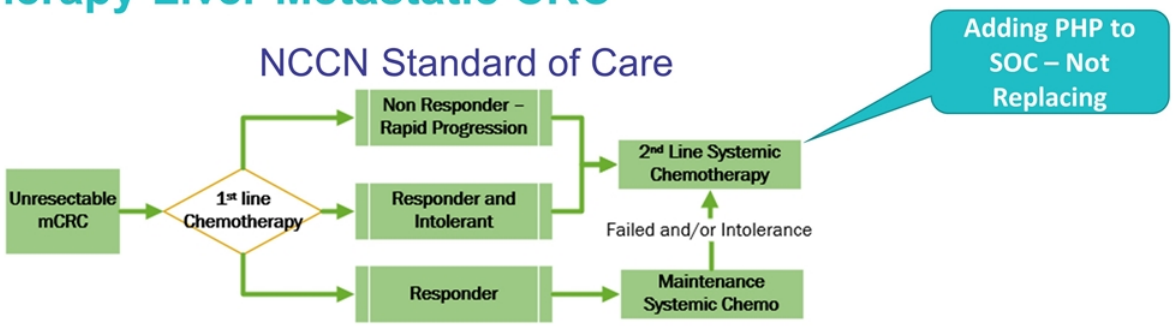
2nd Line Therapy Liver Metastatic CRC



Population Base

US Incidence = 160K new CRC Cases	TAM
50% diagnosed metastatic	80K
50% Liver only metastases	40K
65-75% are unresectable	26-30K
85% fail 1st line therapy by 24-36 months	**22-25K**

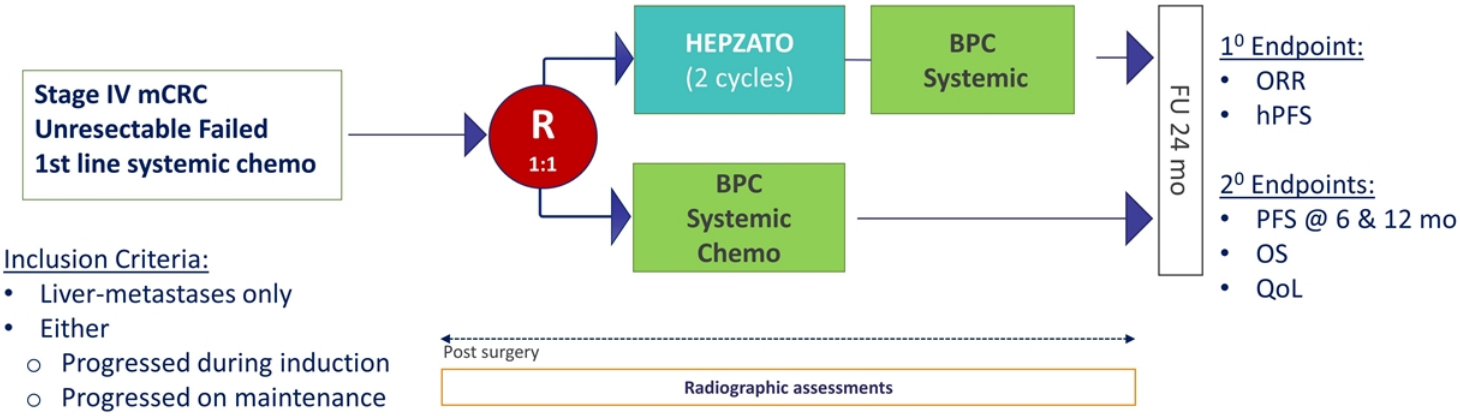
Current Treatment Options

- Therapy Goal = Disease control
- 1st line systemic chemotherapy - 85-90% will have disease progression within 3 yrs

National Cancer Institute. Cancer Stat Facts: Colon and Rectum Cancer. https://seer.cancer.gov/statfacts/html/colorect.html
Bulut G etal PLoS ONE 16(11): e0259622. https://doi.org/10.1371/journal.pone.0259622.

Hepzato in Stage IV Unresectable mCRC

Hepzato + Best Physician Choice vs Best Physician Choice



Inclusion Criteria:

- Liver-metastases only
- Either
  - Progressed during induction
  - Progressed on maintenance
  - Intolerant
- ECOG 1/2

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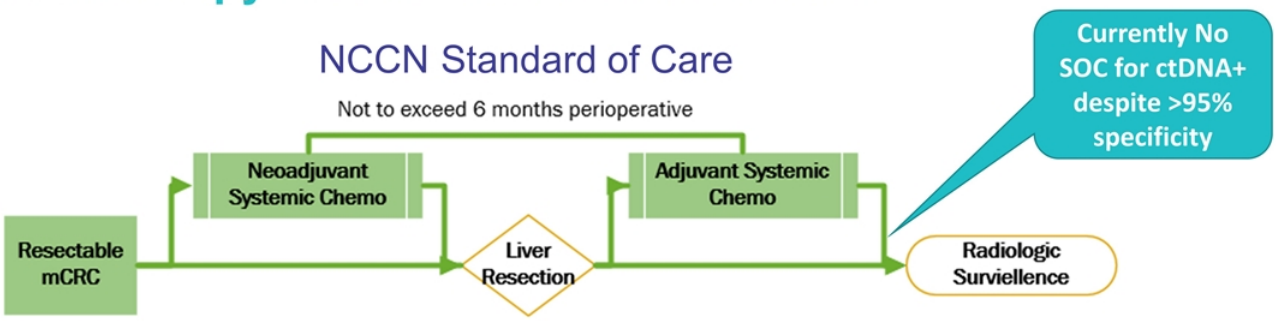
Adjuvant Therapy : CRC Post Liver Resection



Population Base

US Incidence = 160k new CRC Cases	TAM
50% diagnosed metastatic	80K
50% Liver only metastases	40K
25-35% are resectable; initial or converted to resectable	10-14K
70% ctDNA positive (based on recurrence)	**7-10K**

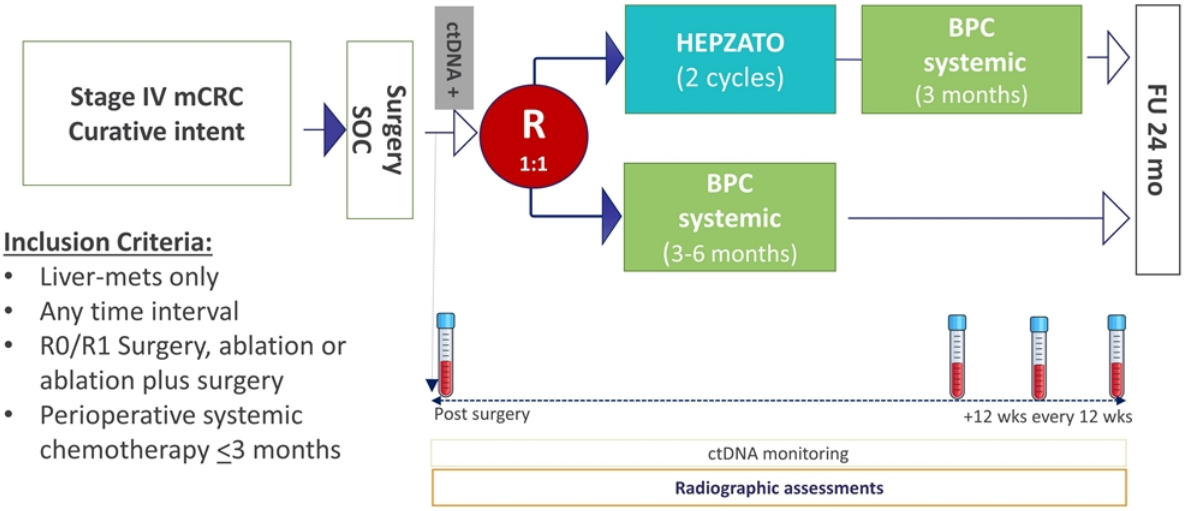
Siegel et al CA CANCER J CLIN 2020;70:145–164
National Cancer Institute. Cancer Stat Facts: Colon and Rectum Cancer. https://seer.cancer.gov/statfacts/html/colorect.html.
Holch et al Visc Med 2017;33:70–75 DOI: 10.1159/000454687

Current Treatment Options

- Therapy Goal = Prevent recurrence
  - ➢50-70% recurrence rate within 24 months
  - ➢ 70% recur in the liver
- Current adjuvant treatment is +/- chemo up to 6 months perioperative treatment duration

HEPZATO in Post-resection Stage IV ctDNA Positive Patients

Hepzato + Best Physician Choice vs Best Physician Choice



Inclusion Criteria:

- Liver-mets only
- Any time interval
- R0/R1 Surgery, ablation or ablation plus surgery
- Perioperative systemic chemotherapy ≤3 months

1^0 Endpoint:

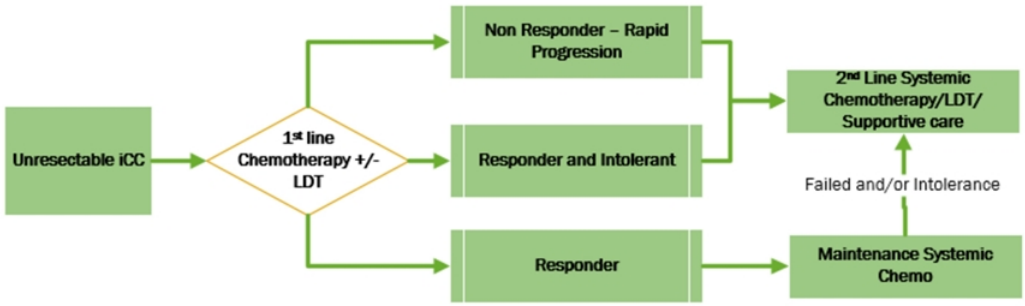
- DFS

2^0 Endpoints:

- PFS by ctDNA status
- OS
- Toxicity / SAE
- QoL

Standard of Care & Epidemiology for iCC

NCCN Standard of Care



Population Base

US Incidence = 3.5k new iCC Cases	TAM
90-95% Unresectable or resection with recurrence	3.2-3.3K

Current Treatment Options

- Therapy Goal = Disease control
- 80% respond to 1st line therapy
- 75% will have disease progression by 1 year

Gupta et al HepatoBiliary Surg Nutr 2017;6(2):101-104

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Advanced ICC – 2nd Line

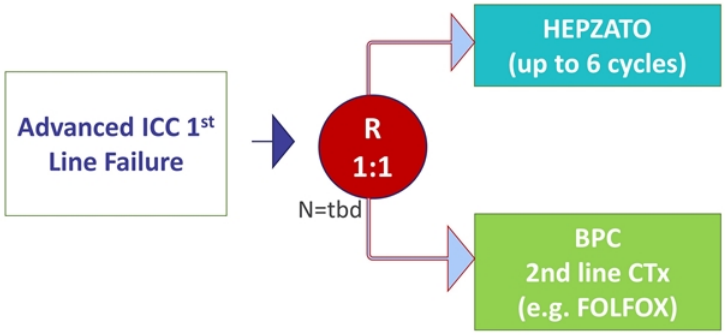
CHEMOSAT in ICC - European Experience[31,32,32]

N	ORR	DCR	CR
20	30%	75%	3

Hepzato 2nd Line vs Best Physician's Choice

Inclusion criteria

- Liver dominant disease
- 1 prior line of CTx (e.g. gemcitabine or 5FU-containing based regimen)
- Adequate liver function
- ECOG 0-1



1⁰ Endpoint:
PFS@ 6 mo and 12 mo

2⁰ Endpoints:

- OS
- ORR
- QoL
- Safety

Critical IITs

Hepatic ctDNA Validation

- The liver clears 70% - 80% of ctDNA
- Systemic ctDNA levels should be higher than hepatic vein levels unless there is residual disease in the liver
- The study will collect samples from CRC patients with confirmed liver and non liver mets
- Validation will enable a study targeting stage II/III CRC patients with hepatic MRD - metachronous liver metastases occur 50% in patients post primary resection[34],
- Hepatic MRD in CRC up to 40K patient TAM

Treating ctDNA+ OM

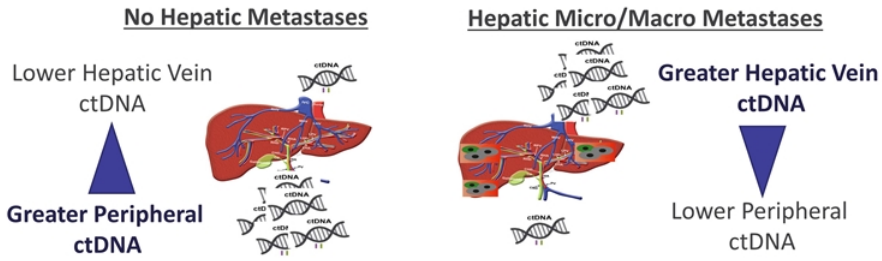
- ~90% of mOM patients present with liver mets
- ctDNA has high specificity for disease recurrence
- ctDNA is likely detectable well prior to radiological evidence enabling earlier treatment

I/O Combination

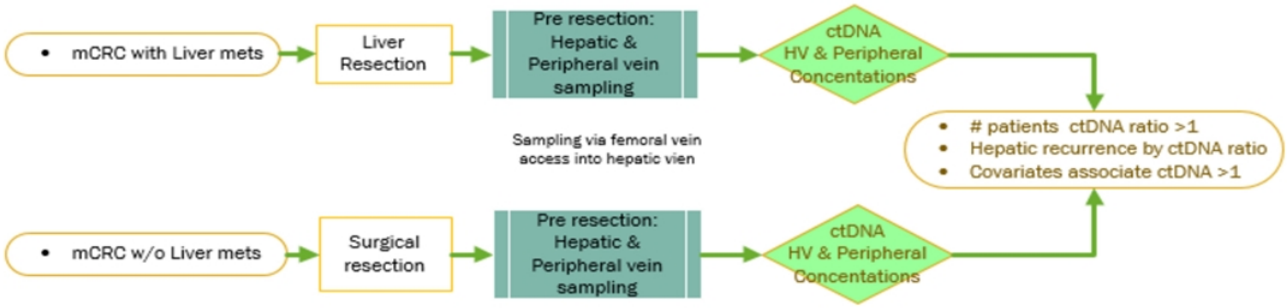
- I/0 agents lose efficacy when liver mets are present due to the immunomodulating role of the liver
- The study will be a basket trial for any patients on I/O therapy with liver mets
- Goal will be to make HEPZATO SOC for any patient with liver mets on I/O therapy

Detecting Liver Minimal Residual Disease

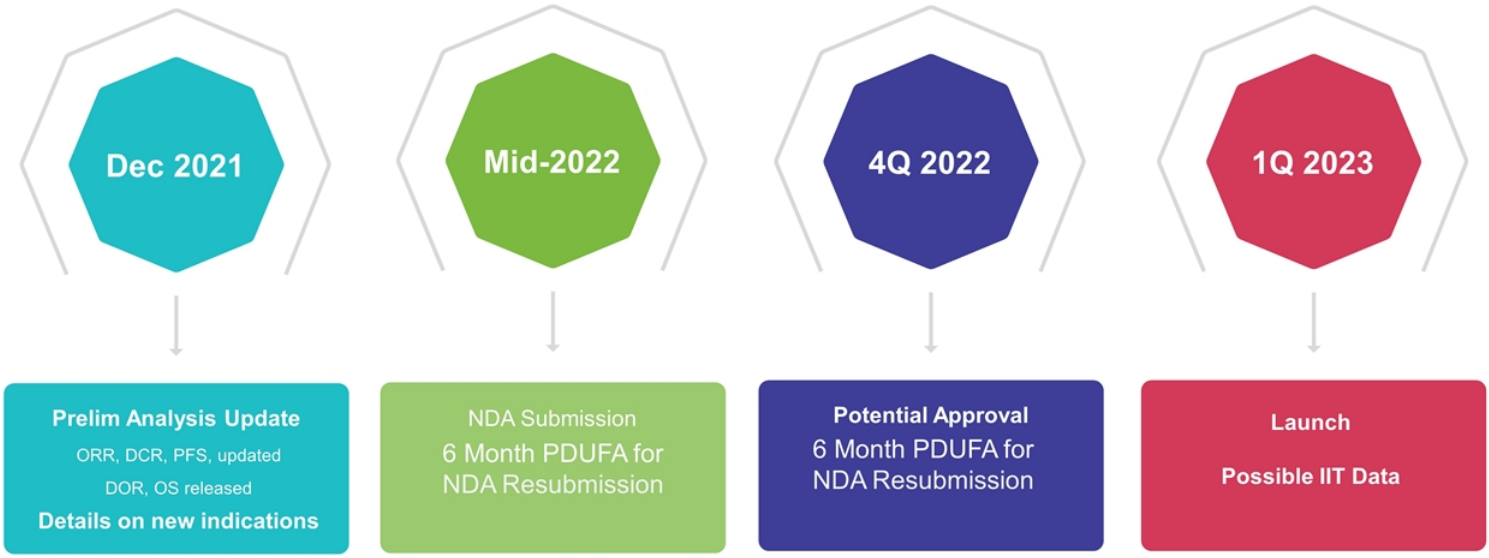
Enabling Technology = ctDNA



~20-30K/year Stage II & III patients recur with liver metastases



FOCUS Study – Upcoming News Flow



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Capital Structure and Share Information - September 30, 2021

Share Listing - Current	DCTH (NASDAQ)
Shares Outstanding[1]	8.81M
Cash and Cash Equivalents[2]	$29.0M
Warrants Outstanding[3]	3.61M
Stock Options Granted	1.70M
2020 Cash Burn (YTD)[4]	$16.2M
Debt[5]	$17.0M
52 week Low – High[6]	$8.28 - $25.18
30d Average Daily Volume[7]	27,533

[1] As of September 30, 2021; includes 7.3M of Common plus 1.2M, Preferred E & E-1 & 0.3M Pre-funded Warrants as converted
[2] As of September 30, 2021; (10-Q filing on November 9, 2021) Includes $4.2M of restricted cash
[3] As of September 30, 2021; Warrants at a $10 exercise price
[4] YTD Net cash used in operating activities through Q3, 2021
[5] Includes $5.0M of notes convertible at $11.98 per common share equivalent
[6] Used NASDAQ price information starting on September 30, 2020 - September 30, 2021
[7] 30-day average calculated between August 19, 2021 - September 30, 2021

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
John R. Sylvester	Director
Elizabeth Czerepak	Director
Steven Salamon	Director
Dr. Gil Aharon, Ph.D.	Director
Gerard Michel	CEO

Delcath

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

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THANK YOU

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Delcath Systems, Inc. Announces Positive Phase 3 FOCUS Trial Results for Hepzato™ in Liver-Dominant Metastatic Ocular Melanoma, Including Initial Survival Data Analysis

On final analysis of the primary overall response (ORR) endpoint, HEPZATO further exceeded the predefined threshold for success with a median duration of response of 14 months

While overall survival data continues to mature, a Hazard Ratio (HR) analysis of survival at 12-months yielded a statistically significant advantage for HEPZATO over a Best Alternative Care (BAC) arm [HR=0.37, p=0.01] in patients who received one or more treatments

HEPZATO had statistically significant improvements over BAC in predefined exploratory analyses on ORR, DCR and PFS

NDA resubmission for HEPZATO expected by mid-2022

NEW YORK, Dec. 2, 2021 — Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced positive results from the phase 3 FOCUS study. The FOCUS study's intent-to-treat (ITT) population was comprised of a total of 102 subjects, across various lines of therapy. Of the ITT group, 91 evaluable patients were administered at least one study treatment.

Treatment with HEPZATO in the ITT analysis resulted in an objective-response-rate (ORR) of 31.4% [95% CI: 22.55-41.31], including 6.9% of patients with a complete response (CR). Median duration of response was 14 months [95% CI: 8.54, NC], with over half of responders continuing to be monitored for progression events. Disease control rate (DCR) was 65.7% [95% CI, 55.63, 74.81].

On the primary ORR endpoint, the lower bound 95% Confidence Interval (CI) of 22.55% exceeded the FOCUS trial's prespecified 8.3% upper bound 95% CI threshold for success. This threshold was derived from a meta-analysis of sixteen checkpoint inhibitor publications documenting the treatment of 476 metastatic ocular melanoma patients.

Supportive, predefined, exploratory analyses were conducted comparing patients in the HEPZATO arm versus a BAC group. The BAC arm was comprised of a total of 42 patients, originally randomized in the FOCUS trial prior to its amendment, in consultation with FDA, to a single-arm pivotal study in 2018. The evaluable BAC subjects were treated predominantly with liver-targeted Transarterial Chemoembolization (TACE).

Among patients who received at least one study treatment, patients in the HEPZATO arm had statistically significant improvements over BAC in the following prespecified endpoints:

- ORR of 35.2% versus 12.5% for the BAC arm (p=0.0154).
- Disease Control Rate of 73.6% versus 37.5% for patients in the BAC arm (p=0.0002).
- Median Progression Free Survival of 9.03 months versus 3.12 months for the BAC arm (HR=0.39; p=0.0002).

Enrollment in the FOCUS trial HEPZATO arm ended in late 2020 with overall survival data continuing to mature. Per the statistical plan, a final predefined exploratory survival analysis, versus BAC, will be conducted at 24-months after last patient last treatment.

As of this analysis, survival at 12-months in the evaluable patients was 75% in the HEPZATO arm versus 47% for BAC [HR=0.37, p=0.01]. Delcath will provide future overall survival analysis updates, as patient follow-up continues, and the Kaplan-Meier analysis matures.

In the HEPZATO safety population, the most commonly reported treatment-emergent serious adverse events were anemia (29.7% of patients), thrombocytopenia (26.4% of patients) and neutropenia (19.8% of patients), which were well-manageable. 5.3% of patients experienced treatment-emergent serious cardiac adverse events. In all cases the events resolved with no ongoing complications. There were no treatment-related deaths in the trial.

“Metastatic ocular melanoma is a disease with a dismal prognosis and new therapies are urgently needed. The FOCUS study results, along with the predefined analyses versus a relevant BAC group, clarify HEPZATO overall clinical benefit in this difficult-to-treat patient population,” noted Dr. Jonathan Zager MD FACS, global lead investigator of the FOCUS study, senior member and Director of Regional Therapies at Moffitt Cancer Center. “The overall efficacy, coupled with an improved safety profile versus the first-generation product, suggests that HEPZATO would offer a compelling clinical benefit were it approved by FDA.”

“We are thrilled by the HEPZATO response rates and duration of response which far exceed that which has been seen with other agents in this difficult-to-treat patient population. Our data further highlights HEPZATO’s potential superiority to other available liver-targeted therapies, which suggests a broader utility for our platform across multiple liver-metastatic tumor types. In addition to re-filing our NDA by mid-2022, Delcath, along with key opinion leaders, intend to study HEPZATO in additional indications in the near future.”

The FOCUS trial results will be presented at a comprehensive Investor Update Meeting taking place today from 10:00am EST – 1:30pm EST. In addition to the FOCUS trial, a distinguished panel of physicians will discuss their personal clinical experience with HEPZATO in both the clinical trial setting and the commercial setting in Europe, as well as the potential for HEPZATO to treat liver metastatic tumor types beyond metastatic ocular melanoma.

Event Details:

Event: Delcath Systems Virtual Investor Update Meeting
Date: Thursday, December 2, 2021
Time: 10:00am – 1:30 p.m. EST

To register for this event, please click **here** .

The live webcast of the event may be accessed through the **Events and Presentation** page of Delcath’s website, under the Investors section. The archived webcast and presentation will be available on the Company’s website after the event.

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company’s proprietary percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is regulated as a Class IIb medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

Safe Harbor / 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 news release 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.

Contact:

Delcath Investor Relations

Email: **investorrelations@delcath.com**

Hayden IR

James Carbonara
(646)-755-7412
james@haydenir.com