# 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): June 6, 2022**

# 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 June 6, 2022, 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 8.01. Other Events.**

On June 6, 2022, the Company issued a press release announcing three American Society of Clinical Oncology presentations related to percutaneous hepatic perfusion, or PHP, namely: (i) positive initial results from the Phase 1b portion of the CHOPIN trial of PHP in combination with ipilimumab plus nivolumab in treatment of advanced uveal melanoma patients, (ii) updated efficacy and safety results from the single-arm phase 3 FOCUS trial in metastatic uveal melanoma and (iii) the publication of an abstract reporting on a retrospective analysis in the change of Quality of Life using the Functional Assessment of Cancer Therapy – General scores for 13 PHP treated patients at the University of Southampton. The full text of the press release is attached as Exhibit 99.2 and incorporated in this Item 8.01 by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

| | |
|---|---|
| 99.1 | Delcath Systems, Inc. corporate presentation dated June 2022 |
| 99.2 | Delcath Systems, Inc. press release dated June 6, 2022 |
| 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: June 7, 2022

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

Exhibit 99.1

Delcath

# Corporate Presentation

(NASDAQ: DCTH)

June 2022

# 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.

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# 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 3Q '22

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

ANTICIPATED FDA APPROVAL: Q1 2023

### LARGE MARKET OPPORTUNITY

Near-term (mOM)
- >$300M 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]

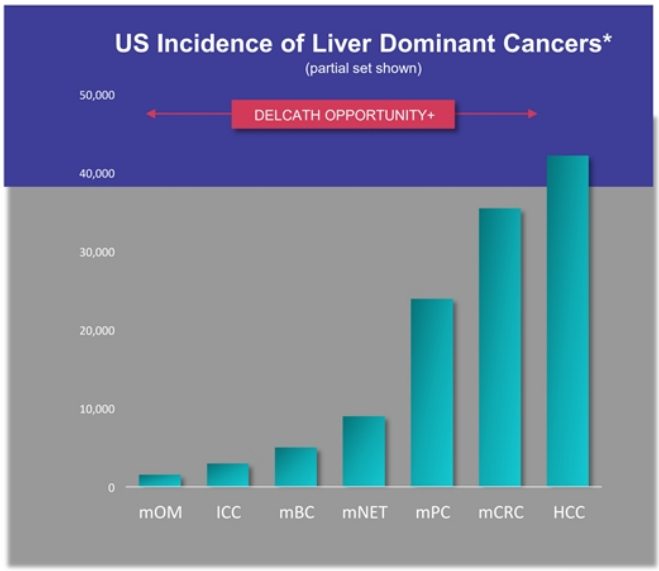
### Liver: Common Site of Metastases

### 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)

## Y90[16]

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

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

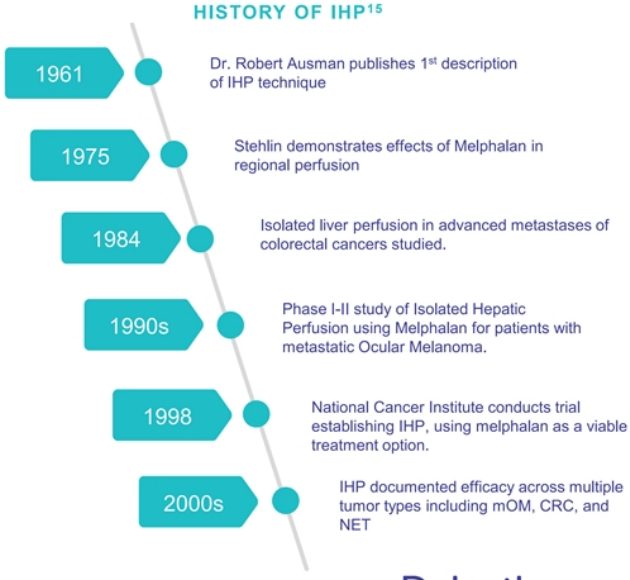
**Benefits**

- 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[15]**

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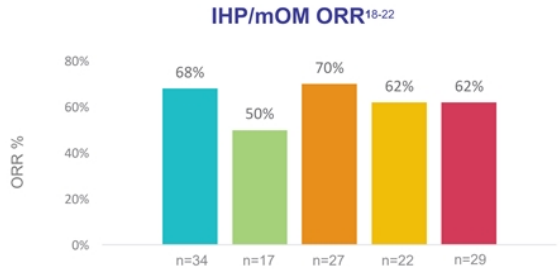
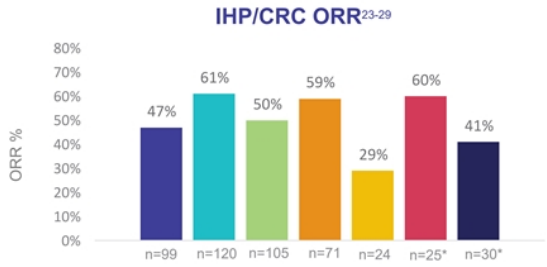
# IHP Results in mOM Provided Rationale for PHP in mOM and Provides Rationale for CRC and Other Tumor Types




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]

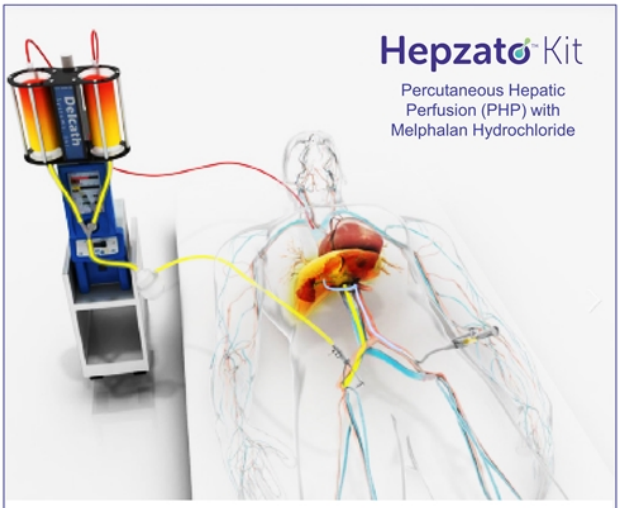
*Hepatic arterial infusion used adjunctively.

# HEPZATO™ Kit: Percutaneous Hepatic Perfusion (PHP)

Repeatable, safe & effective liver-focused disease control

**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.




**~2-3 hr. cath-lab based procedure**

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# Three Steps. Targeted Treatment.

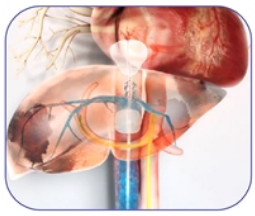
## Hepzato™ Kit

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

1

### ISOLATION

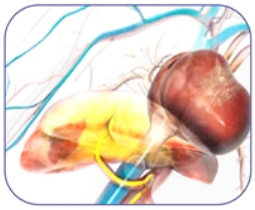
Hepatic venous flow is isolated, enabling 12x increased dose



2

### SATURATION

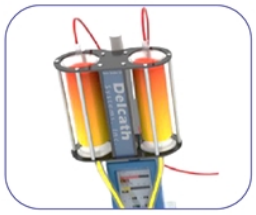
Melphalan (chemo) treats micro and macro lesions simultaneously



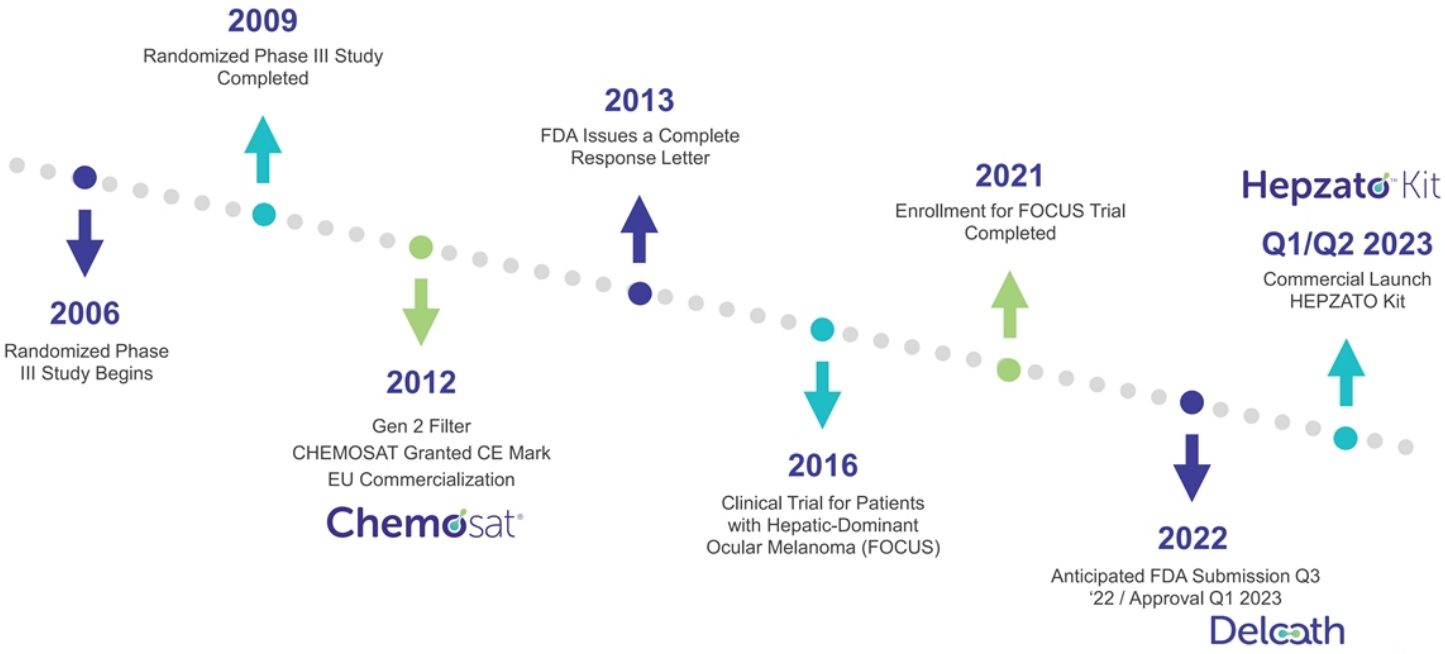
3

### FILTRATION

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



# History of HEPZATO Kit Development



# 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

- Payer/hospital financial stakeholder interviews suggest expected pricing to be on par with immuno-oncological agents (currently $250K - $450k annually)
- 20 US treatment centers = ~80% patients

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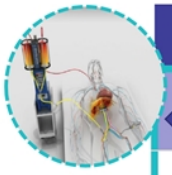
# Competitive Landscape for mOM



| | 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 | Q4 2022 | X | X | Melanoma | ✓ |
| Applicable to most mOM patients | ✓ | ✓ | ✓ | ✓ | X |

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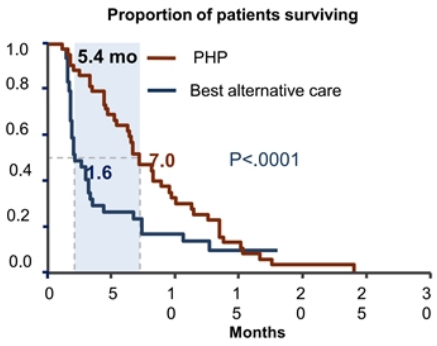
*HLA A+ patient indication only ** Treated Population 29-Apr-2022 data cut ***Post hoc analysis Treated Population, BAC OS 59%, HR 0.48 , 95% CI 0.22, 1.08, p-value = 0.075 based on 1-Jun-2022 data cut
****Control OS 59%, HR 0.51, 95% CI 0.37, 0.71, p-value <0.001

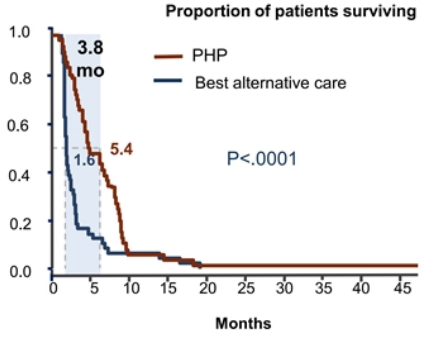
# First Phase 3 RCT Results*

### 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 |

## 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% ↓** |

**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

- 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 30 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<br><br>**ORR** Study 1 = 45%<br>**ORR** Study 2 = 34% | Metastatic *RET* NSCLC<br><br>**ORR naïve** = 70%<br>**ORR exp.** = 57% | Relapsed or refractory large B-cell lymphoma<br><br>**ORR** = 39% | Lymphoma positive for EXH2 mutation<br><br>**ORR mutant** = 69%<br>**ORR** wild-type = 34% | Metastatic SMLC 2nd Line<br><br>**ORR** = 35% | mNSCLC with mutation MET exon 14 skipping<br><br>**ORR naive** = 68%<br>**ORR exp.** = 41% | 3rd Line Metastatic triple-negative BC<br><br>**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<br><br>**ORR** = 66% | mGIST with PDGFRA exon 18 mutation<br><br>**ORR** = 84% | Previously treated ICC with FGFR2 fusion<br><br>**ORR** = 36% | Malignant perivascular epithelioid cell tumor<br><br>**ORR** = 39% | 2nd Line cervical cancer<br><br>**ORR** = 24% | mNSCLC with EGF exon 20 insertion mutations<br><br>**ORR** = 28% | MMRD recurrent or advanced solid tumors – 2nd line<br><br>**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<br><br>**ORR** = 49% | 2nd Line ICC with a FGF 2 fusion<br><br>**ORR** = 23% | KRAS G12C mutated mNSCLC<br><br>**ORR** = 36% | mNSCLC with EGFR exon 20 insertion mutations<br><br>**ORR** = 40% | MMRD endometrial cancer, 2nd Line.<br><br>**ORR** = 42.3% | Metastatic BCC<br><br>**ORR meta.** = 21%<br>**ORR adv.** = 29% | mNSCLC w/ met exon 14<br><br>**ORR naïve** = 43%<br>**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

- 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 |

- Significantly improved safety relative to first pivotal trial

* 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

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# FOCUS Trial Analysis: Prespecified Endpoint Met*

## ORR Advantage Coupled With Meaningful Duration of Response

### ORR and DCR in the Treated Population

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

### DOR in the Treated Population

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

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

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# Progression Free Survival

## Kaplan Meier Curves in Treated Populations*

## Pre-Specified Exploratory Analyses*

Exploratory comparison versus BAC supportive

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

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# Overall Survival

## Kaplan Meier Curves in Treated Populations*

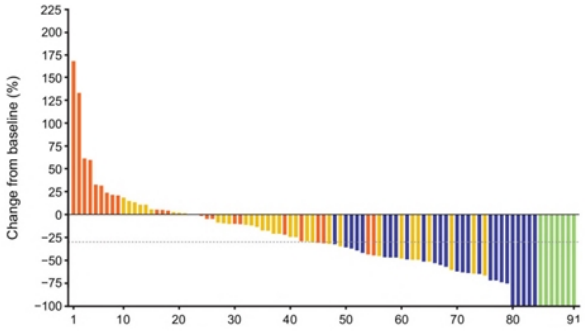
## Pre-Specified Exploratory Analyses*

Exploratory comparison versus BAC supportive

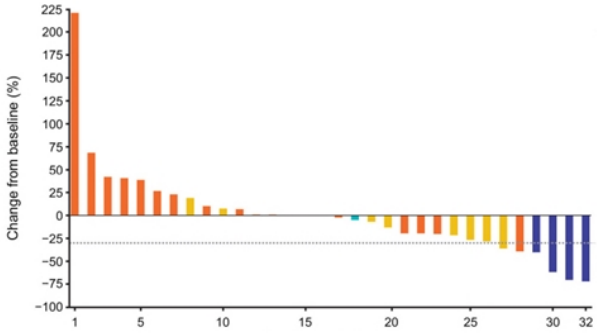
** 29-Apr-2022 data cut, data continues to mature and patients will be followed at least through May, 2023

# 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

# 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

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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 ~$250k per yr.
- Tebentafusp is priced at an estimated ~$400K per patient** and generated $10M in US revenue first quarter post launch (<2 months revenue)
- 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, ** Consensus estimates from Immunocore's covering analysts

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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

## Leveraging EAP and Longitudinal Data

### EAP (FDA Approved)

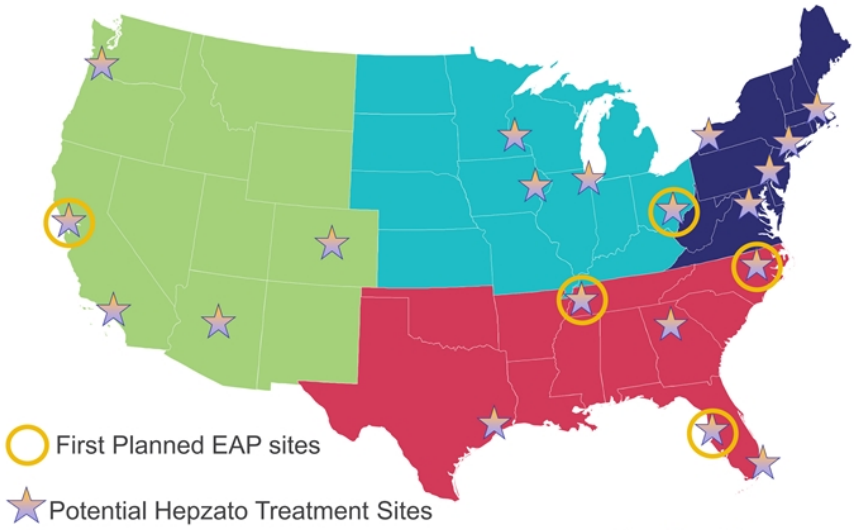
- Provide immediate access to patients
- First Commercial Sites
- Train new medical teams to use Hepzato after launch

### 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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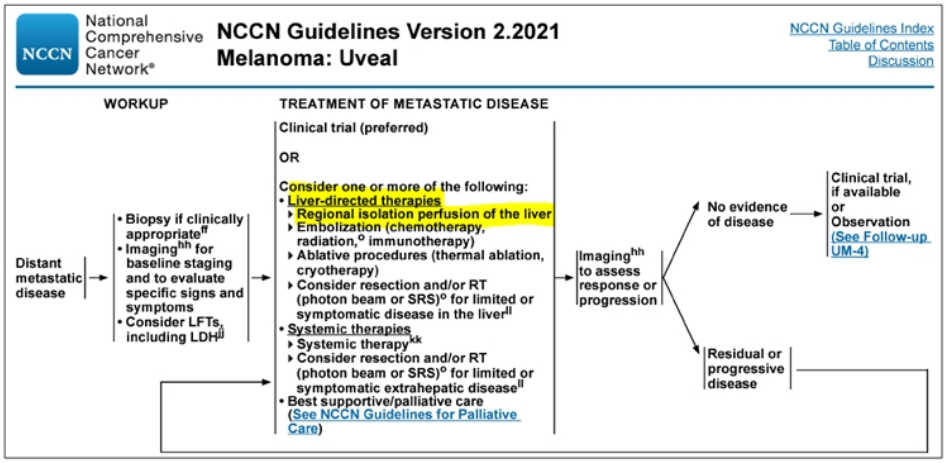
# PHP Is Likely Part of Current NCCN Guidelines for mOM

"Regional Isolation Perfusion of the Liver"

## PHP- Percutaneous Hepatic Perfusion



# 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.**

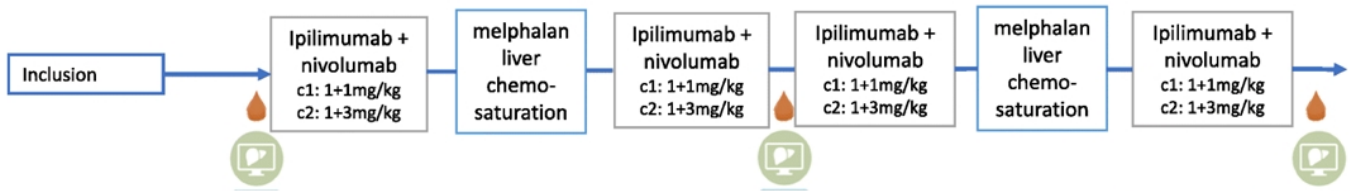
Abstract Number: 9560 (2022 ASCO)

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: NCT03833089.

**Phase Ib: Two M-PHP-procedures: cohort 1 and 2**



# 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
- 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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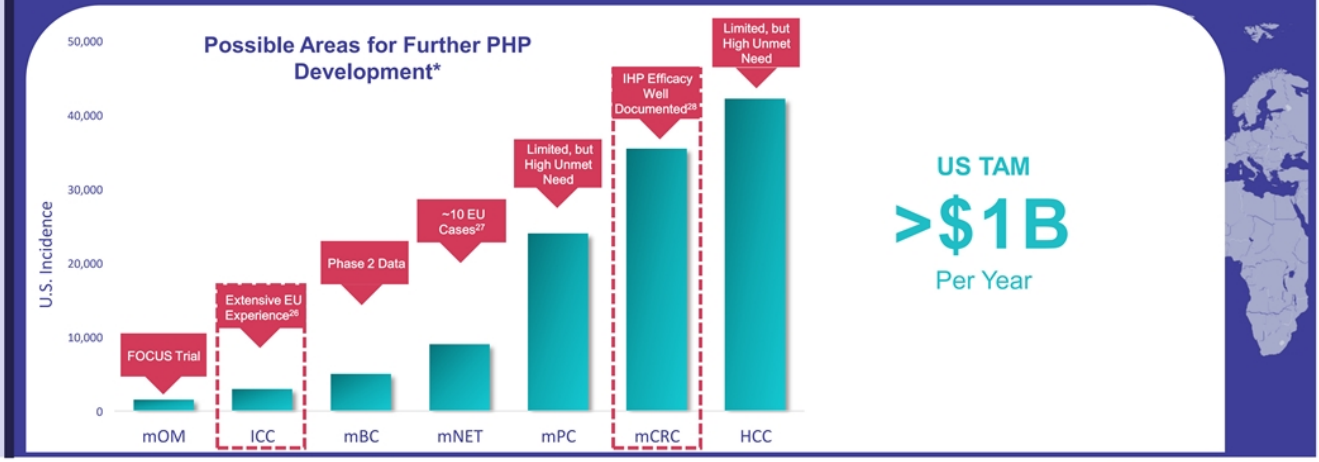
# Market Expansion: Liver Disease

BEACHHEAD MARKET | mOM

LIVER DISEASE




Deloath

*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<br>• 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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# FOCUS Study – Upcoming News Flow

# Capital Structure and Share Information – May 31, 2022

| Share Listing - Current | DCTH (NASDAQ) |
|---|---|
| Shares Outstanding[1] | 9.33M |
| Cash and Cash Equivalents[2] | $20.5M |
| Warrants Outstanding[3] | 3.61M |
| Stock Options Granted | 2.2M |
| 2022 Q1 Cash Burn (YTD)[4] | $6.4M |
| Debt[5] | $17.6M |
| 52 week Low – High[6] | $4.30 - $13.50 |
| 30d Average Daily Volume[7] | 26,023 |

[1] As of March 31, 2022; includes 7.9M of Common plus 1.1M, Preferred E & E-1 & 0.3M Pre-funded Warrants as converted
[2] As of March 31, 2022; (10-Q filing on May 11, 2022) Includes $4.2M of restricted cash
[3] As of March 31, 2022; Warrants at a $10 exercise price
[4] Q1 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 June 1, 2021- May 31, 2022
[7] 30-day average calculated between April 18, 2022- May 31, 2022

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# 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: 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

Delcath

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**Positive Initial Results from CHOPIN Phase 1b Trial, FOCUS Trial Update and QoL Study Presented at the 2022 ASCO Annual Meeting**

**Initial results from the Phase 1b portion of the CHOPIN trial of PHP in combination with ipilimumab plus nivolumab in advanced uveal melanoma in seven patients resulted in 85.7% Best Overall Response and 100% Disease Control Rate. Median progression free survival currently is 22.4 months with all patients still alive as of last follow-up**

**FOCUS trial update presented with maturing results consistent with earlier presentations**

**Abstract published reporting on a retrospective analysis in the change of Quality of Life in PHP treated patients at the University of Southampton**

NEW YORK — Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced further details regarding presentations relating to its proprietary percutaneous hepatic perfusion (PHP) system at the American Society of Clinical Oncology (ASCO) Annual Meeting being held June 3-7, 2022, in Chicago, Illinois and virtually.

**Initial CHOPIN Trial Results**

The goal of the CHOPIN trial is to study the safety and potential synergistic effects of systemic immunotherapy ipilimumab plus nivolumab (IPI+NIVO) when combined with Delcath's proprietary liver-targeted PHP treatment in metastatic uveal melanoma patients. The poster presented initial safety and efficacy results from the Phase 1b portion of the trial which enrolled seven patients who were treated with two courses of six-weekly PHPs (melphalan 3mg/kg, max 220mg) combined with four courses IPI+NIVO three-weekly escalating the dosing from 1mg/kg each IPI+NIVO (cohort 1) to IPI 1mg/kg + NIVO 3mg/kg (cohort 2). The poster reports a Best Overall Response of 1 complete response, 5 partial responses and 1 stable disease accounting for an Objective Response Rate of 85.7%. At a median follow up time of 20.2 months, 4 patients have an ongoing response. Currently the median progression free survival is 22.4 months, and all patients are still alive.

“Initial CHOPIN data suggests that combining Delcath’s proprietary PHP liver targeted therapy with systemic immunotherapy is tolerated and can potentially achieve promising overall disease control rates in patients that otherwise would have limited treatment options. Uveal melanoma predominantly metastasizes to the liver and to date, the efficacy of immunotherapy in achieving meaningful disease control rates in this setting has been limited,” said Johnny John, MD Delcath’s Senior Vice President of Clinical Development and Medical Affairs. “We are excited by the results of the Phase 1b portion of the study and look forward to the additional study of this this combination therapy to address both hepatic and extra hepatic lesions and meaningfully alter the course of this disease.”

**Updated FOCUS Trial Results**

Updated efficacy and safety results from the single-arm phase 3 FOCUS trial in metastatic uveal melanoma including Overall Response Rate (ORR), median Duration of Response (mDOR), Disease Control Rate (DCR), median Progression Free Survival (mPFS) and Overall Survival (OS) data were presented that were largely consistent with prior presentations. In addition, predefined exploratory analyses comparing PHP to a Best-Alternative-Care (BAC) arm enrolled prior to the trial’s protocol amendment to a single-arm study were included.

Updated values reflect the latest data from clinical sites. OS data continues to mature with a final, predefined analysis expected in May 2023, two years after the study’s last treatment. As of last analysis the FOCUS trial results are as follows:

- A 36.3% ORR in the Treated Population, including 8% Complete Responses (CR) with a mDOR of 14 months. A DCR of 73.6%, a median PFS of 9.03 months and a median OS of 19.25 months.
- PHP analyses against the BAC arm yielded statistically significant ($p<0.05$) results on ORR (36.3% vs. 12.5%), DCR (73.6% vs. 37.5%) and mPFS (9.03 months vs. 3.12).
- While OS data continues to mature, as of the last analysis, the median OS for the PHP arm is 19.25 months vs. 14.49 months for BAC (HR=0.70, p=0.14). Final analysis expected in 2023.

**Retrospective Quality of Life Analysis**

This abstract reported on a retrospective analysis in the change of Quality of Life (QoL) using the Functional Assessment of Cancer Therapy – General scores for 13 PHP treated patients at the University of Southampton. The analysis found no significant difference in QoL score on discharge post procedure versus baseline (prior to treatment) and noted a trend for overall improved QoL on day 28 from baseline.

Additional details about these three PHP-related ASCO presentations can be found below:

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

**Session Title:** Melanoma/Skin Cancers

**Session Date and Time:** June 6, 2022, 1:15-4:15 PM CDT (Display)

**Abstract Number:** 9560

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

**Title:** FOCUS Phase 3 Trial Results: Percutaneous Hepatic Perfusion (PHP) With Melphalan for Patients With Ocular Melanoma Liver Metastases (PHP-OCM-301/301A)

**Session Title:** Melanoma/Skin Cancers

**Session Date and Time:** June 6, 2022, 1:15-4:15 PM CDT (Display) and 4:30-6:30 PM CDT (Discussion)

**Abstract Number:** 9510

**Presenter:** Dr. Jonathan Zager, Director of Regional Therapies and Chief Academic Officer, Moffitt Cancer Center; Professor and Chair, Department of Oncologic Sciences, USF Morsani School of Medicine.

The Poster will be available at **https://delcath.com/investors/events-presentations/.**

**Title:** Temporal evolution in quality-of-life following melphalan percutaneous hepatic perfusion for patients with metastatic uveal melanoma.

**Session Title:** Melanoma/Skin Cancers

**Abstract Number:** e21520

**Presenter:** Ganesh Vigneswaran University of Southampton, Southampton, United Kingdom

Visit the ASCO Annual Meeting **website** for further information regarding the conference.

**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, for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM) 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 now regulated as a Class lll 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.

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