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Monopar Therapeutics Corporate Presentation

Monopar Therapeutics

September 2019

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Investment Highlights

- Clinical stage biopharmaceutical company focused on the development and commercialization of oncology and oncology supportive care medicines
- Therapeutic pipeline addressing multiple unmet medical needs that represent large market opportunities
  - Validive® for severe oral mucositis (SOM) in oropharyngeal cancer (OPC) is Phase 3 ready
  - Camsirubicin is a novel doxorubicin analog, Phase 2 stage, being developed for 1st line advanced soft tissue sarcoma (ASTS). Designed to retain anticancer activity without the cardiotoxicity
  - MNPR-101 is a humanized monoclonal antibody (mAb) to the urokinase plasminogen activator receptor for the treatment of advanced cancers, Pre-IND
- In-licensing strategy which leverages existing scientific and clinical data mitigates the risk of clinical development and is capital efficient
- Executive team with deep clinical, M&A, and commercialization experience

Clinical Pipeline

	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
Validive	*Radiation induced SOM in OPC*					Completed Phase 2 Trial, Phase 3 ready
Camsirubicin	*Advanced Soft Tissue Sarcoma*					Phase 2 Data in Soft Tissue Sarcoma, Collaboration with GEIS for larger Phase 2
MNPR-101	*Advanced Solid Cancers*					Pre-IND

Experienced Management

Strong management team with industry expertise in all phases of drug development

Christopher M. Starr, PhD Co-Founder, Executive Chairman	▪ Co-Founder, Former CEO and board member of Raptor Pharmaceuticals (RPTP) – Developed PROCYSBI® for nephropathic cystinosis through clinical trials to commercialization – Raised $200M in public markets, sold to Horizon Pharma (HZNP) for $800M ▪ Co-Founder, Former SVP/CSO, Head of R&D, Manufacturing/Quality/Regulatory of BioMarin Pharmaceutical (BMRN) – Oversaw the approval of three drugs	raptor BIOMARIN
Chandler D. Robinson, MD, MBA, MSc Co-Founder, Chief Executive Officer	▪ Co-Founder, Former CEO of Tactic Pharmaceuticals – Arranged for Named Patient Sales of Decuprate in EU / successfully sold WW rights – Decuprate (Phase 3) was acquired by Alexion for $764M ▪ UK Fulbright and Gates Scholar who co-developed and published in *Science* on Tactic's Wilson Disease drug Decuprate	BEAR STEARNS ONYX PHARMACEUTICALS Tactic Pharma, LLC
Andrew P. Mazar, PhD Co-Founder, Chief Scientific Officer	▪ Co-Founder and Former Chief Scientific Officer of Tactic Pharmaceuticals – Invented and developed Decuprate ▪ >27 years translational experience in oncology ▪ Co-inventor of several oncology drugs currently in development, and co-author on 118 peer-reviewed publications, 11 reviews and 6 book chapters	Tactic Pharma, LLC Abbott
Kim R. Tsuchimoto Chief Financial Officer	▪ Former CFO of Raptor Pharmaceuticals; acquired by Horizon Pharma (HZNP) ▪ Former VP, Treasurer at BioMarin	raptor BIOMARIN
Patrice Rioux, MD, PhD Chief Medical Officer	▪ Former Chief Medical Officer of Raptor Pharmaceuticals ▪ Responsible for securing regulatory approval of PROCYSBI® in the US and EU	edison raptor Biogen REPLIGEN

Validive®

Monopar Therapeutics

OPC Treatment Causes Debilitating Severe Oral Mucositis

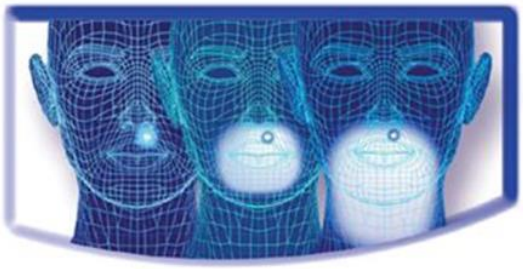
- Chemoradiotherapy causes severe oral mucositis (SOM) in patients being treated for oropharyngeal cancer (OPC)
  - Radiation treatment, and especially chemoradiation, is the Standard-of-Care in patients with OPC
  - No preventative treatment for SOM in OPC, or any head and neck cancer (HNC), is currently approved
- SOM is caused by inflammation and ulceration of the oral mucosa induced by radiotherapy
  - OPC patients have higher risk of developing SOM than patients with other types of HNC
- SOM often leads to complications that negatively affect clinical outcomes
  - Early termination or interruption of treatment
  - Increased hospitalization during and after treatment
  - Post-treatment toxicities such as dysphagia, trismus, and aspiration-induced lung injury
- Majority of HNC cases in US are OPC (incidence of OPC ~40,000 for 2019)
  - Increasing due to oral human papillomavirus (HPV) epidemic, a major driver of OPC

Validive Overview

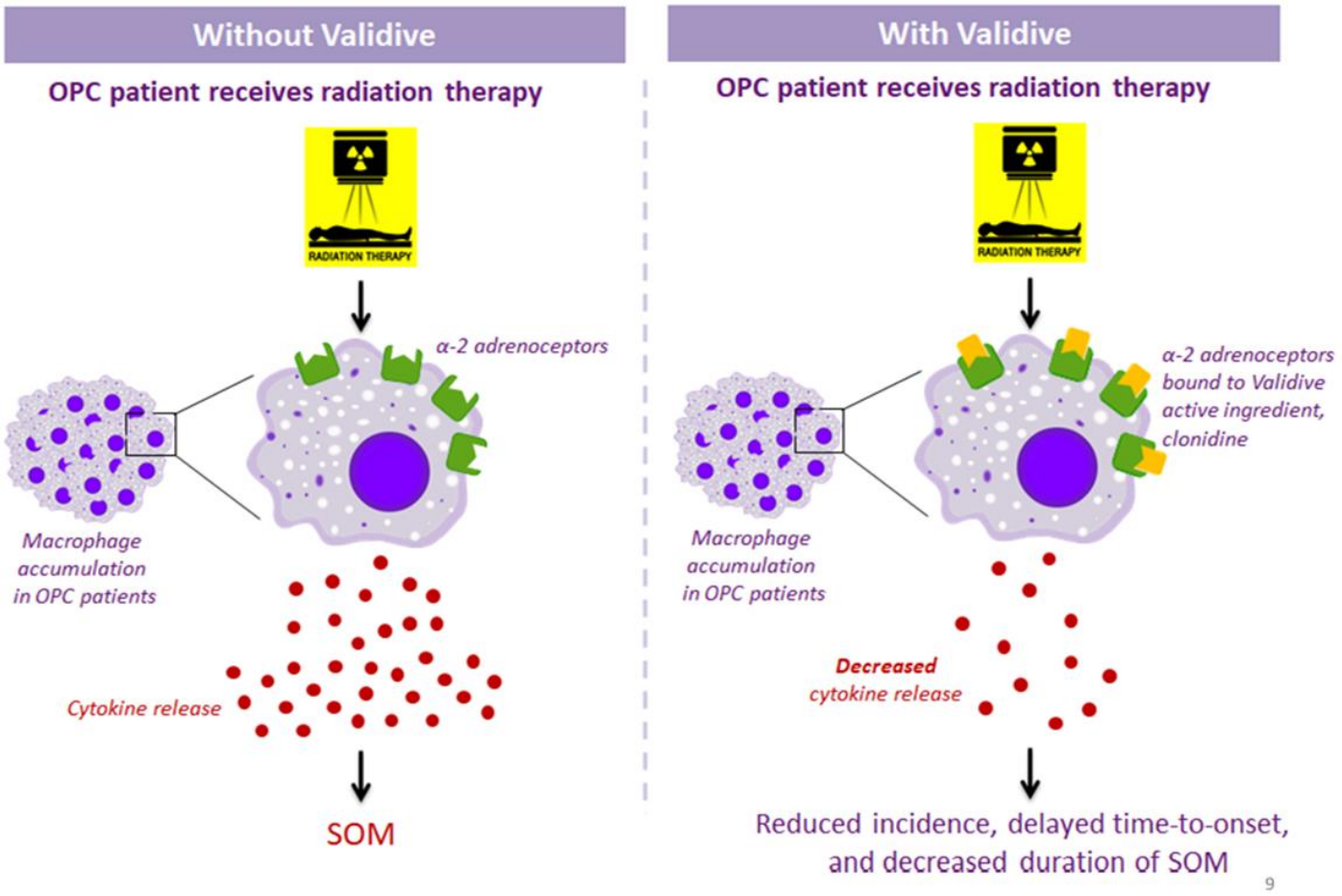
- The active ingredient of Validive®, clonidine, has a well-established safety profile
- Validive is a tasteless muco-adhesive buccal tablet (MBT) administered once daily, resulting in an extended release of clonidine into the local oral mucosa
- Validive's novel formulation for clonidine delivers sustained high/local concentrations of the drug to the oropharynx while minimizing systemic absorption
- Validive therapy is started on day 1 of radiation treatment and continued daily through the completion of treatment

Administered by affixing to upper gum

Dissolves slowly over several hours, resulting in the extended release of clonidine into the oropharynx



Validive Mechanism of Action Targets Cause of SOM in OPC

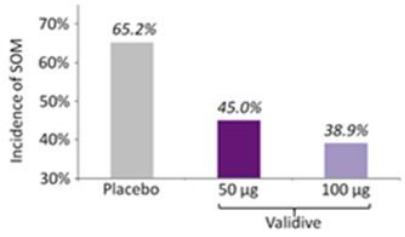


Validive Phase 2 Instructs our Phase 3 Trial Design in OPC

- International randomized, double-blind, placebo controlled three-arm study of all HNC, regardless of anatomical location of disease (N=183)
  - SOM developed in fewer patients receiving Validive (45%) than in patients receiving placebo (60%)
- Favorable safety profile
  - Occurrence of adverse events similar between placebo and Validive patients
- Superior outcomes and dose response observed in patients with OPC (N=64)

Reduced Incidence

- Validive has shown a reduction in the incidence of SOM in patients with OPC
- Reduced incidence of SOM may lower the risk of acute and chronic comorbidities and improve quality of life



Delayed Time to Onset

- Validive has demonstrated the ability to delay the time to onset of SOM
- Prolonging time to onset of SOM may lead to fewer missed chemoradiotherapy treatments, resulting in improved overall survival outcomes

Placebo	Validive 50µg	Validive 100µg
37 days	45 days	**N.D.***

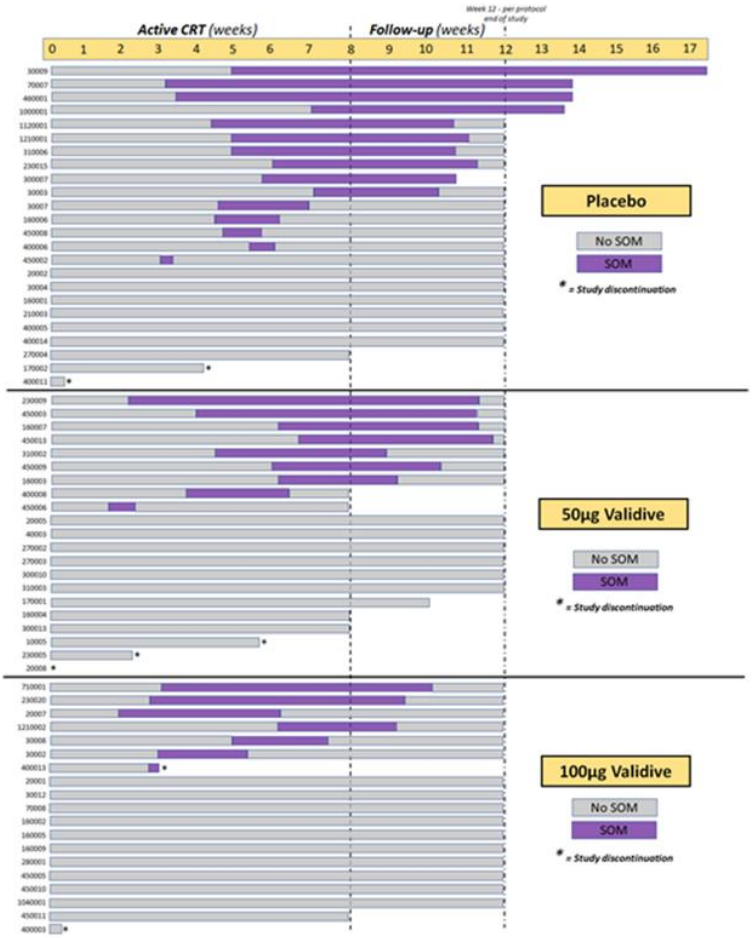
Decreased Duration

- Validive has shown a decrease in the median duration of SOM in OPC patients
- Reduced duration of SOM may result in lower risk of malnourishment and feeding tube intervention, and fewer treatment terminations/delays

Placebo	Validive 50µg	Validive 100µg
17 days	0 days	**0 days**

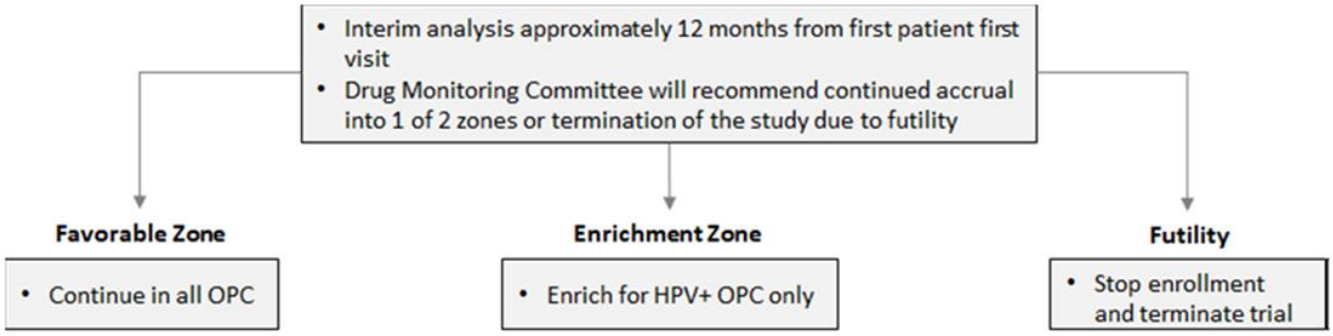
* Not determined: median was not reached as too few patients developed SOM

Individual OPC Patient Phase 2 Data Shows Positive Dose Response



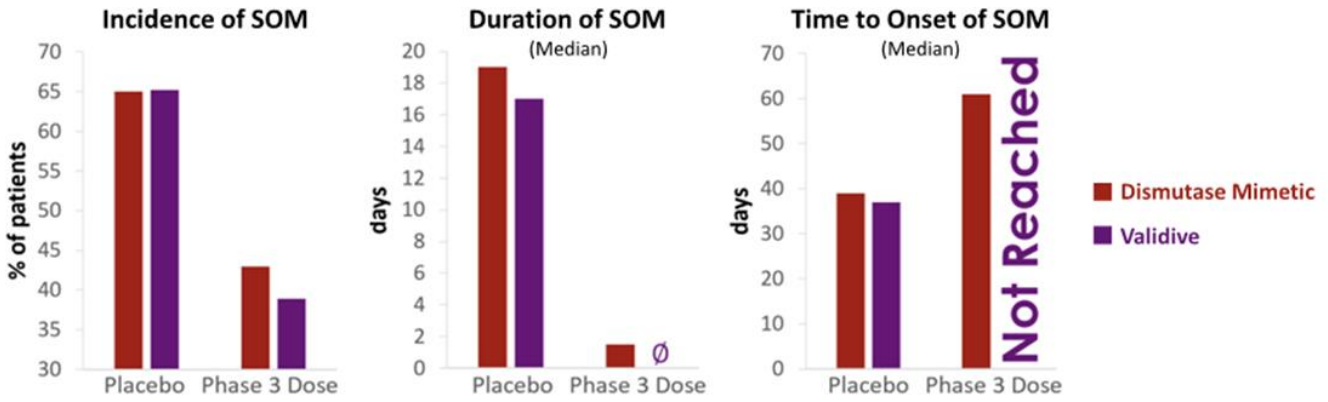
Adaptive Phase 3 Design Allows for Optimal Responder Enrichment

- Adaptive Phase 3 trial design stratified based on HPV status (N=250), confirmatory second trial (N=200)
- Phase 3 program is powered based on Phase 2 results in OPC patients
- Primary endpoint is incidence of SOM in OPC
  - The adaptive design first trial is planned to have an interim analysis after approximately 12 months
- Secondary endpoints will be supportive for clinical benefit
  - Includes total number of days of SOM per patient (i.e. duration) and risk of onset of SOM (which is based on time to onset)



Validive Compares Favorably to the Other Late Stage SOM Therapies

	Validive	Dismutase Mimetic
API	FDA approved, used in patients for several decades	Not approved, in development in various indications since 2002
Route of Administration & Dosing	Oral adhesive tablet; Once per day, dissolves over several hours	IV; Once per day (M-F), 1 hr infusion that must be completed within 1 hr prior to radiation treatment
Safety	Well-known molecule; Local delivery → low dose; Limited systemic exposure	Systemic effects; MOA is of potential concern as radiation treatment works through reactive oxygen species
505(b)(2) Pathway possible	Yes	No

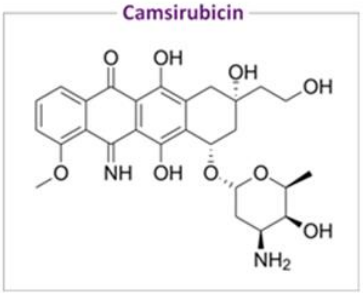


Camsirubicin

Monopar Therapeutics

Camsirubicin and the Significant Advanced STS Opportunity

- Camsirubicin (MNPR-201) has a great opportunity to replace doxorubicin as 1st line for ASTS (Advanced Soft Tissue Sarcoma)
  - Camsirubicin has shown anti-cancer activity in Phase 1, as well as in Phase 2 first line ASTS
  - MOA of anti-cancer activity is clear as it is an analog of doxorubicin, designed to retain the anti-cancer activity without the irreversible cardiotoxicity of doxorubicin
- A large void was recently created in 1st line ASTS
  - Lilly's Lartruvo was recently pulled from the market after being granted accelerated approval a little over two years ago based on its open label Phase 2 study
  - No drug had shown superiority over doxorubicin since it was approved decades ago for ASTS. Physicians in the US and abroad were excited, and sales of Lartruvo quickly reached >$300M in annual revenue by its second year on the market (2018)
  - 1st line for ASTS is back to doxorubicin monotherapy
- Camsirubicin has potential for accelerated approval given historical precedent and MOA is well known



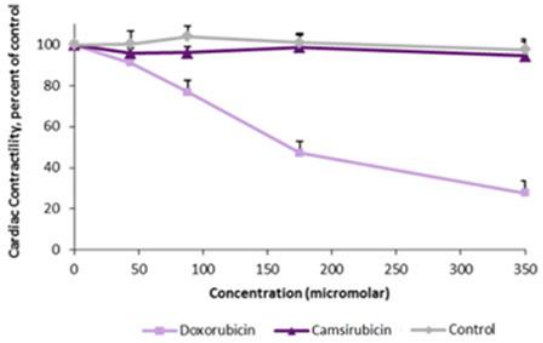
Background on ASTS and Camsirubicin

- In 2018, there were an estimated 13,040 new cases of soft tissue sarcoma (STS) in the US, and approximately 5,150 deaths from STS, mainly from metastatic disease
- Doxorubicin is the current 1st line treatment
  - Clear dose response for doxorubicin in ASTS, but cumulative dose is restricted due to irreversible cardiotoxicity (high dose 75 mg/m^2 response rate of 37% vs. low dose 45 mg/m^2 response rate of 18%)
  - Median overall survival in ASTS is around 12-15 months
- Camsirubicin was designed specifically to modify doxorubicin at 5 and 13 positions to mitigate cardiotoxicity and increase selectivity for topoisomerase IIα over IIβ, while retaining anticancer activity
  - The objective is to achieve superior efficacy to doxorubicin by being able to use this novel analog without restriction on cumulative dose (to take advantage of dose response, to dose higher and longer)
  - Orphan drug designation in the US, application submitted in the EU

Camsirubicin: Evidence of Activity with Minimal Cardiotoxicity

- Preclinical data demonstrate Camsirubicin lacks cardiotoxicity compared to doxorubicin
- Phase 1 dose escalation trial completed in patients with advanced solid tumors
  - No evidence of irreversible cardiotoxicity, and clinical benefit observed in the higher-dose patients
  - Preliminary evidence of antitumor activity in leiomyosarcoma provided rationale for Phase 2
  - No growth factor support given, DLT was neutropenia
- Phase 2 open-label trial completed in unresectable metastatic soft tissue sarcoma
  - All patients given growth factor support, so MTD not reached, yet still showed results comparable to historical doxorubicin data
  - Camsirubicin administered for up to 16 cycles* (doxorubicin limited to 6-8 cycles for entire lifetime)
  - No evidence of irreversible cardiotoxicity, and clinical benefit correlated with higher cumulative dose
  - Suggests potential to administer without restriction on cumulative dose

Rabbit Atria Model of Cardiotoxicity



Phase 1 Endpoint	Result
% patients with clinical benefit (PR+SD)	55.0%

Phase 2 Endpoint	Result
% patients with clinical benefit (PR+SD)	52.6%
Progression free survival at 6 months†	38%

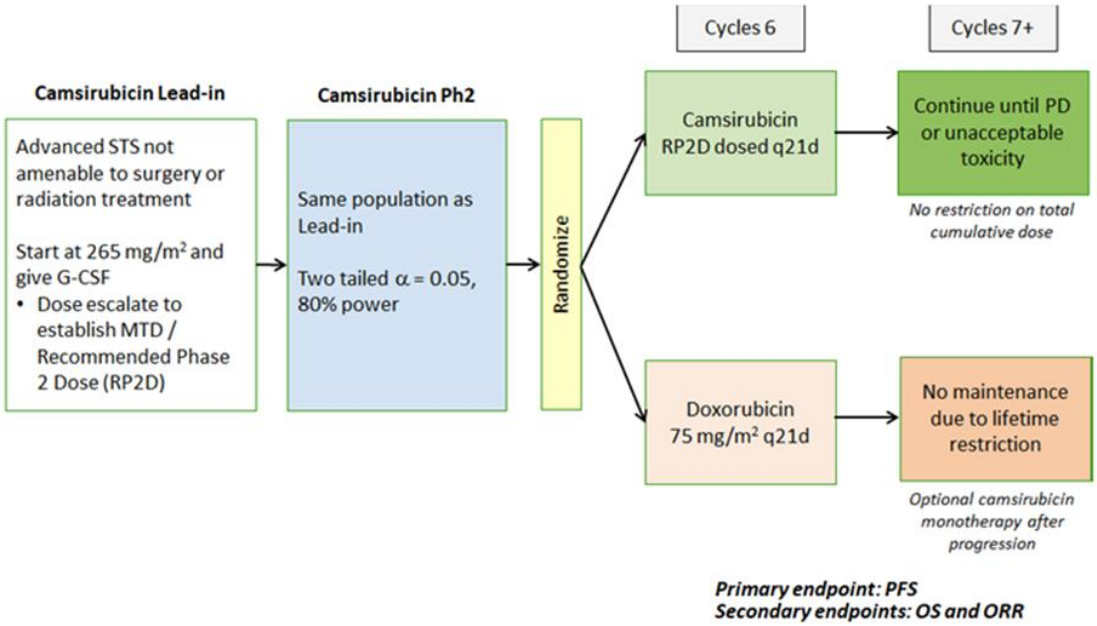
† doxorubicin 6 month PFS of 25, 33, and 23% in three separate studies

*One patient received 20 cycles on compassionate use

DLT = Dose-Limiting Toxicity; MTD = Maximum Tolerated Dose

International Collaboration for Camsirubicin Trial

- Entered into a clinical trial collaboration with the Spanish Sarcoma Group (GEIS)
- GEIS to conduct a multi-country, randomized, open-label Phase 2 trial in 1st line ASTS, planned to enroll approximately 170 patients over about 2 years
- Established precedent for accelerated approval

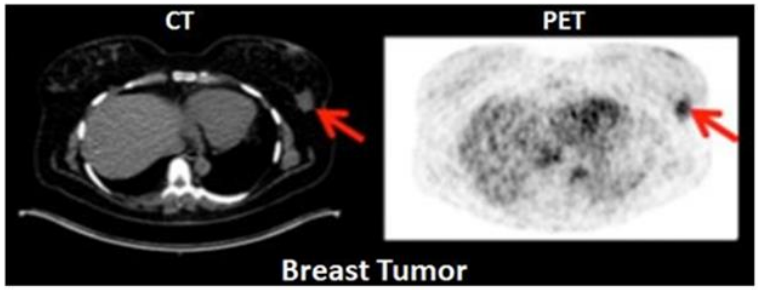


MNPR-101

Monopar Therapeutics

MNPR-101: A Novel Monoclonal Antibody for Advanced Cancers

- Humanized monoclonal antibody (mAb) to urokinase plasminogen activator receptor (uPAR)
  - Well-characterized cancer therapeutic target overexpressed in many deadly cancers
  - Targets key factors in growth and metastasis of tumors
  - Potential to enhance antitumor activity of chemotherapy, targeted agents, and immunotherapies
- Phase 1 human PET imaging data for uPAR expression demonstrates tumor-selective expression[1]
  - uPAR expression observed in primary and metastatic tumors in patients
  - Consistent with histology data that shows uPAR expression is rarely detected in most normal quiescent human tissues
  - Potential use of MNPR-101 as a targeting agent for radiopharmaceuticals, ADCs

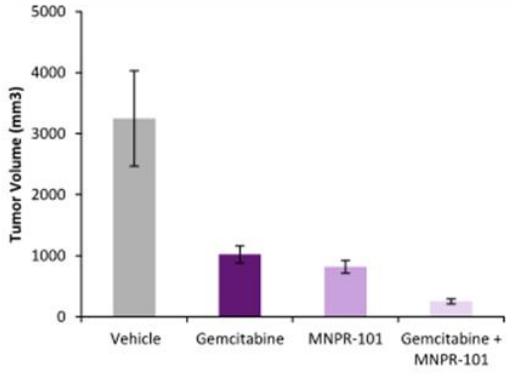


[1] Skovgaard et al., 2017

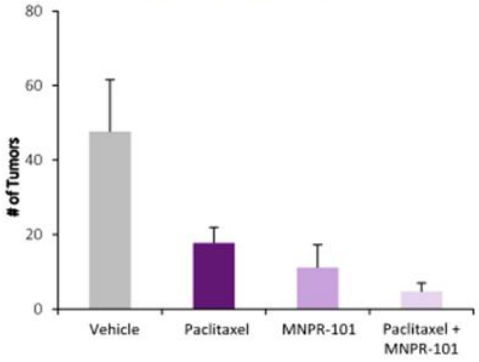
MNPR-101: Potential as Standalone or Combination Therapeutic

- Novel binding properties of MNPR-101 are key to anti-cancer mechanism
  - MNPR-101 represents a novel approach for drug targeting of uPAR as it does not interfere with normal binding of uPA to uPAR
  - Blocks the CD11b (αM)-uPAR interaction, a possible regulator of tumor immunity expressed by myeloid derived suppressor cells
  - Blocks signaling of multiple oncogenes including activated MAPK, AKT, MEK, and FAK
  - Mediates ADCC
- Pre-IND asset: Phase 1a/1b trial in indications where uPAR expression is highly prevalent
  - Explore novel combinations in Phase 1b expansion trial
  - Pancreatic, glioblastoma, metastatic breast cancer, metastatic melanoma, ovarian cancers

Pancreatic Cancer
L3.6pl xenograft



Ovarian Cancer
CaOV3 xenograft



Source: Bauer *et al.*, Cancer Res. 2005; 65:7775-81, Kenny *et al.*, Clin Cancer Res 2011; 17: 459-71

Financial Overview

Cash Balance (as of 6/30/2019)	$5.1 million
Current Annual Cash Burn	~$4.0 million
Debt (as of 6/30/2019)	-
Basic Shares Outstanding (as of 6/30/2019)	9.3 million
Fully Diluted Shares Outstanding (as of 6/30/2019)*	10.4 million

*Consists of common stock plus outstanding stock options

Investment Highlights and Upcoming Milestones

Event	Timing
First Patient dosed in Validive Phase 3	**0-6 months**
First Patient dosed in Camsirubicin Phase 2	
Initiate ongoing updates from open-label Camsirubicin Phase 2, such as dose escalation results	**6-12 months**
Interim analysis of Validive Phase 3 trial	**12-18 months**
Initiate second Validive Phase 3 trial	
Interim analysis of Camsirubicin Phase 2 trial	**18-24 months**
Topline Validive Phase 3 first trial data readout	**24-30 months**
Topline Camsirubicin Phase 2 trial data readout	
Initiate Validive rolling NDA submission with Fast Track	**30-36 months**

Monopar Therapeutics Inc.