Power and Precision in Cancer Radiotherapeutics

PLUS™ THERAPEUTICS

Norman LaFrance, MD
Chief Medical Officer
nlafrance@plustherapeutics.com

2022 SNMMI Therapeutics Conference

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We believe in the critical importance in developing & delivering innovative, targeted radiotherapeutics for patients battling rare & difficult-to-treat cancers.

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Radiopharmaceuticals for Cancer

GUGGENHEIM February 3, 2022

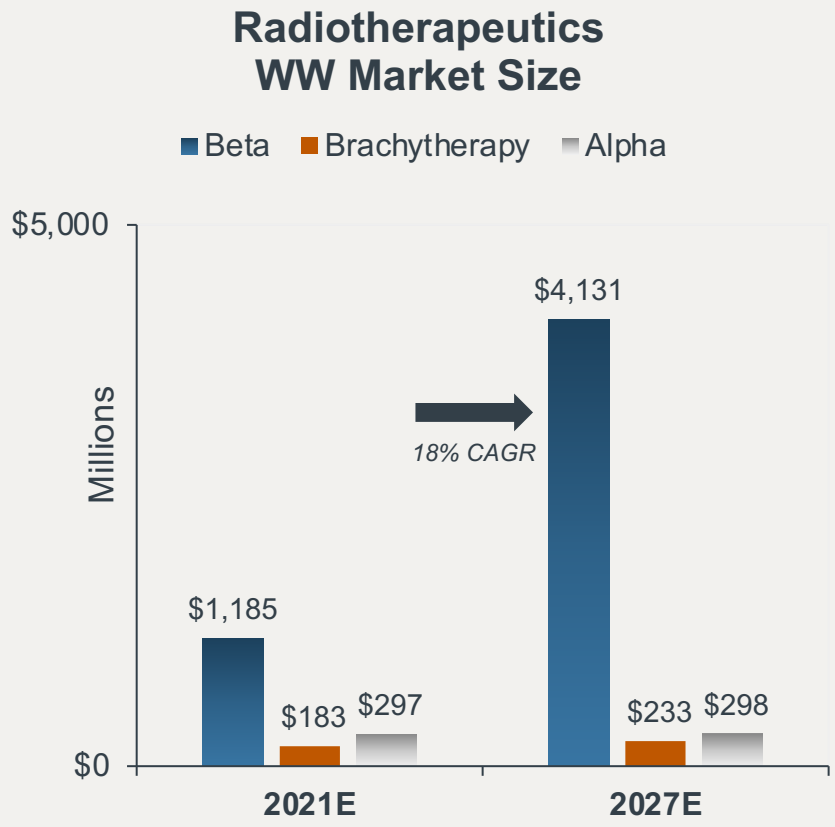
High Alpha & Low Beta: A Primer on Therapeutic Radiopharmaceuticals as a Compelling Next-Gen Approach for Solid Tumors

"Theoretically, any cancer can be cured if **enough radiation** can be **delivered** to it."

Dr. Andrew Brenner
Professor Neuro Oncology & Neurosurgery
Kolitz/Zachry Endowed Chair Neuro-Oncology Research

In 2016, there were **~3 million cancer survivors treated with radiation (29% of all cancer survivors)** & this number is projected to see a large increase over the next several years.

Cancer Epidemiol Biomarkers Prev 2017 Jun;26(6):963-970



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Source: Nuclear Medicine/Radiopharmaceuticals Global Market

Targeted Radiation Therapy & Mechanism of Action

Types of Radiation

External Beam Radiation

Internal Targeted Radiation

Absorbed Radiation & DNA Damage

1 Gray Radiation

=

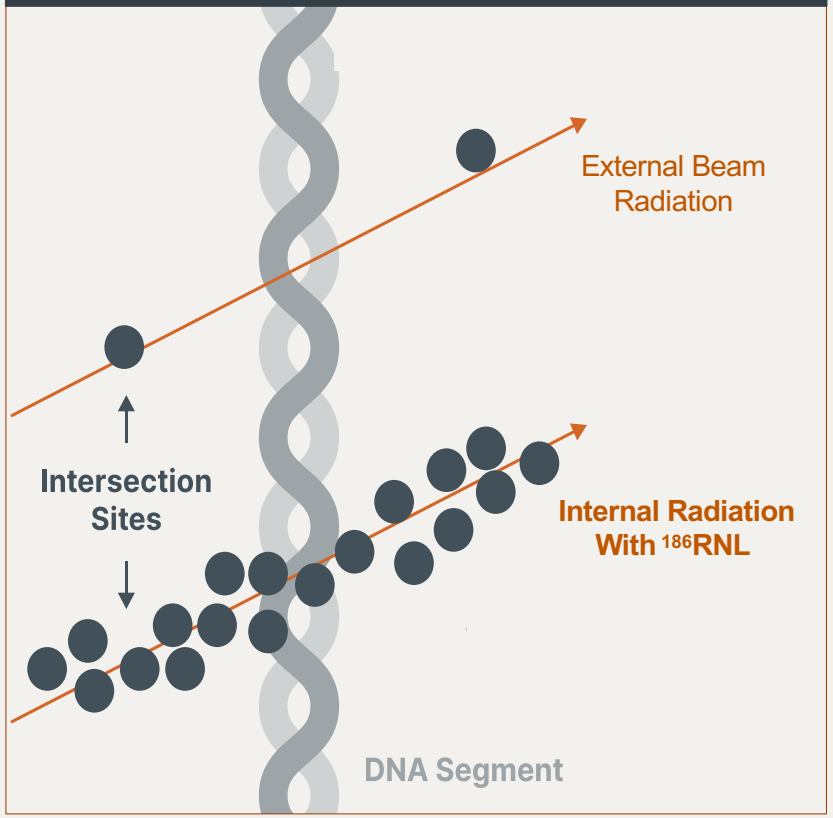
10^5 Ionizations

1,000 damaged DNA bases
1,000 single strand (SS) breaks
20-40 double strand (DS) breaks

Absorbed Radiation & Recurrent GBM

	DS DNA Breaks
EBRT (35 Gy)	700 - 1,400
^{186}RNL (600 Gy)	**12,000 - 24,000**

Radiation Mechanism of Action



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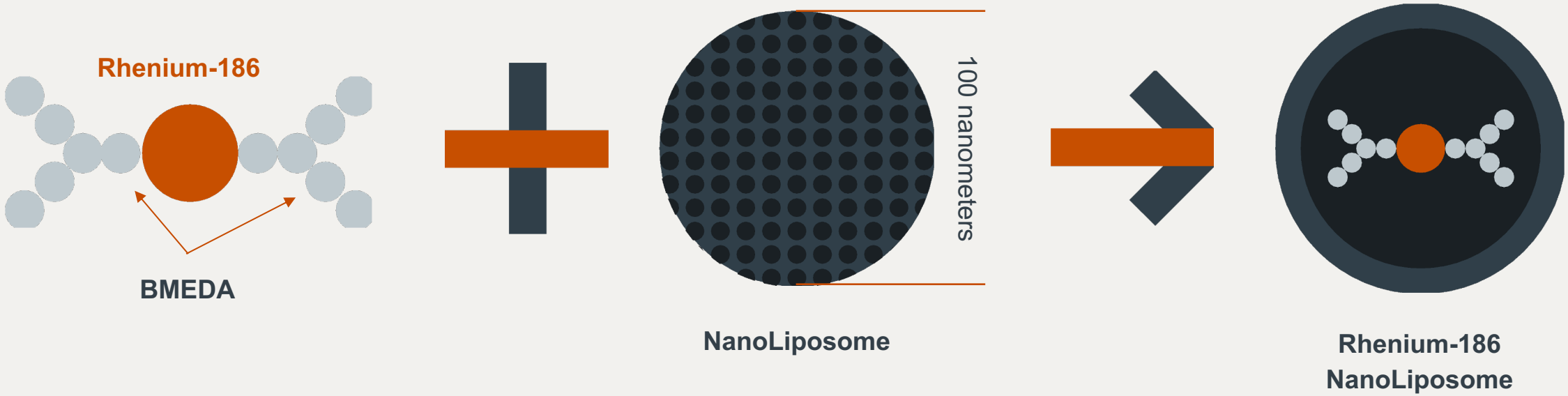
Lead Investigational Drug: Rhenium-186 NanoLiposome (^{186}RNL)

Rhenium-186

+ Dual energy emitter: beta (cytotoxic) & gamma (imaging)
+ Short average path length (1.8 mm): high precision
+ Low dose rate: safer for normal tissues
+ High radiation density: overwhelms innate DNA repair mechanisms

Proprietary Nanoscale Compound with a Unique Isotope



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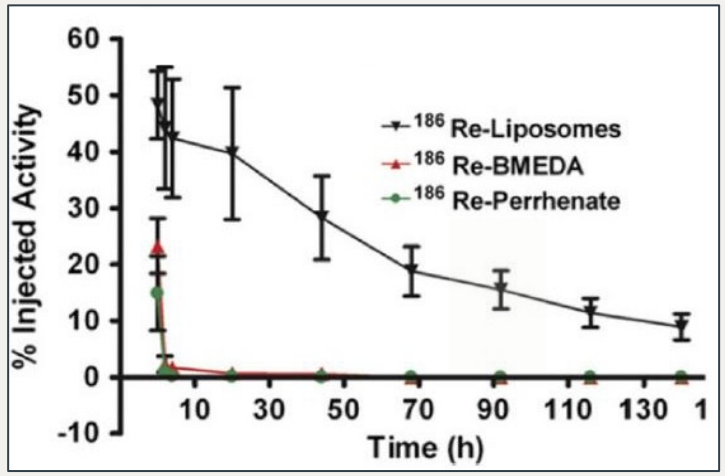
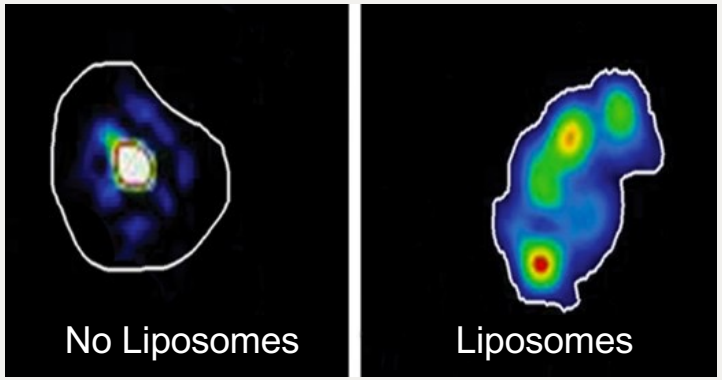
Spatiotemporal Behavior of ^{186}RNL Following Direct Brain Delivery

Prolonged Half-Life & Brain Retention





Prolonged Tumor Retention
Liposomal encapsulation significantly extends the in vivo intracranial half-life of Rhenium-186 (90 hours) & decreases clearance rate from the brain.

Reduced Tumor Dispersion
Liposomal encapsulation significantly extends Rhenium-186 retention within the tumor & therefore improves dispersion characteristics in tissues.

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Source: Phillips, W et al. *Advanced Drug Delivery Reviews,* 2014

Rare & Difficult-to-Treat Cancers

Responsible for Substantial Morbidity & Mortality Worldwide

+ Rare cancers represent 27% of all cancers; all pediatric cancers are rare
+ Rare cancers account for 25% of all cancer deaths; 5-year survival rate is lower for patients with a rare cancer than those with a more common cancer
+ Treatments for rare cancers are eligible for orphan drug designations

FACTS ABOUT CNS TUMORS

Glioblastoma: deadliest, most common brain cancer in adults

Leptomeningeal Metastases: late complication in 5% of cancer patients

Pediatric Brain Cancer: 2nd most common type of cancer in children

FACTS ABOUT LIVER TUMORS

Primary Liver Cancer: 42k cases diagnosed annually in U.S. with 5-year survival of 20%

Secondary Liver Cancer: ~50-60% of colorectal cancer patients develop metastases to liver

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Sources: CBTRUS Statistical Report, NBTS, NCI

Plus Therapeutics Pipeline

Investigational Drug	Indication	FDA Designation(s)	External Funding	Stage	Status
^{186}RNL	Recurrent Glioblastoma	Orphan Drug Fast Track	NIH/NCI to Phase 2	Phase 1 Dose Escalation	Enrolling
	Recurrent Glioblastoma (22.3 mCi)	Orphan Drug Fast Track	NIH/NCI to Phase 2	Phase 2	2022
	Recurrent Glioblastoma - retreatment	—	—	—	Submitted 2021 FDA
	Leptomeningeal Metastases	Fast Track	—	Phase 1	Enrolling
	Pediatric Brain Cancer	—	—	Pre-IND	IND Submission 2022
^{188}RNL-BAM	Hepatocellular Carcinoma	Pre-clinical			IND Enabling CMC & Pre-clinical
	Liver Metastases	Pre-clinical			IND Enabling CMC & Pre-clinical

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Innovative, targeted radiotherapeutics for patients with central nervous system tumors.

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Glioblastoma (GBM)

A Rare, Incurable, & Fatal Brain Cancer with No Good Treatment Options

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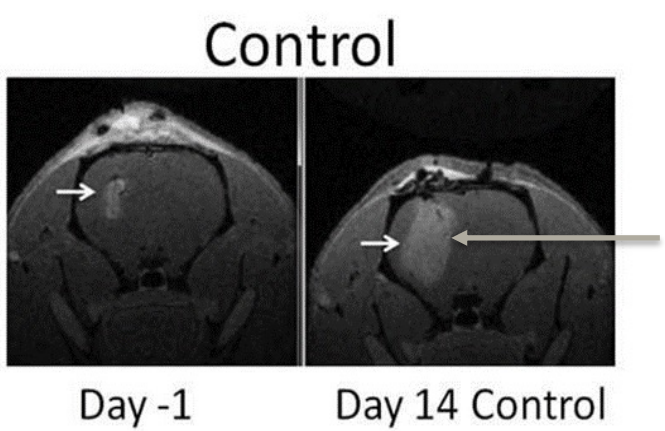
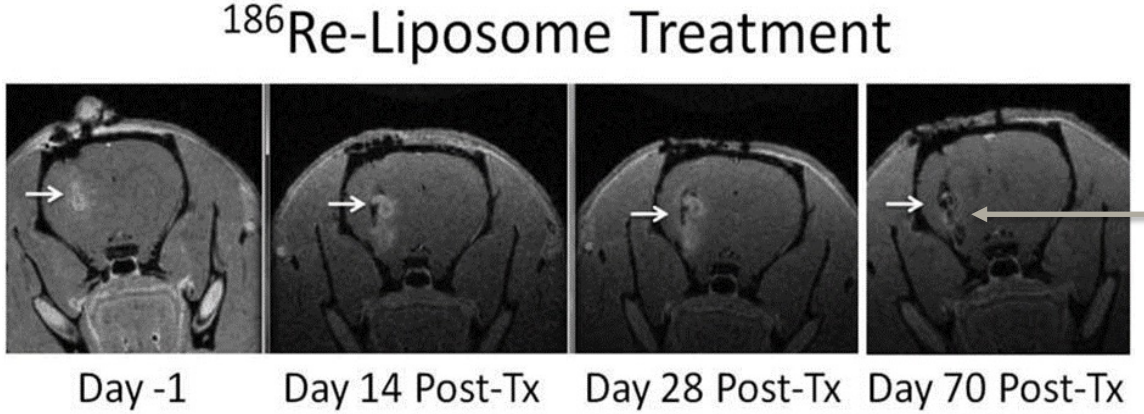
^{186}RNL Preclinical GBM Data

Tumor Regression in U87 & U251 Intracranial Xenograft Models



Tumor growth & expansion in untreated control animals with brain cancer.



Tumor regression in ^{186}RNL treated brain cancers.

- Bioluminescence assay showed many of the treated animals had a loss of activity to background levels suggesting complete eradication of the tumor.
- MRI analysis (above) supported the observation of tumor eradication.
- Blinded histologic evaluation by neuropathologist showed no residual disease.

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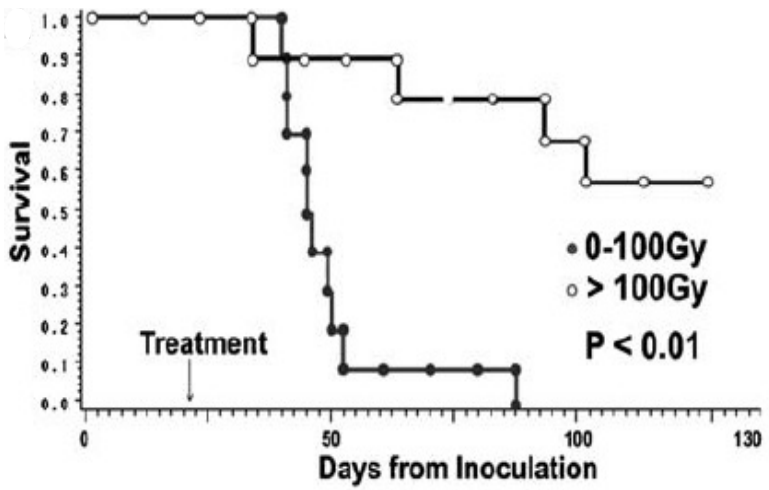
Source: Phillips, W et al. *Advanced Drug Delivery Reviews,* 2014

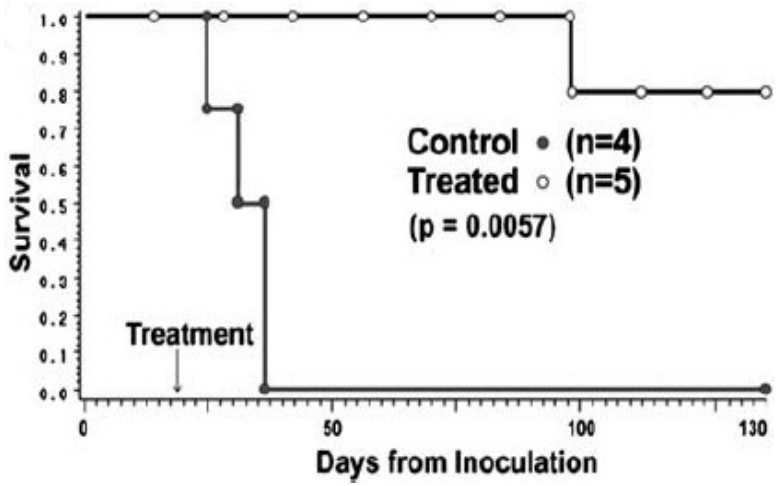
^{186}RNL Preclinical GBM Data

^{186}RNL Significantly Prolongs Survival in U87 & U251 Intracranial Xenograft Models

U87



U251



- Doses of up to 1,845 Gy were tolerated without weight loss or neurological deficit.
- No maximum tolerated dose of ^{186}RNL reached.
- Statistically significant prolongation in survival, limited only be the end of the experiment.
- Blinded histologic analysis by neuropathologist showed no residual tumor all treated animals.

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Source: Phillips, W et al. *Advanced Drug Delivery Reviews,* 2014

ReSPECT-GBM Phase 1/2 Clinical Trial Design

Multi-center, sequential cohort, open-label, volume & dose finding study of the safety, tolerability, & distribution of ^{186}RNL given by convection enhanced delivery to patients with recurrent or progressive malignant glioma after standard surgical, radiation, and/or chemotherapy treatment.

- Single arm, prospective Phase 1/2 study utilizing a modified Fibonacci dose escalation scheme, followed by an expansion at the designated recommended phase 2 dose (RP2D).
- Maximum number of planned subjects: up to 55 subjects (including patients enrolled in the Phase 1 dose escalation trial & a subsequent cohort at the RP2D).
- Supported by a NIH/NCI grant through Phase 2.

ClinicalTrials.gov: NCT01906385

^{186}RNL for Recurrent Glioblastoma

Potential Advantages Compared to External Beam Radiation Therapy

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Trial Enrollment & Patient Demographics

Patient Demographics (N=22)

Gender	
Male	14 (64%)
Female	8 (36%)
Tumor Volume	Average = 8.3 cc; Range = 0.9 cc - 22.8 cc
Prior Treatments	Average = 1.7 treatments; Range = 1 – 3 treatments
Prior Bevacizumab	N = 5 patients
IDH Mutational Status	
Wild type	18 (90%)
Mutated	2 (10%)
MGMT Status	
Methylated	4 (25%)
Unmethylated	12 (75%)
Glioma grade	
Grade IV	20 (91%)
Grade III	2 (9%)

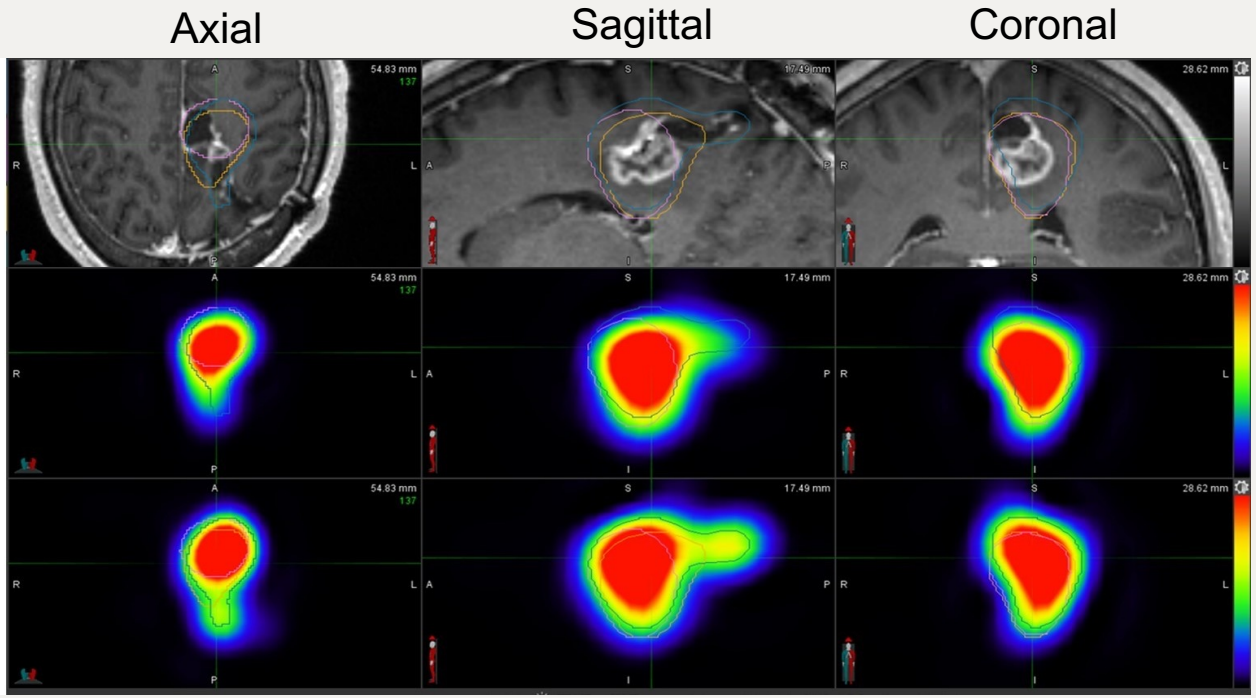
Updated Trial Enrollment

Cohort	Infused Volume (mL)	Total ^{186}RNL Activity (mCi)	Concentration (mCi/mL)	Average Absorbed Dose (Gy)	Status
1	0.66	1.0	1.5	198	Enrolling Cohort 8 (n = 23 subjects)
2	1.32	2.0	1.5	122	
3	2.64	4.0	1.5	234	
4	5.28	8.0	1.5	171	
5	5.28	13.4	2.5	423	
6	8.80	22.3	2.5	287	
7*	8.80	22.3	2.5	584	
8	12.3	31.2	2.5	TBD	

Cohort 7 utilized same volume & dose as cohort 6 but with increase in maximum flow rate to 20 microliters/minute

Case Study: Tumor Coverage & Retention

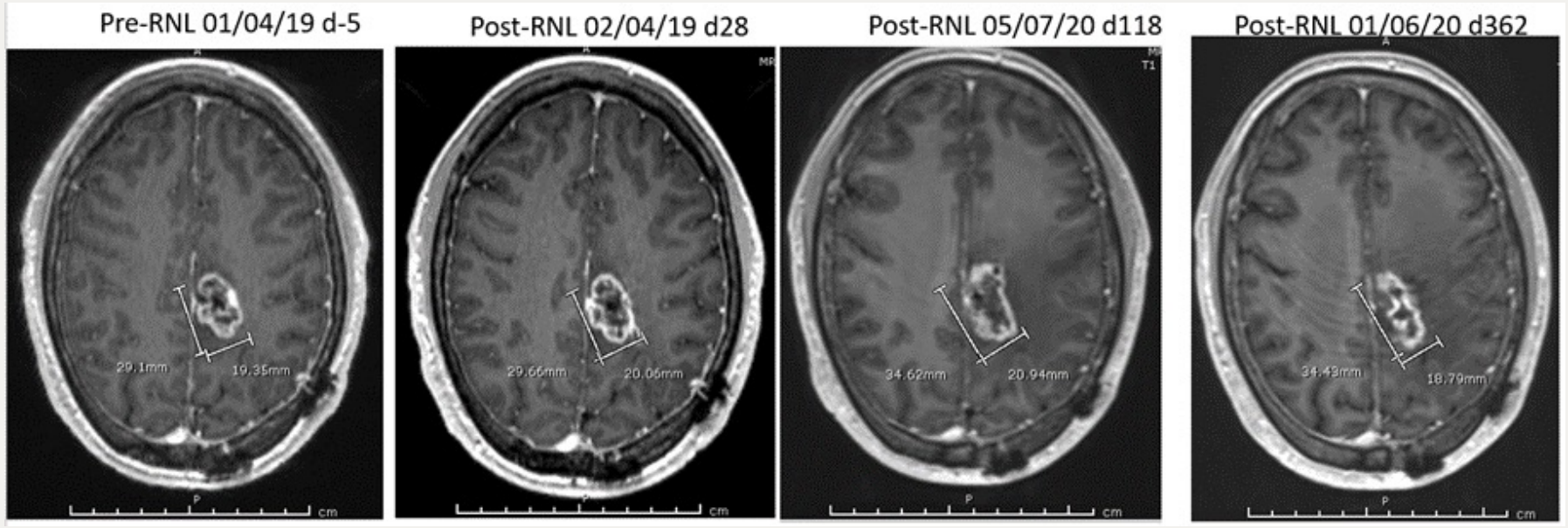
Cohort 5/Subject 01-014: MRI & SPECT/Radiation Dosimetry



+ Deep brain tumor recurrence
+ Tumor Volume: 6.5 mL
+ Tumor Coverage: >90%
+ Absorbed Dose Delivered to Tumor: 419 Gy

Natural History of Recurrent GBM Lesions After ^{186}RNL

Cohort 5/Subject 01-014: Tumor Response Observed to Day 362



- MRI scans revealed an initial increase in size which peaked at Day 118, with some associated edema, pseudo-progression
- Tumor shrinkage out to at least Day 362
- Remains alive at 160 weeks after single treatment

Patient Safety

^{186}RNL Appears to be Safe & Well Tolerated

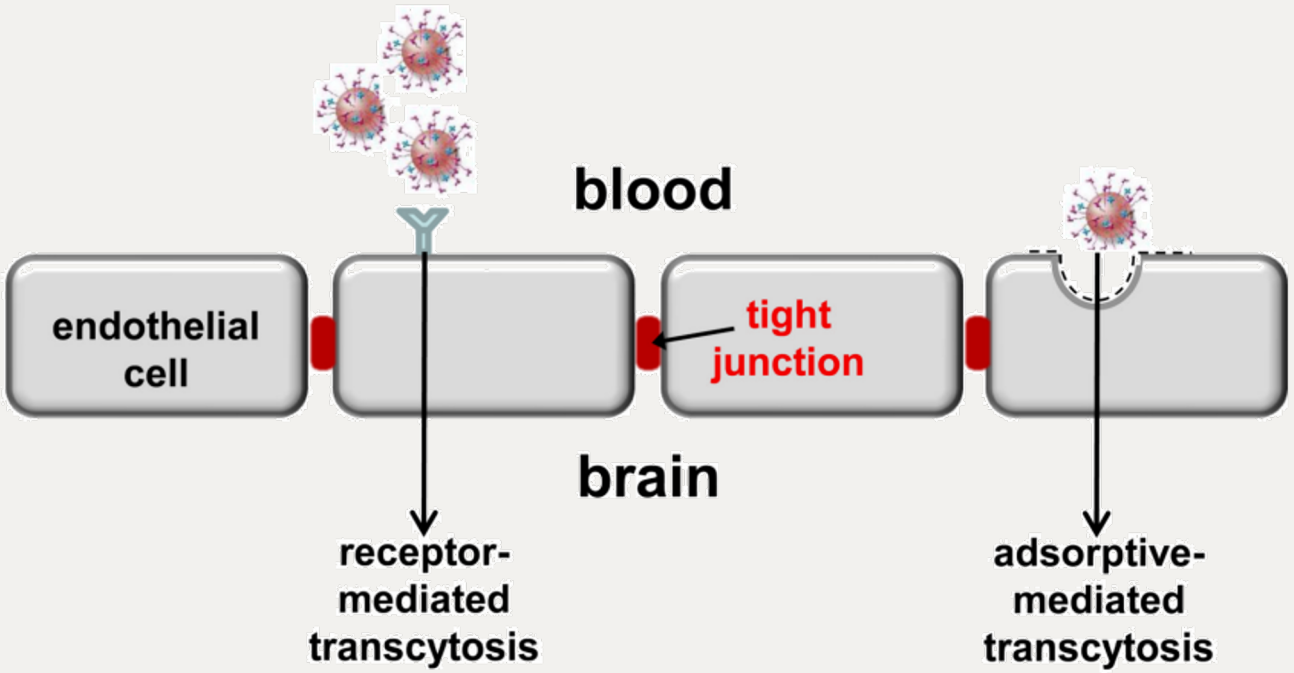
Thus far, in the Phase 1 study of 23 subjects in 8 dosing cohorts with recurrent glioblastoma receiving a single dose of ^{186}RNL:

+ There have been no dose limiting toxicities.
+ The majority of AEs reported were mild or moderate (Grade 1 or 2) in intensity.
+ Most AEs were considered causally unrelated to ^{186}RNL except scalp discomfort, which was considered related to the surgical procedure.
+ Serious adverse events:

Serious Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Osteonecrosis (Left Shoulder)	0	0	1	0	0	**1**
Seizure	0	1	2	0	0	**3**
Vasogenic cerebral edema	0	0	2	0	0	**2**
Pneumonia	0	0	1	0	0	**1**

Drug Delivery to the Central Nervous System

BBB Significantly Hinders Passage of Systemically Delivered Therapeutics & the Brain Extracellular Matrix Limits the Longevity of Locally Delivered Agents



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Source: Patel, T. et al. *Adv Drug Deliv Rev*. 2012 May 15; 64(7): 701-705

Convection Enhanced Delivery (CED)

Proposed & Introduced by NIH Researchers in 1990s to Deliver Drugs That Do Not Cross the BBB & Are Too Large to Diffuse Effectively Over the Required Distances

Complicated Modeling

Optimize simulations for flow trajectory & infusion parameters

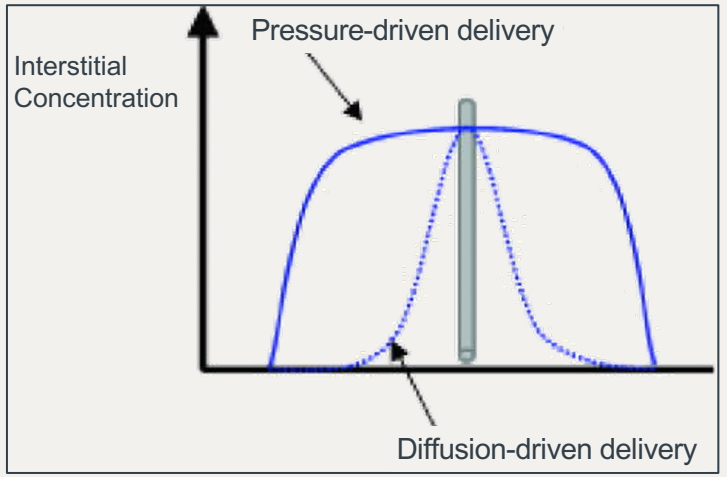
Simplified Modeling

Define clinical use (protocol development)

Darcy's Law

$$q = -\frac{\kappa}{\mu}\nabla\rho \quad where$$

q = instantaneous flow rate
κ = permeability
μ = dynamic viscosity of the fluid
$\nabla\rho$ = pressure drop



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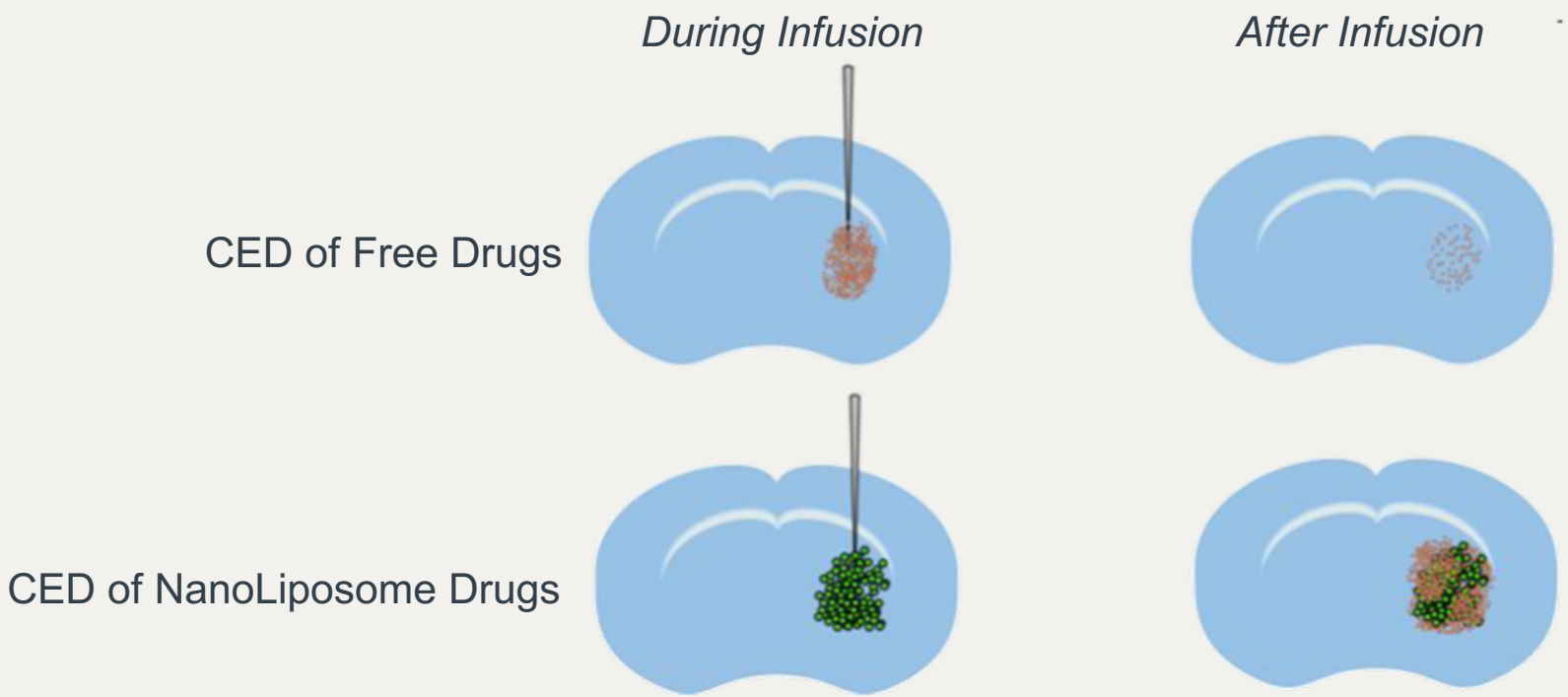
Source: Raghavan R. et al. *JNS,* Volume 20 Issue 4, 2006

Convection Enhanced Delivery (CED)

Locally Delivered NanoLiposomes Bypass the BBB Altogether, are Widely-Distributed, & Provide Long-Lasting Drug Release



Source: Patel, T. et al. *Adv Drug Deliv Rev*. 2012 May 15; 64(7): 701-705

Convection Enhanced Delivery (CED)

Technique Generates a Pressure Gradient To Deliver ^{186}RNL Through the Interstitial Spaces of the Central Nervous System

Workflow

1) Treatment planning
2) Imaged guided catheter placement
3) Catheter placement confirmation
4) Bedside infusion
5) Monitoring

Potential Benefits

+ Large target coverage volumes
+ High local concentration at target volume
+ Low systemic exposure, less side effects
+ Minimized systemic drug-drug interaction
+ Homogeneous concentration profiles

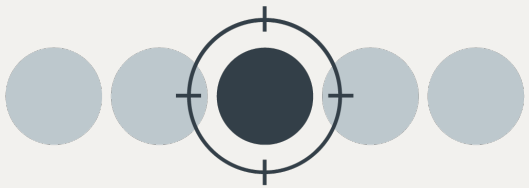
Delivery via CED Catheter

Convection Enhanced Delivery (CED)

Feasibility Demonstrated in All Cohorts, With Up to 4 Catheters Placed Per Patient

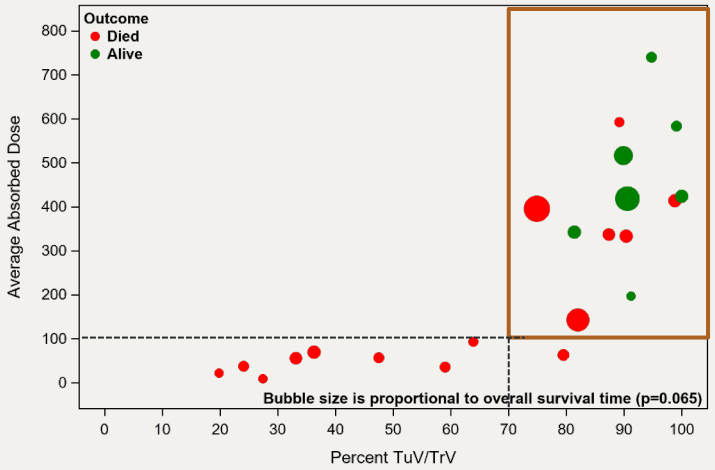
Evolution of Key Delivery Parameters	Absorbed Radiation Dose Correlates with OS	Delivery Reliability in Later Cohorts

+ Targeted Delivery



Activity	**1.0– 31.2 mCi**
Volume	**0.6 – 12.3 mL**
Max Flow Rate	**5 – 20 ul/min**
CED Catheters	**1 – 4 catheters/patient**

Therapeutic Threshold >100 Gy



P = 0.065

Cohort 1-4

+ 12 patients treated
+ 5/12 (42%) >100Gy

Cohort 5-7

+ 11 patients treated
+ 9/11 (82%) >100Gy

ReSPECT-GBM Updated Efficacy Data Since SNO 2021

Current Enrollment is 23 in 7 Dosing Cohorts (March 2022)

Overall Survival Data, N=23
(Stratification by Radiation Dose & Cohort)

Dose (Gy)	Cohort	N	Median OS (wks)	Mean OS (wks)	Alive	FPI	LPI	Duration
>100	1 to 5	8	82	88	2	3/10/15	7/22/20	280
>100	6 to 7	6	44	40	5	10/22/20	1/12/22	64
	Subtotal	**14**	**46**	**67**	**7**			
<100	1 to 5	7	22	23	0	3/10/15	7/22/20	280
<100	6 to 7	2	23	23	0	10/22/20	1/12/22	64
	Subtotal	**9**	**22**	**23**	**0**			

***Mono Tx Bevacizumab**	**32.1**

Table 3 (Online only). Studies Included in the Meta-analysis of rGBM Patients Treated with Bevacizumab Monotherapy

Study/Authors	Design	Year Published	N	Median Age (years)	> First Recurrence (%)	Performance Status	Median Survival (weeks)
BELOB Trial Taal et al. [18]	Phase II RCT	2014	50	58	0	ECOG (patients) 0 (13); 1 (32); 2(5)	34.8
BRAIN Trial Friedman et al. [3]	Phase II RCT	2009	85	54	19	KPS (patients) 90-100 (38); 10-80 (47)	40.5
Kreisl et al. [20]	Phase II RCT	2009	48	53	N/A	KPS median (range) 90 (60-100)	31.0
Chamberlain et al. [26]	Retrospective	2010	50	64	68	KPS median (range) 80 (60-100)	37.0
Field et al. [21]	Phase II RCT	2015	62	55	31	KPS (patients) 90-100 (22); 70-80 (28), <70 (10); NA (2)	32.6
Nagane et al. [22]	Phase II single-arm	2012	29	57	42	KPS (patients) 90-100 (17); 70-80 (12)	45.7
Chen et al. [25]	Retrospective	2015	57	61	0	KPS (patients) 90-100 (13); 70-80 (10); <70 (20); NA (14)	29.4
Ducreux et al. [17]	Prospective cohort	2015	313	55	88	ECOG (patients) 0 (30); 1 (204); 2 (57); 3 (12); NA (10)	26.0
Pooled Historical Cohort			**694**				**32.1**
VB-111 TTbP cohort	Phase II single-arm	NA	24	60	50	KPS median (range) 80 (60-100)	59.1

Abbreviations: ECOG, Eastern Cooperative Oncology Group; KPS, Karnofsky performance status; N, number of patients treated; NA = not applicable; RCT, randomized controlled trial; TTbP, treatment through progression

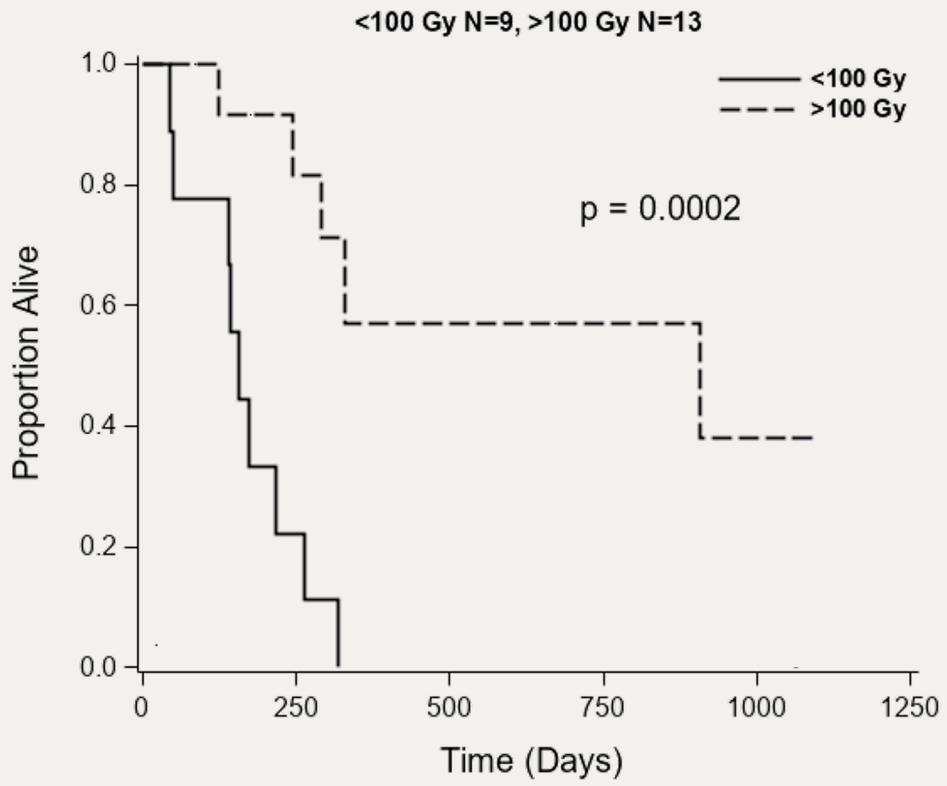
Key Points

- Cohorts 1-5 represent patients treated from 2015 to 2020
  - 2 pts. still alive
  - The median & mean survival is between 2-3 times monotherapy with Bevacizumab
- Cohorts 6-7 have been treated recently, since October 2020
  - Low overall survival related to recent enrollment
  - 5/6 still alive
- Empirically, patients with rGBM receiving >100 Gy survive longer than those receiving <100 Gy & longer than those receiving monotherapy bevacizumab

* Cloughesy, T. et al. *Neuro-Oncology*, 22(5), 705–717, 2020
Brenner, A. et al. *Neuro-Oncology*, 22(5), 694–704, 2020
Wenger, K. et al. *Oncol Lett.* 14(1), 1141-1146, 2017

ReSPECT-GBM Clinical Trial

Comparative OS Based on Average Absorbed Radiation Dose



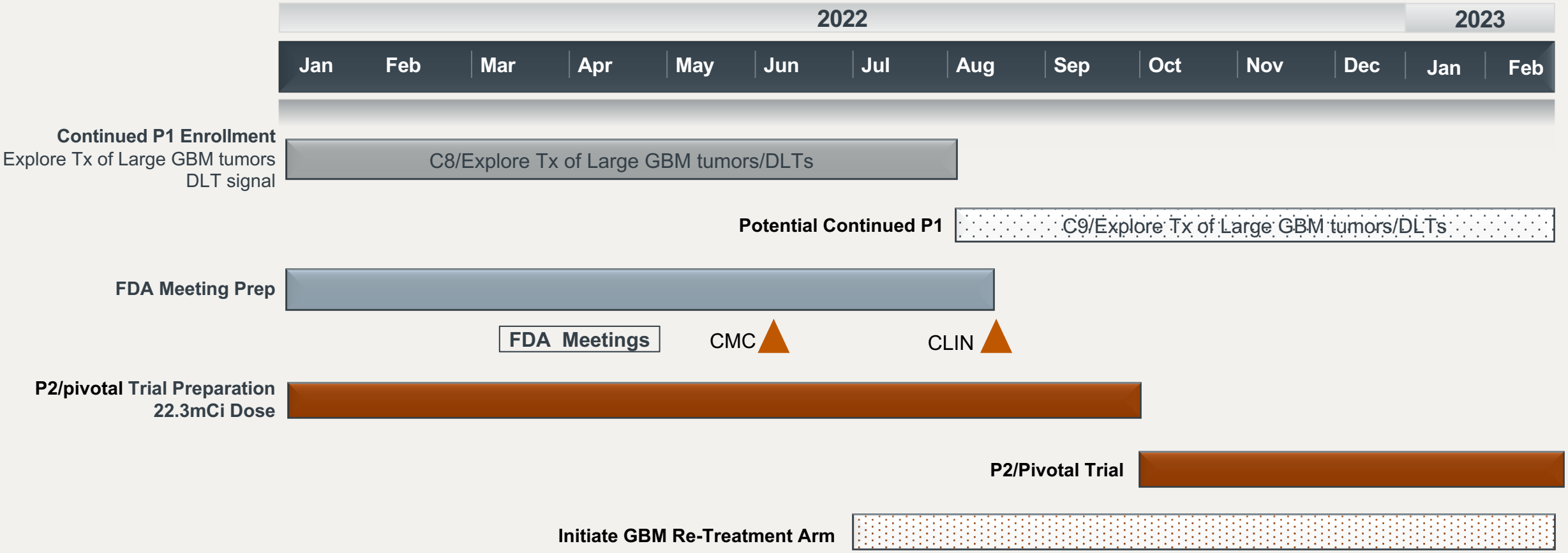
Summary

- No DLTs, favorable safety & tolerability profile
- Delivery >100 Gy radiation correlates with increased OS
- Recent cohorts (5-7) >80% delivery success
- Radiation distribution volume in cohort 6/7 treats >50% market of rGBM
- At cohort 6/7 level

Cohort	Infused Volume (mL)	Total ^{186}RNL Activity (mCi)	Concentration (mCi/mL)	Average Absorbed Dose (Gy)
6*	8.80	22.3	2.5	584

- Plan: Take cohort 6/7 22.3mCi dose to Phase 2/pivotal

2022 ReSPECT-GBM Clinical Timeline



^{186}RNL in Leptomeningeal Metastases

Disease Background

+ Leptomeningeal metastases, also known as carcinomatosis, is a cancer that starts in one part of the body spreads to the leptomeningeal lining of the brain & spinal cord surrounding the cerebrospinal fluid (CSF) space.

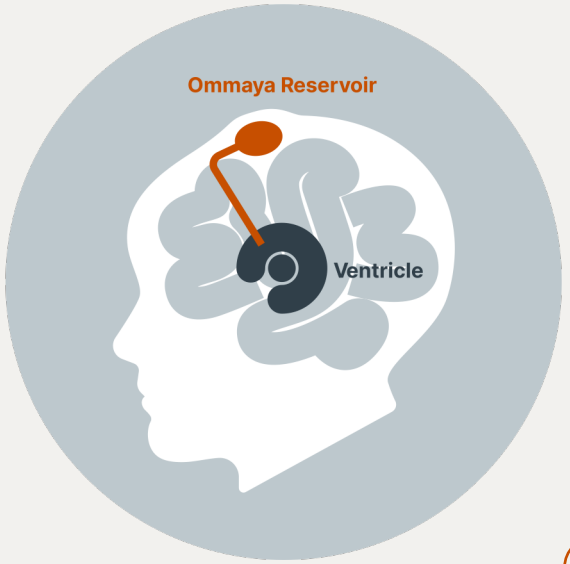
100 nm NanoLiposomes in CSF

+ Circulate feely throughout the CSF
+ Migrate to meningeal surfaces where LMC is located
+ Have an extended half life - several weeks vs. hours with unencapsulated drugs
+ Safe & effective in preclinical models

Phase 1 Clinical Trial

+ 2-part dose escalation trial
+ 1st site at UTSW enrolling
+ Planned 5 sites
+ 5 cc delivered via Omaya reservoir
+ Feasibility & safety

Delivery via Standard Ommaya Reservoir



ReSPECT-LM Trial Protocol Synopsis

Leptomeningeal Metastases

A Two-Part, Multicenter Phase 1 Study to Determine the Maximum Tolerated Dose/ Maximum Feasible Dose, Safety, & Efficacy of Single Dose Rhenium-186 Nanoliposome (^{186}RNL) Administered via the Intraventricular Route for Leptomeningeal Metastasis

- **Primary Objectives**
  - To characterize the safety & tolerability of a single dose of ^{186}RNL by the intraventricular route & to identify a maximum tolerated dose (MTD) and/or maximum feasible dose (MFD).
- **Secondary Objectives**
  - Characterize the pharmacokinetic & dosimetry profile of a single dose of ^{186}RNL when administered intraventricularly via Ommaya reservoir.
  - Develop a multiple dosing strategy of ^{186}RNL for subsequent clinical trials.
  - Determine the overall response rate (ORR) defined as the proportion of all evaluable patients achieving a response as the best overall response at the time of progression.
  - Determine the duration or response (DoR) defined as the time from first response to LM progression.
  - Determine progression free survival (PFS) defined as the time from first treatment to date of LM progression or death from any cause.
  - Determine the overall survival (OS) define as the time from first treatment to date of death.
- **Endpoints**
  - **Primary Endpoints**
    - Incidence & severity of adverse events (AE) & serious adverse events (SAE)
    - Incidence of dose limiting toxicities (DLT)

Innovative, targeted radiotherapeutics for patients with liver tumors.

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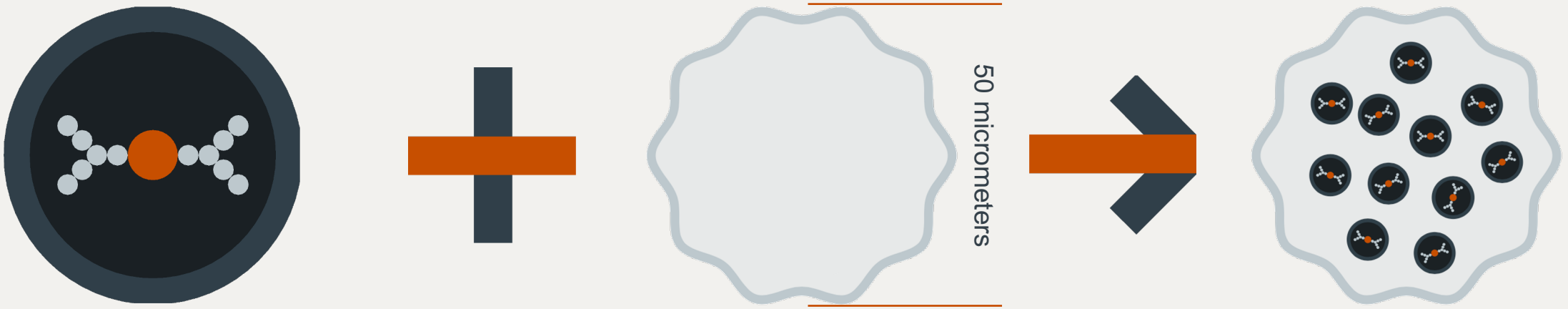
Second Investigational Drug: Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (^{188}RNL-BAM)

Proprietary Microscale Compound with a Unique Isotope

Rhenium-188

+ Dual energy emitter: beta (cytotoxic) & gamma (imaging)
+ Short average path length (3.1 mm): offers greater precision
+ Low dose rate: safer for normal tissues
+ High radiation density: overwhelms innate DNA repair mechanisms
+ Generator-produced for quick availability



Rhenium-188 NanoLiposome

Biodegradable Alginate Microsphere

Rhenium-188 NanoLiposome
Biodegradable Alginate Microsphere

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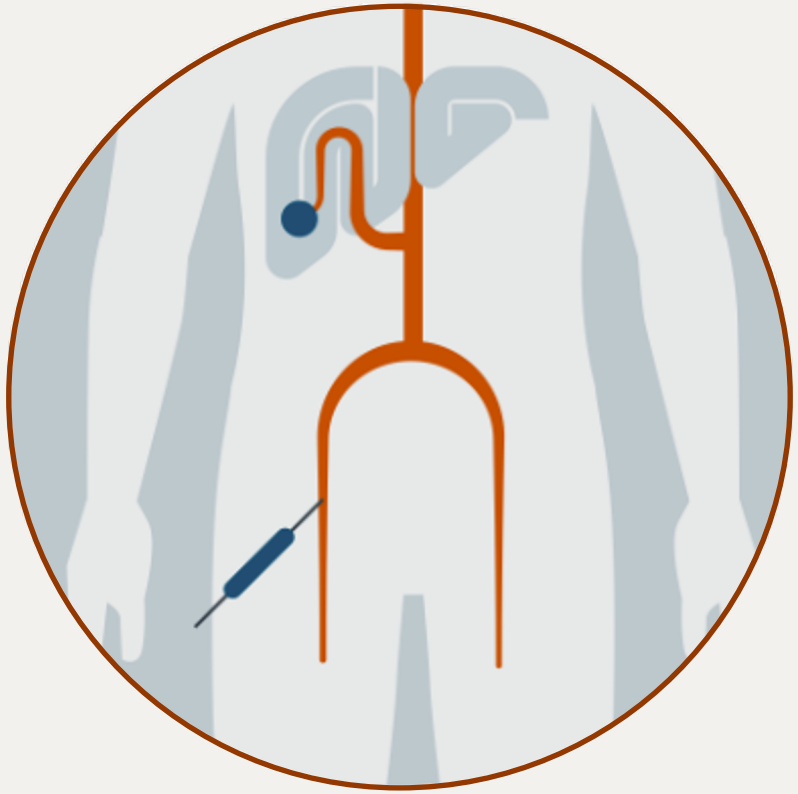
^{188}RNL-BAM Radioembolization Therapy

In Development as a Non-Surgical Locoregional Treatment Option for Solid Organ Tumors

The **Approach**

A single intra-arterial injection of ^{188}RNL-BAM in which biodegradable microspheres block the blood flow to the targeted solid organ tumors & simultaneously deliver a therapeutic payload of radiation.



The **Potential Advantages**

Compared to 2 radioembolization therapies currently available, ^{188}RNL-BAM may offer:

1) Biodegradable microspheres
2) Higher quality imaging
3) Work-up predictive of final clinical outcome
4) Shorter production time via generator
5) Improved patient access, incl. ex-U.S.
6) Higher margins
7) Better translate to other indications

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^{188}RNL-BAM Radioembolization Therapy: Initial Targets

Liver Cancer is the 6th Most Common & 3rd Deadliest Cancer

The Challenges

Hepatocellular Carcinoma

The most common type of primary liver cancer.

+ Incidence: 42k
+ 5-Year Survival: 20%

Metastatic Colorectal Cancer

A secondary form of liver cancer with a high level of severity.

+ Incidence: 150K
+ 5-Year Survival: 14%

The Opportunities

Pursue new & relevant routes of administration & mechanisms of delivery/action.

Extend the life of patients with liver cancer through a safer, more targeted, & convenient treatment approach.

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2022 Corporate Milestones

Recurrent Glioblastoma (GBM)

- ReSPECT-GBM Phase 2/pivotal clinical trial
  - FDA CMC & Clinical Meetings
  - Complete CMC activities for 186RNL for GMP/Phase 3 drug supply
  - Initiate ReSPECT-GBM P2/pivotal trial
- ReSPECT-GBM Phase 1 clinical trial of ^{186}RNL, dose escalation & report data
- Initiate & open ReSPECT-GBM retreatment protocol

Leptomeningeal Metastases (LM)

- Complete initial cohort enrollment, feasibility assessment in ReSPECT-LM Phase 1 clinical trial

Pediatric Brain Cancer (PBC)

- Obtain FDA IND approval & initiate ReSPECT-PBC Phase 1 clinical trial of ^{186}RNL

Liver Cancer

- Complete technology transfer & key CMC, FDA IND-enabling studies for ^{188}RNL-BAM asset

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+ Headquarters: Austin, Texas
+ Manufacturing: San Antonio, Texas
+ Nasdaq: PSTV
+ Corporate Website: PlusTherapeutics.com
+ ReSPECT™ Website: ReSPECT-Trials.com