Transforming **radiotherapy** for patients with cancer

April 2021

Galera Therapeutics, Inc

Forward-Looking Statements

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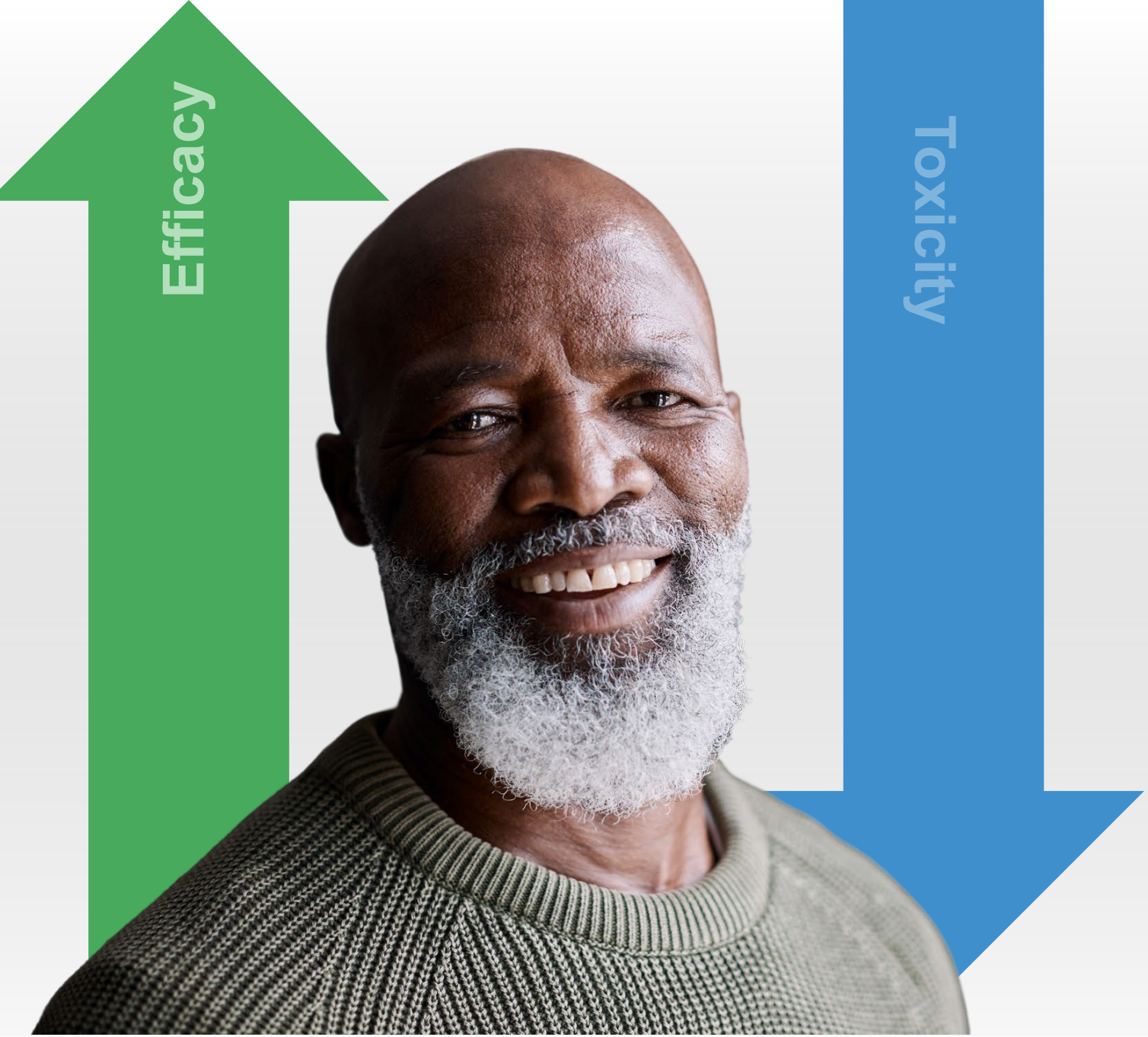
Whenever the Company uses the terms "transform radiotherapy" or "transforming radiotherapy" in this presentation, it is referring to its mission statement.



Transforming radiotherapy by **reducing side effects** and **increasing anti-cancer efficacy**

Over 50% of Cancer Patients Receive Radiotherapy

REDUCING TOXICITY

In radiotherapy Galera shifts the balance from normal tissue-damaging high levels of superoxide….

...WHILE INCREASING EFFICACY

to potentially
tumor-toxic
high levels of
hydrogen peroxide.

Transforming Radiotherapy

Reducing IMRT Toxicity

In Phase 3 with Breakthrough Therapy Designation

Severe Oral Mucositis
In Head & Neck Cancer

Esophagitis
in Lung Cancer

Increasing SBRT Efficacy

Encouraging Survival Data in Pancreatic Cancer Trial

Pancreatic Cancer
Locally Advanced

Lung Cancer
Locally Advanced

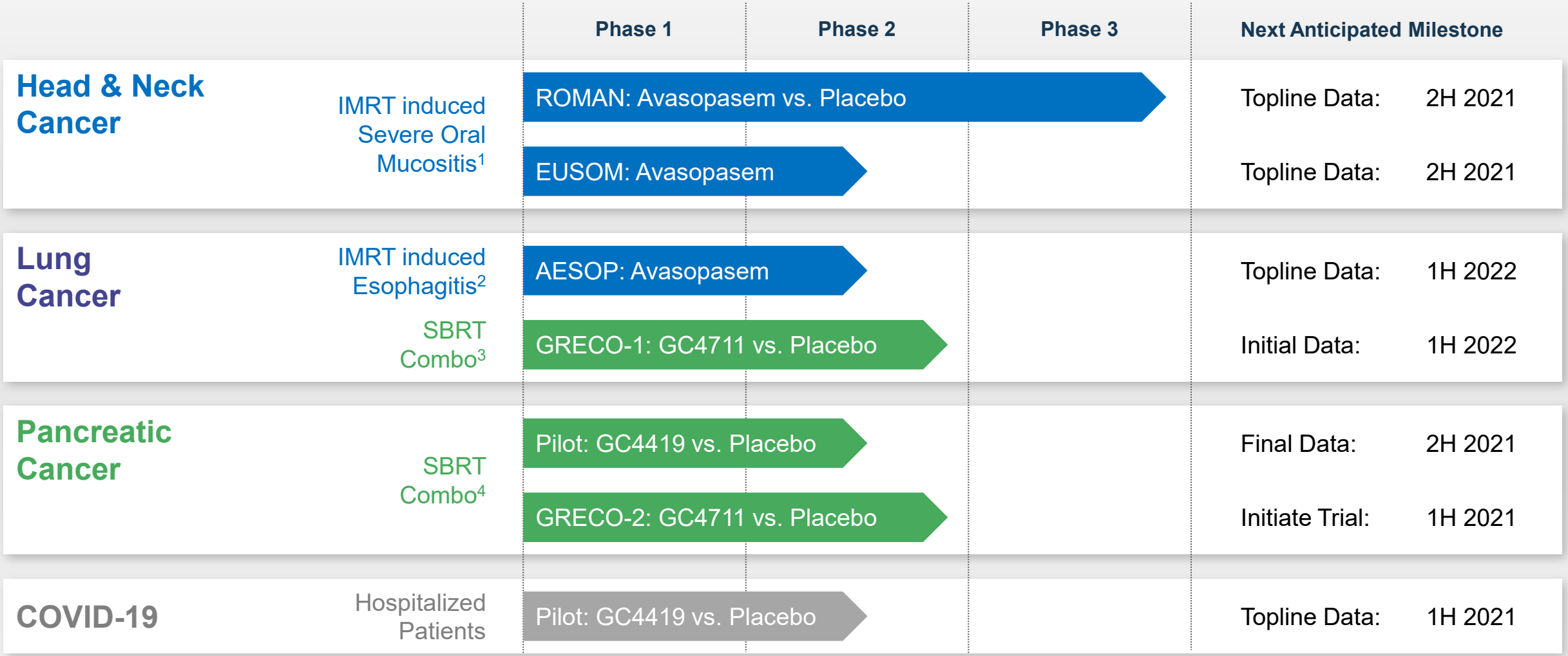
Large Market Opportunities

High Unmet Medical Need & Limited Therapeutic Options

Radiotherapy needed by over half of patients with cancer

Galera building US commercial team for Avasopasem Launch

Robust Pipeline



(1) EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe
(2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
(3) Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711
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Reducing IMRT Toxicity

Toxicity

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223 Patient Phase 2b Trial – Robust Results

Randomized Placebo-Controlled Severe Oral Mucositis (SOM) Trial

Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks

Treatment

- Avasopasem 90mg, 30mg, or placebo
- 60-minute IV infusion just before IMRT

Endpoints

- Primary: Reduction in SOM duration
- Secondary: Reduction in SOM incidence & severity

Randomized 1:1:1

- **Avasopasem 90mg x 7 weeks**
- R
- **Avasopasem 30mg x 7 weeks**
- **Placebo x 7 weeks**

Stratification

- Tumor HPV status: + / -
- Cisplatin schedule: qwk / q3wk

Tumor Outcomes

- Survival (OS, PFS)
- Locoregional control (LRC)
- Distant Metastases Free (DMF)

WHO Grading Scale:

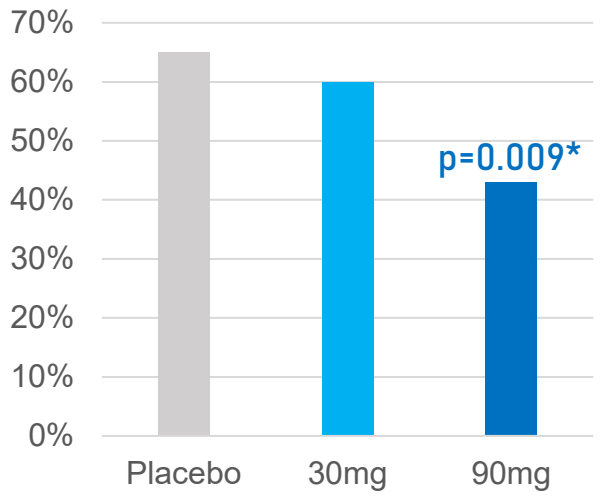
1	2	3	4
No ulcers Erythema & soreness	**Ulcers** Able to eat solid diet	**Ulcers** Require liquid diet	**Ulcers** Unable to eat or drink

Consistent and Encouraging Results

Across SOM Endpoints

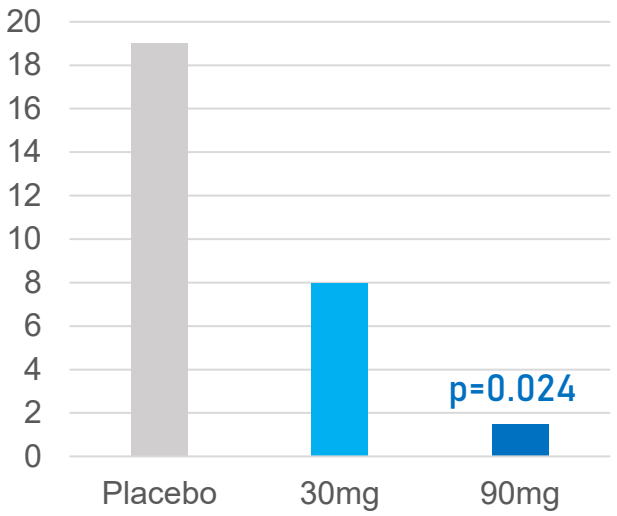
SOM Incidence

34% Reduction in incidence



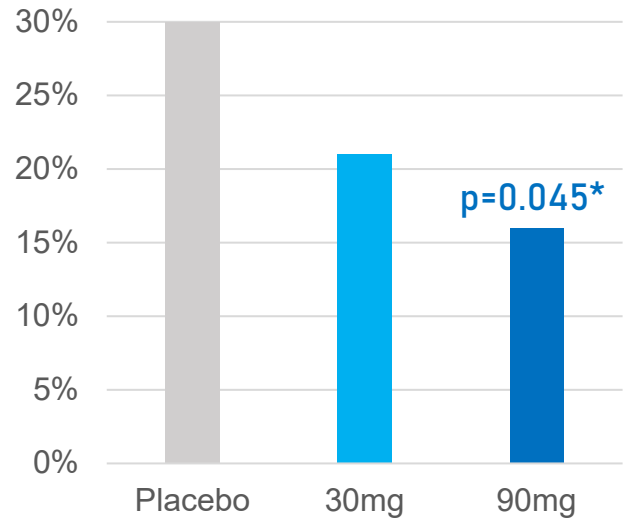
SOM Duration

92% Reduction in median days



SOM Severity

47% Reduction in incidence of Grade 4

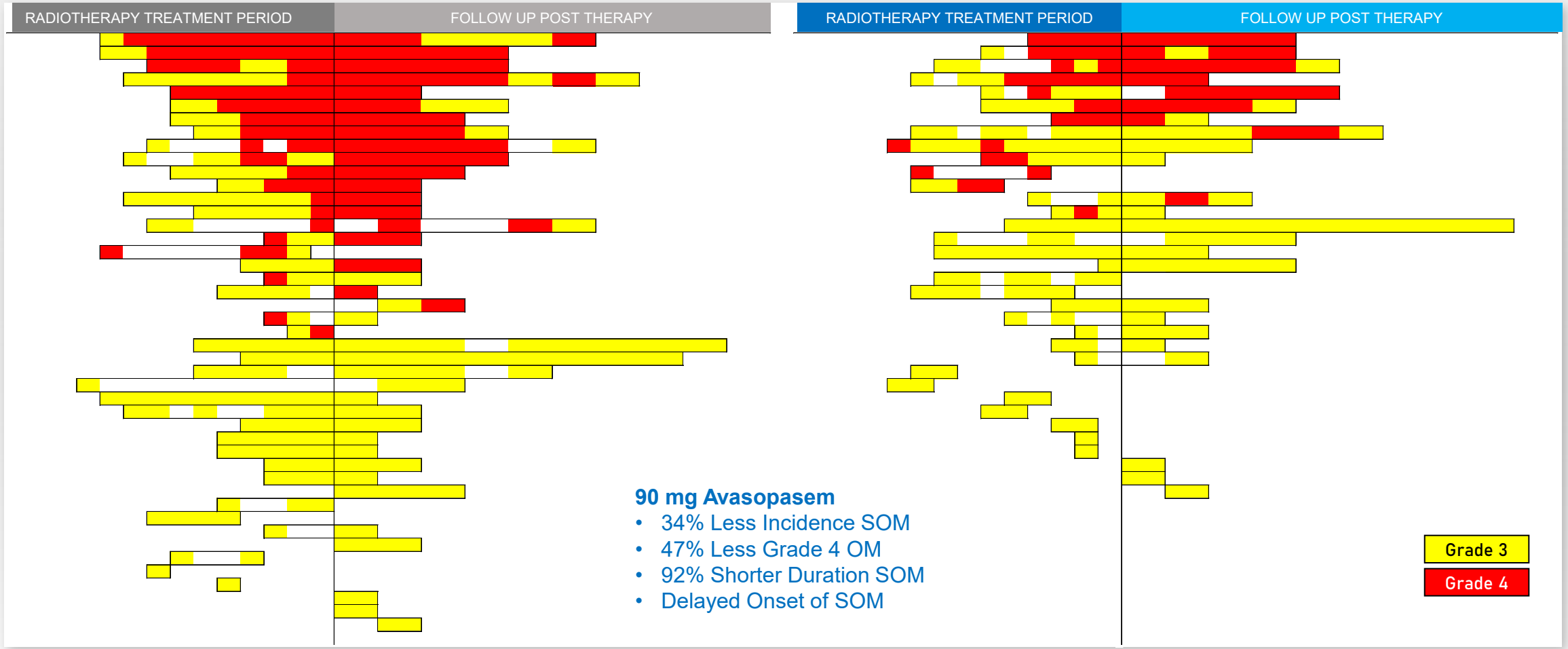


Intent-To-Treat (ITT) Population
*Secondary endpoints (incidence and severity) have nominal p values compared to placebo

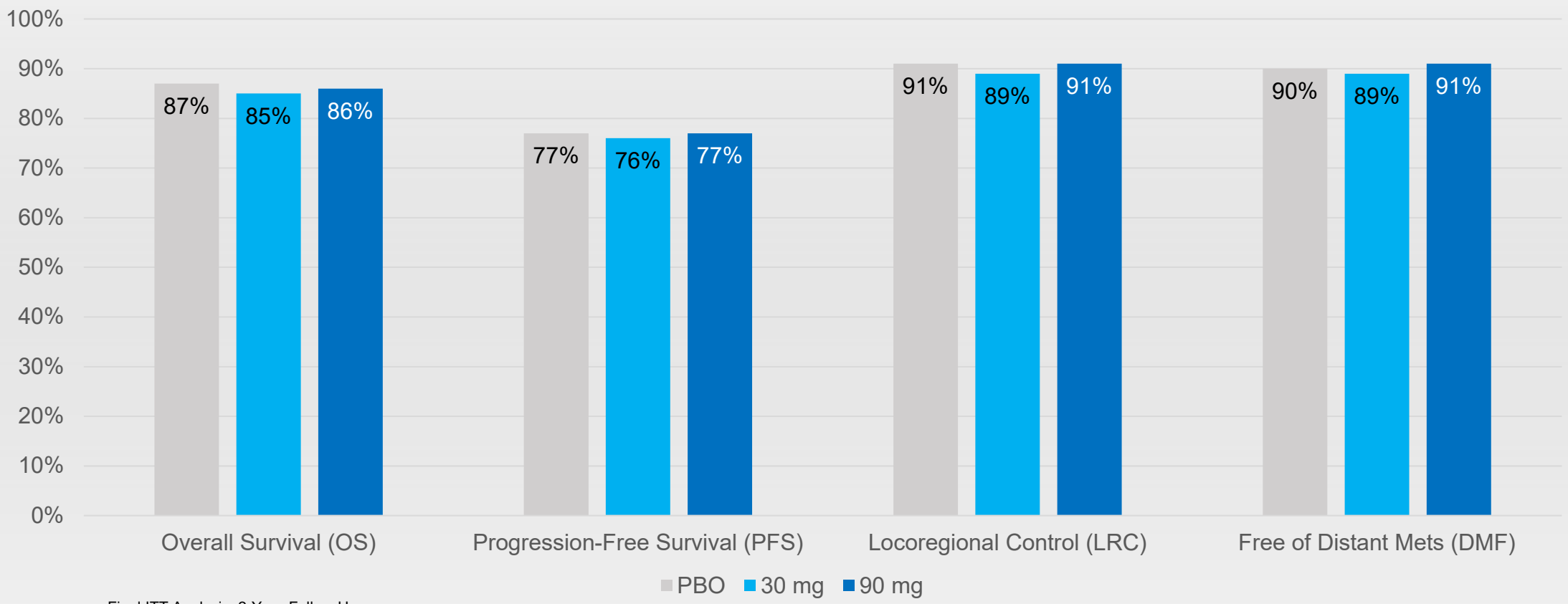
Avasopasem Efficacy Significantly Better than Placebo

PLACEBO Arm (45 of 74 Pts had ≥1 visit with SOM)

90MG Avasopasem Arm (35 of 76 Pts had ≥1 visit with SOM)



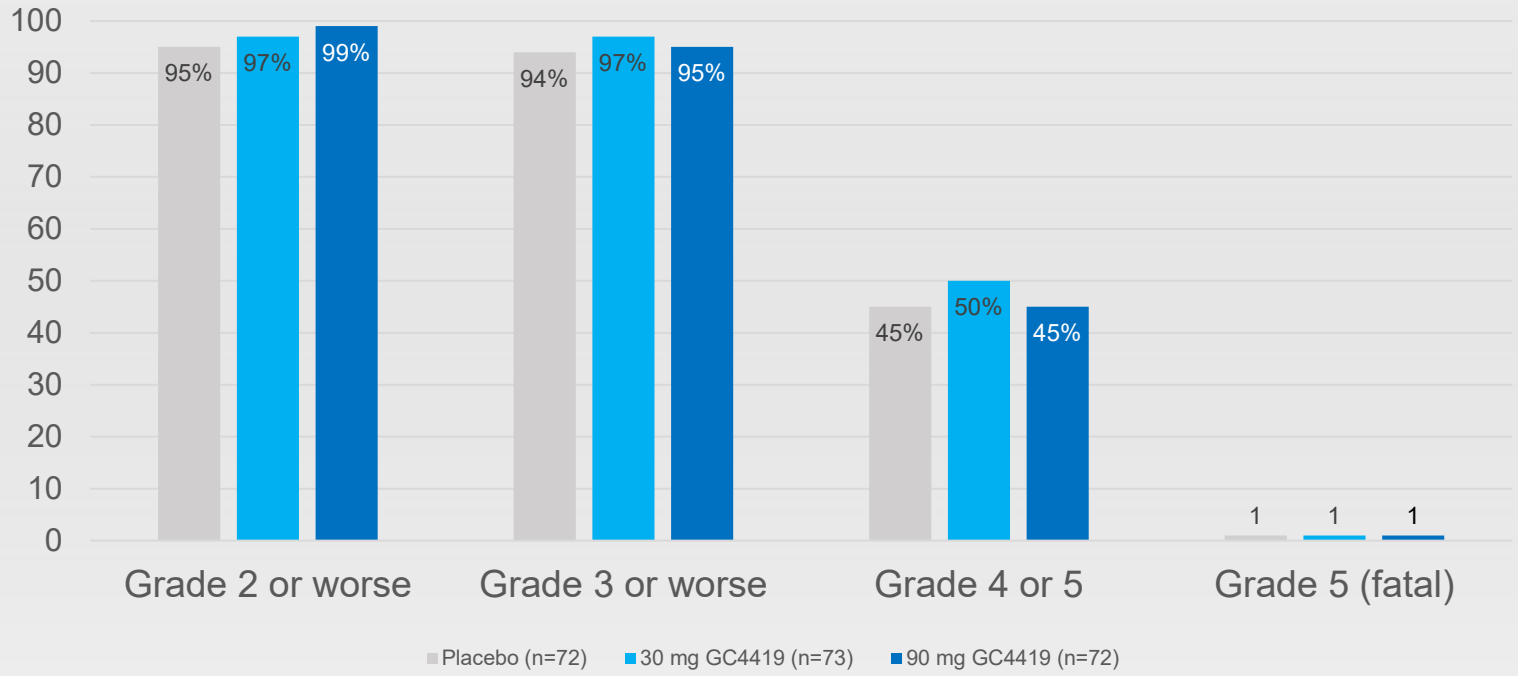
Radiotherapy Efficacy Results Maintained Over Two Years



Final ITT Analysis; 2-Year Follow-Up

Safety Results Comparable to Placebo

Avasopasem Generally Well Tolerated



Most Frequent AEs (any grade)	Placebo (n=72)	30 mg Avasopasem (n=73)	90 mg Avasopasem (n=72)
Lymphopenia	89%	92%	88%
Nausea	75%	68%	82%
Fatigue	69%	60%	65%
Oropharyngeal pain	64%	63%	61%
Constipation	53%	59%	64%
Radiation skin injury	47%	51%	53%
Vomiting	47%	52%	49%
Dysgeusia (taste)	49%	55%	43%
Dysphagia	43%	42%	47%
Weight decreased	35%	40%	44%
Oral candidiasis	29%	45%	43%
Leukopenia	39%	37%	39%

450 Patient Phase 3 Trial – Results this Year

Randomized Placebo-Controlled Severe Oral Mucositis Trial

Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks

Treatment

- Avasopasem 90mg or placebo
- 60-minute IV infusion just before IMRT

Endpoints

- Primary: Reduction in SOM incidence
- Secondary: Reduction in SOM duration & severity

Randomized 3:2

R

- **Avasopasem 90mg x 7 weeks**
- **Placebo x 7 weeks**

Stratification

- Surgery status: + / - before Rx
- Cisplatin schedule: qwk / q3wk

Tumor Outcomes

- Survival (OS, PFS)
- Locoregional control (LRC)
- Distant Metastases Free (DMF)

WHO Grading Scale:

1	2	3	4
No ulcers Erythema & soreness	**Ulcers** Able to eat solid diet	**Ulcers** Require liquid diet	**Ulcers** Unable to eat or drink

SOM Market Opportunity

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Head and Neck Cancer – Large Market Opportunity

Severe Oral Mucositis is most burdensome side effect – 70% get SOM

650,000

Global Head & Neck Cancer Incidence

65,630

US Patients Diagnosed each year

42,000

US Patients at Risk for RT-related SOM

Locally advanced HNC curable with the standard-of-care IMRT and cisplatin regimen

Head and Neck Cancer Can Affect Anyone

Babe Ruth, Lana Turner, Jamie Dimon, Ulysses S. Grant, Sigmund Freud, Humphrey Bogart, Grover Cleveland, Eddie Van Halen
Sammy Davis Jr., George Harrison, Michael Douglas, Ann Richards, Tony Gwynn

Avasopasem: First-to-Market Potential

Current Approaches Lack Efficacy

MAASC Guidelines focus only on symptoms[1]

- Basic Oral care
- Opioids, anesthetics
- Coating agents
- Benzydamine
- Anti-inflammatories

Rad Oncs Consider Topicals Ineffective

Market Research with 150 Radiation Oncologists[2]

- Only 20% of physicians believe topical agents perform well for oral mucositis

Avasopasem is Disease Modifying

Only Breakthrough Therapy Designation for SOM[3]

- Consistent and encouraging results across SOM endpoints
- Largest Phase 3 Trial
- Data anticipated in 2021

[1]Elad S et al, MASCC/ISOO Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. Cancer 2020;126:4423-4431
[2]Galera Market Research
[3]FDA breakthrough therapy designation received for avasopasem for reduction of SOM induced by radiotherapy, with or without systemic therapy

Concentrated Physician Population

SOM is Most Burdensome Side Effect of Curative IMRT + Cisplatin Regimen

5,000
Radiation Oncologists in U.S

2,500
Radiotherapy Treatment Sites

700
Top centers where >80% HNC Patients are treated

72%
Sites with Existing Infusion Capability[1]

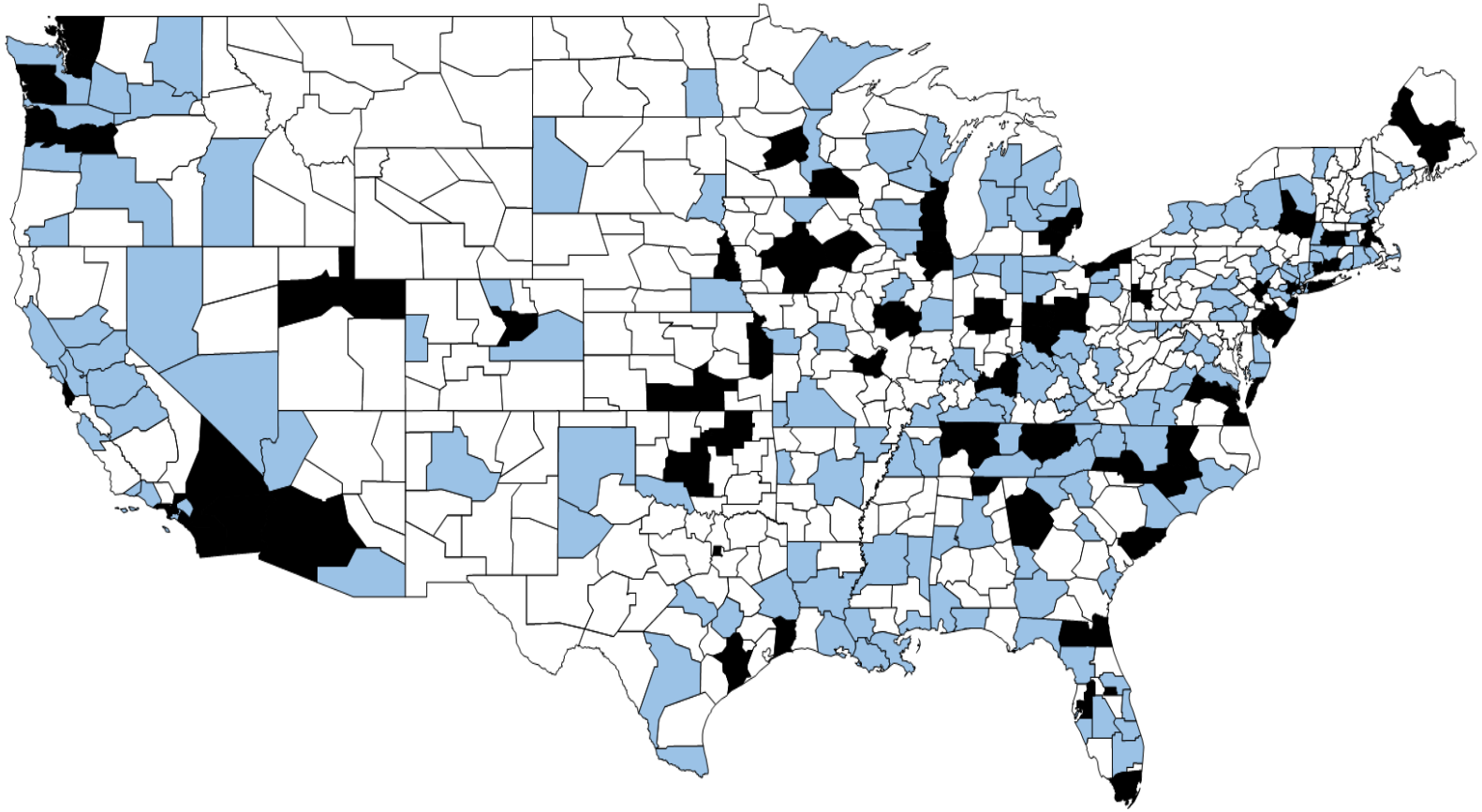
64%
Market Patient Share

38% IMRT centers currently infuse drugs[1]
34% more coordinate with medical oncology to infuse patients
Additional 17% can add capabilities to infuse patients

[1]Primary market research with 125 IMRT centers in the US

Where Patients with Head & Neck Cancer are Treated

76% Treated in only 29% Zip Code Areas



3-Zip Code Counts		Cases	
>104	72	16,701	58%
>53	141	21,786	76%
≤53	348	6,787	24%
	489	28,573	

Galera Market Research (122 Zip Codes are 0)

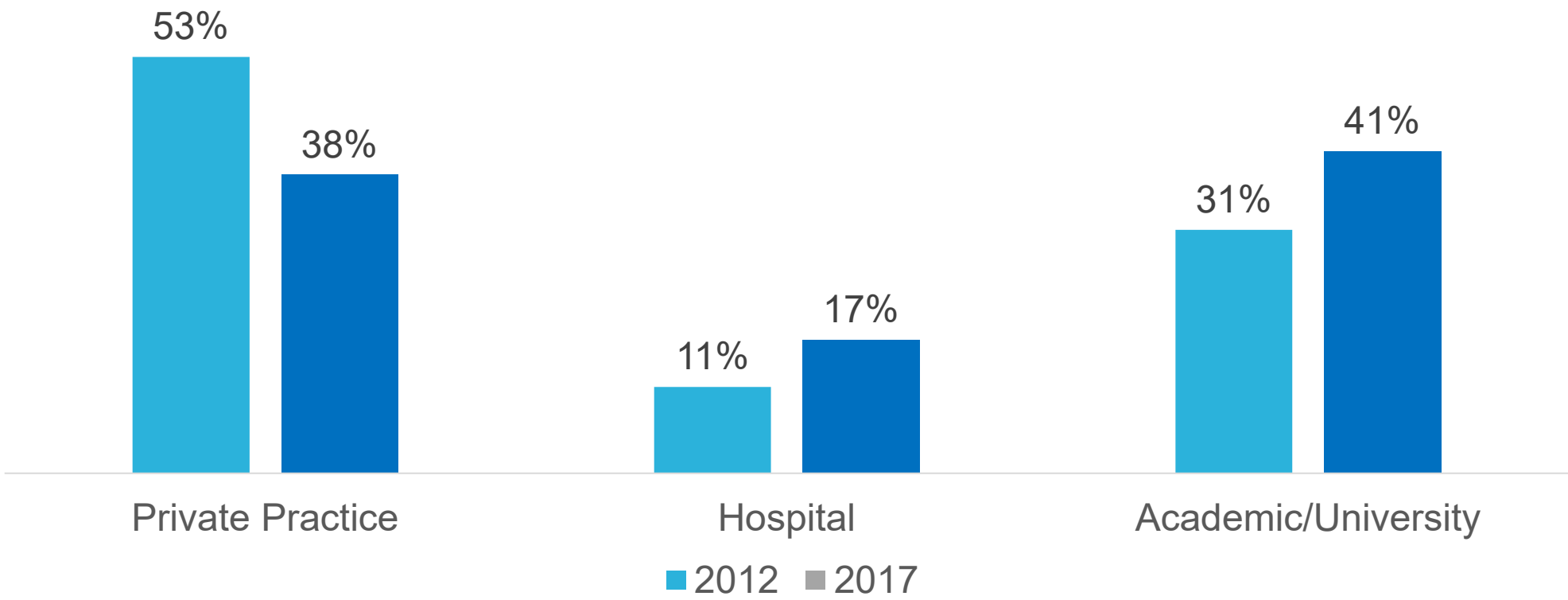
Most IMRT Centers Have Ability to Infuse Today

72% Radiotherapy Sites Have Existing Infusion Capability

Adoption Archetype Determinants	A Rad Oncs Have Current Capabilities	B Med Oncs Administer Infusions for Rad Onc	C Rad Oncs Need to Add Capabilities	D Rad Oncs Unlikely to Add Capabilities
Avasopasem Infusion Owner	Rad Onc	Med Onc	Rad Onc	-
MD-Stated Patient Volume	**High**	Low	**High**	Moderate
Ease of Coordination Today	**High**	**High**	Low	Low
Likelihood of Prescribing Avasopasem	**High**	**High**	**High**	Low
Total % Sample Distribution (n)	38% (51)	34% (39)	17% (23)	11% (12)

Data in above table based on primary market research with 125 IMRT centers in the US

US Radiation Oncologists Trending Away from Private Practice



[1]Data from ASTRO

Favorable Payer Landscape

$40,000

Additional medical expenses incurred by patients who develop OM

$15-25K

Indicative price of full course of therapy based on initial payer research

Price strategy intended to optimize patient access

Head and neck cancer not a focus for cost control measure

Step Edits Unlikely

High unmet need with limited treatment options

Esophagitis in Lung Cancer

50% patients get Grade 2 or worse

2,500,000

Global NSCLC Incidence

175,000

US Patients Diagnosed each year

50,000

US Patients at Risk for RT-related Esophagitis

Locally advanced NSCLC frequently treated with IMRT and chemotherapy

Increasing SBRT Efficacy

Efficacy

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People we Have Lost to Pancreatic Cancer

Pavarotti, Donna Reed, Dizzy Gillespie, Cardinal Bernardin, Eiko Ishioka, Bonanza's Pernell Roberts, Joan Crawford
Ben Gazzara, Alex Trebek, Alan Bates, Jack Benny, Dr. Sydney Salmon, Billy Paul, Rand Pausch (last lecture)
Ruth Bader Ginsburg, John Lewis, Henry Mancini, Sally Ride, Munster's Fred Gwynne, Columnist William Safire, Michal Landon

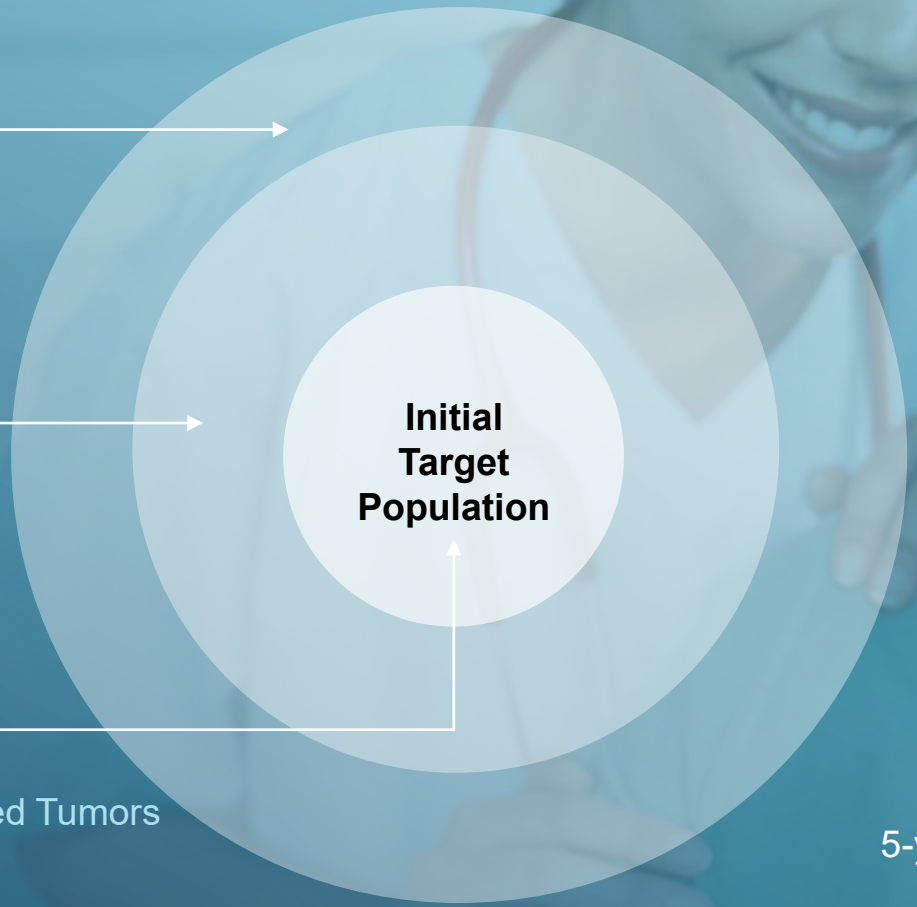
Pancreatic Cancer

High Unmet Medical Need With Limited Therapeutic Options

500,000
Global Incidence

60,000
US Patients Diagnosed each year

18,000
Patients with Unresectable Locally Advanced Tumors

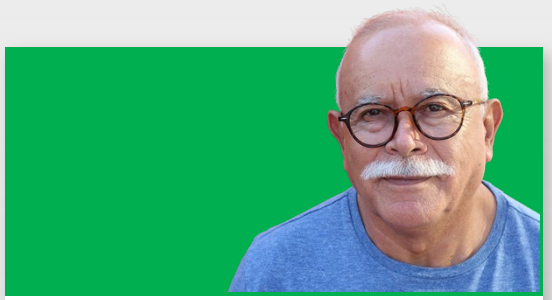


5-year survival rate only ~10%

SBRT use increasing for locoregional control of pancreatic cancer

Pilot Trial in Pancreatic Cancer

42-Patient Double-blind, Placebo-controlled, Randomized Trial



Population

- Patients with Locally-advanced Pancreatic Cancer (LAPC)
- Enrolled after 4-6 months of chemotherapy

Treatment

- High-Dose Stereotactic RT (SBRT) 10-11Gy x 5 doses
- 60-minute IV infusion of 90mg GC4419 or placebo

Endpoints

- Safety and Feasibility of dismutase mimetic with SBRT
- Survival (OS, PFS)
- Response Rate
- Tumor Control (DMC, LRC)

Design

R

- SBRT + GC4419 90mg x 5 doses
- SBRT+ Placebo x 5 doses

42 Patients

	Single Center	Multi Center
Placebo	N=8	N=10
GC4419	N=11	N=13
	>1 Year Follow-Up	>6 Months Follow-Up

Enrolling Centers

- MD Anderson, Houston, TX
- Moffitt Cancer Center, Tampa, FL
- UT Southwestern, Dallas, TX
- Duke University, Durham, NC

Highlights of Current Analysis

Follow-up through at least 6 months on all patients

85% Increase in Overall Survival

Survival

Median Overall Survival

GC **20.1 Mos**

PBO **10.9 Mos**

2.5-fold Increase in Response Rate

Response

Partial Response Rate

GC **29%**

PBO **11%**

2-fold Increase in Time to Metastases

Metastases

Median Time to Mets

GC **13.9 Mos**

PBO **7.0 Mos**

Surgical Resection

- 5/24 on GC
  All with clear tumor margins
- 2/18 on PBO
  1 with clear tumor margins

Hazard Ratios (GC vs. PBO)

OS	0.4
PFS	0.4
LRC	0.3
DMC	0.3

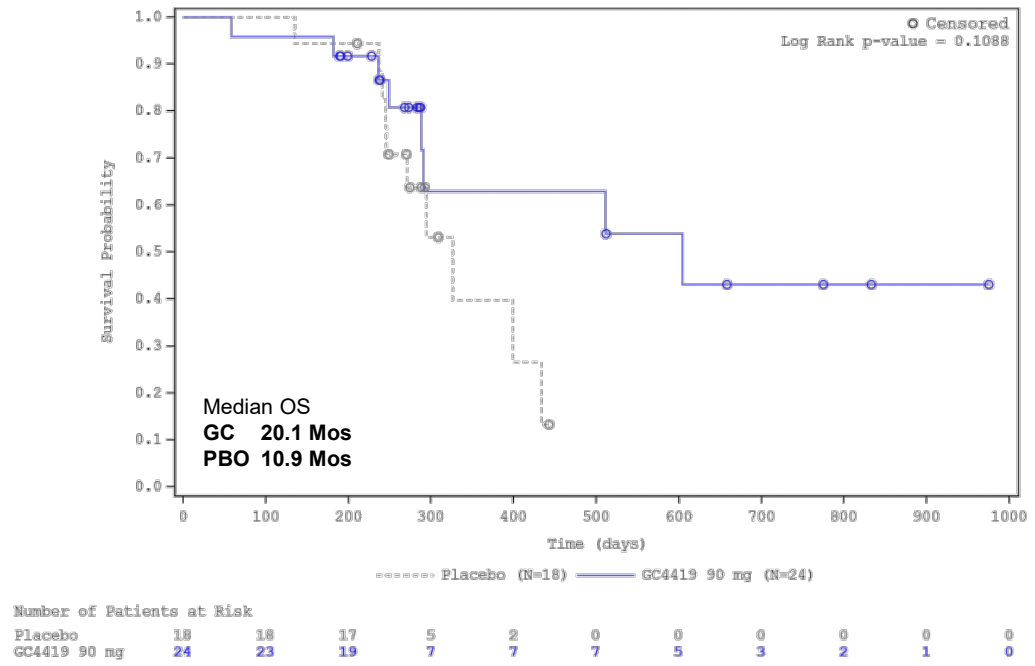
OS = Overall Survival
PFS = Progression-Free Survival
LRC = Locoregional Control
DMC = Control of Distant Metastases

Median follow-up of 9 months as of this data analysis (maximum follow-up 32 months)

Median Overall Survival Increased 85%

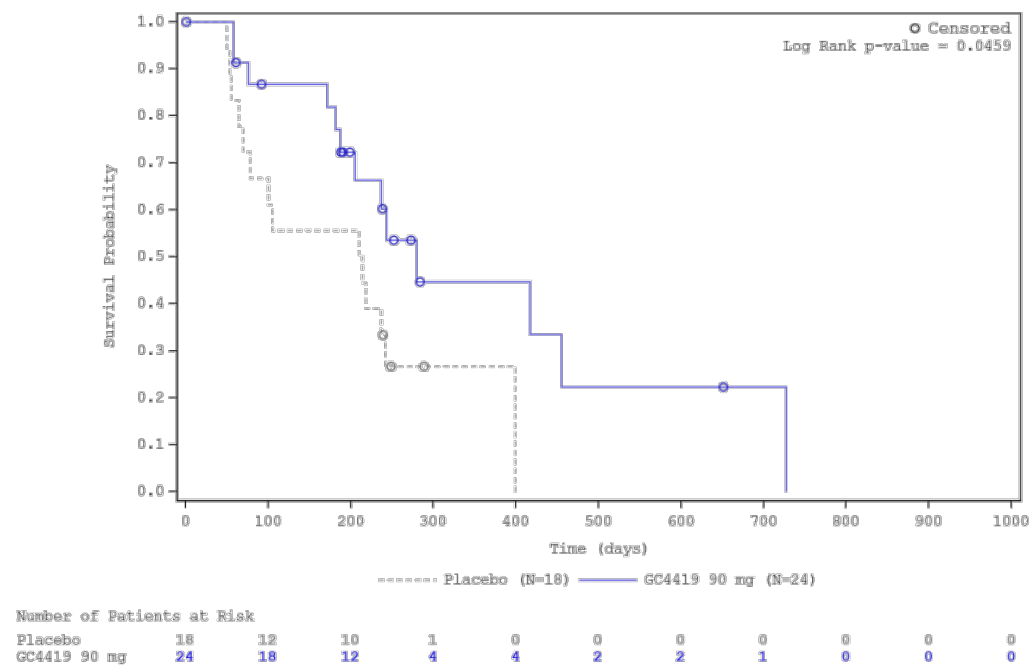
Encouraging hazard ratios for both OS and PFS

Overall Survival (OS)



Hazard Ratio = 0.4

Progression-Free Survival (PFS)[1]

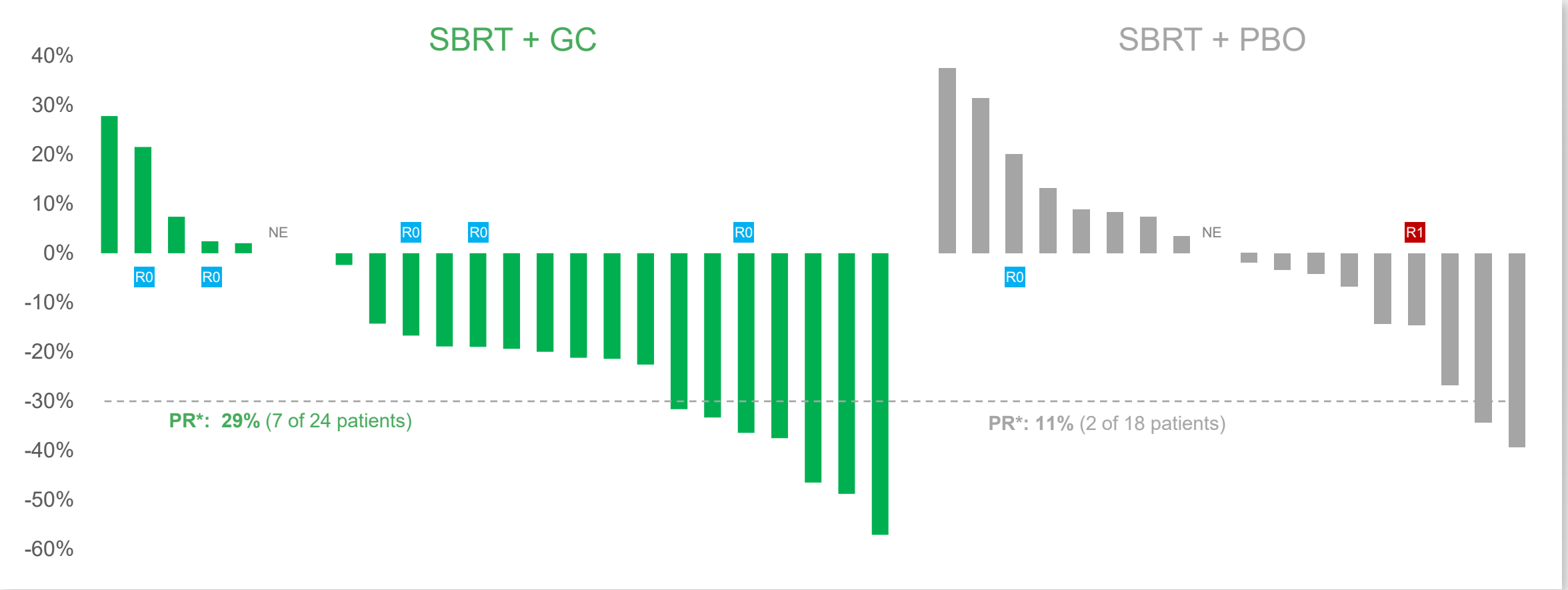


Hazard Ratio = 0.4

[1]PFS defined as local progression or distant metastasis; not censored for treatment post SBRT

Partial Response Rate Increased 2.5-fold

Best Local Response with follow-up through at least 6 months on all patients (ITT, n=42)



R0 = Surgical resection (R0 = clear margins).

R1 = Surgical resection (R1 = tumor at margins).

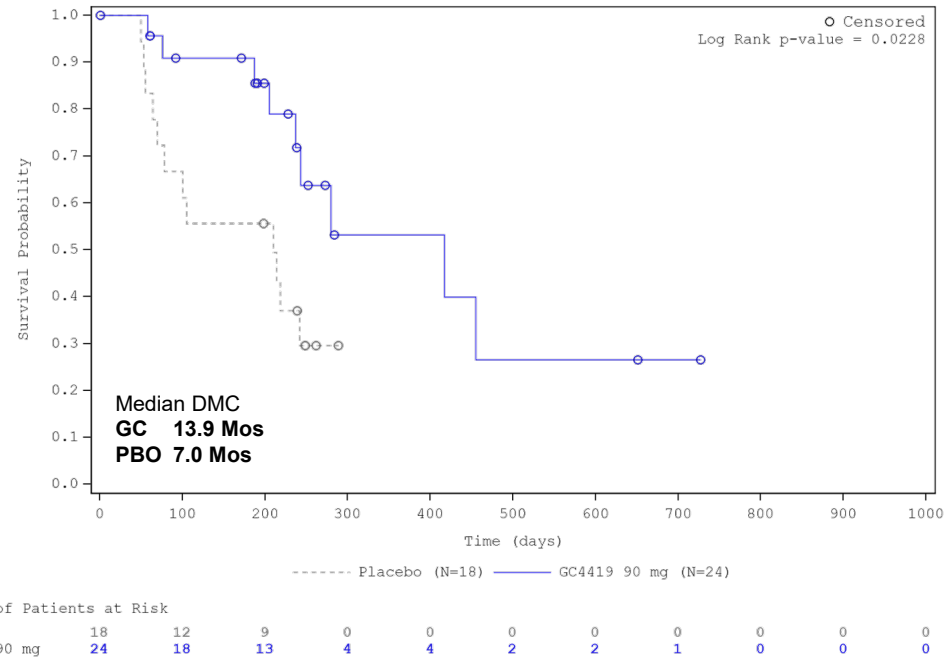
NE = not evaluable.

*Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)

Time to Distant Metastases Increased 2-fold

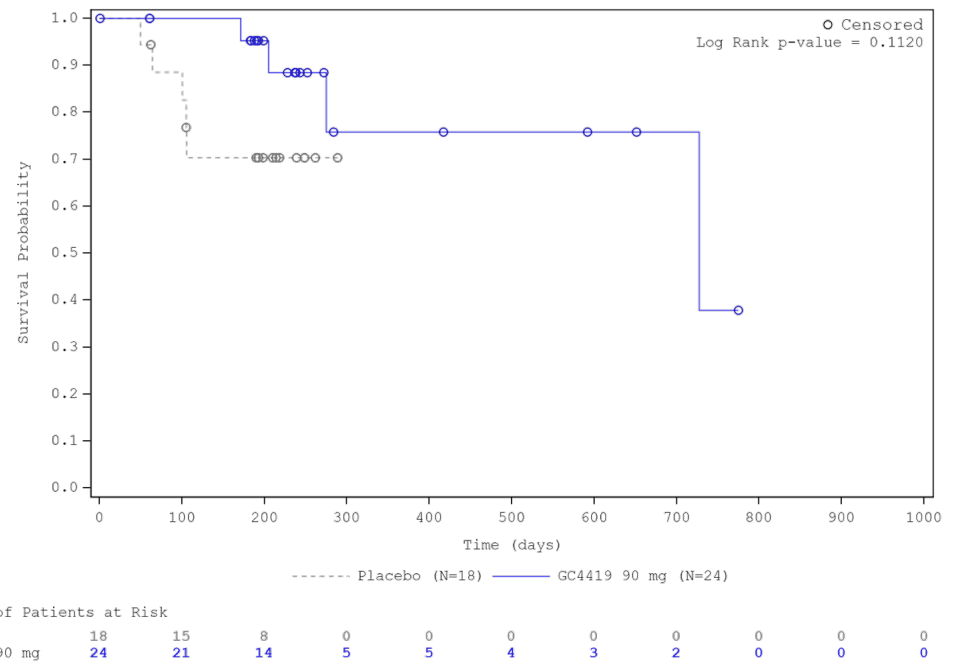
And Improved Locoregional Control

Distant Metastases Control
– outside RT Field



Hazard Ratio = 0.3

Locoregional Control (LRC)
– within RT Field



Hazard Ratio = 0.3

DMC and LRC defined as distant metastasis or local regional progression; not censored for treatment post SBRT

Regimen Generally Well Tolerated

Toxicity reports through first 90 days after SBRT (ITT, n=42)

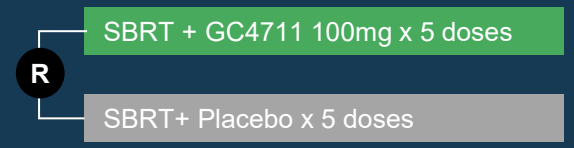
Acute Adverse Events (up to 90 days post SBRT)	Placebo (n=18)	Avasopasem (n=24)
Grade 3+ AEs	4 (22%)	6 (25%)
Grade 3 Gastrointestinal AEs[1]	2 (11%)	2 (8%)

[1]No bleeding ulcers by 12-week endoscopy, no GI toxicity > Grade 3

Next Steps

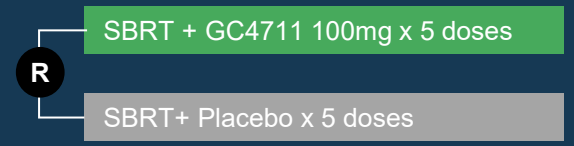
Proof of Concept	Efficacy results from blinded controlled trial consistent with preclinical studies that showed synergy with RT
Consistent Synergy	Magnitude of synergy with RT and consistency across efficacy parameters is very encouraging
GRECO Trials	Galera advanced its dismutase mimetics into larger placebo-controlled trials, in pancreatic and lung cancer

GRECO-1



- Placebo-controlled multicenter trial
- Locally Advanced NSC Lung Cancer – large & central tumors
- 71 Patients
- Status: Open & Recruiting Patients

GRECO-2



- Placebo-controlled multicenter trial
- Locally Advanced Pancreatic Cancer – following neoadjuvant chemotherapy
- 160 Patients
- Status: Soon to open to enrollment

SBRT for Non-Small Cell Lung Cancer

SBRT is an established treatment for central and large peripheral NSCLC tumors

2,500,000
Global NSCLC Incidence

175,000
US Patients Diagnosed each year

55,100
Node-Negative NSCLC

All SBRT	14,600	12,120	15,430
Node-Negative NSCLC	Peripheral Tumor >3cm	Central Tumor <3cm	Central Tumor >3cm
Surgery ONLY	16%	30%	12%
SBRT (+/- other modalities)	81%	67%	85%
Other	3%	2%	4%

Corporate Highlights

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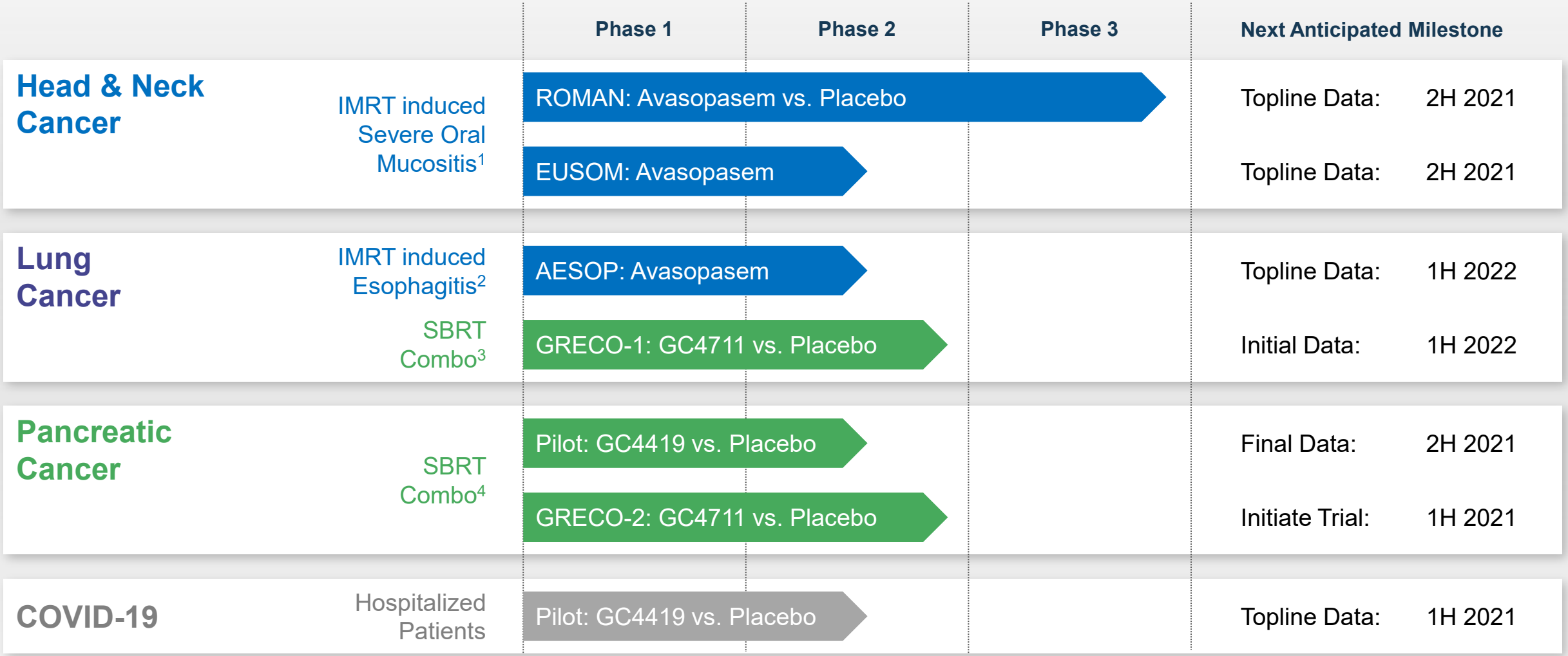
Robust Pipeline



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Back-up Slides

Mechanistic and Preclinical Data

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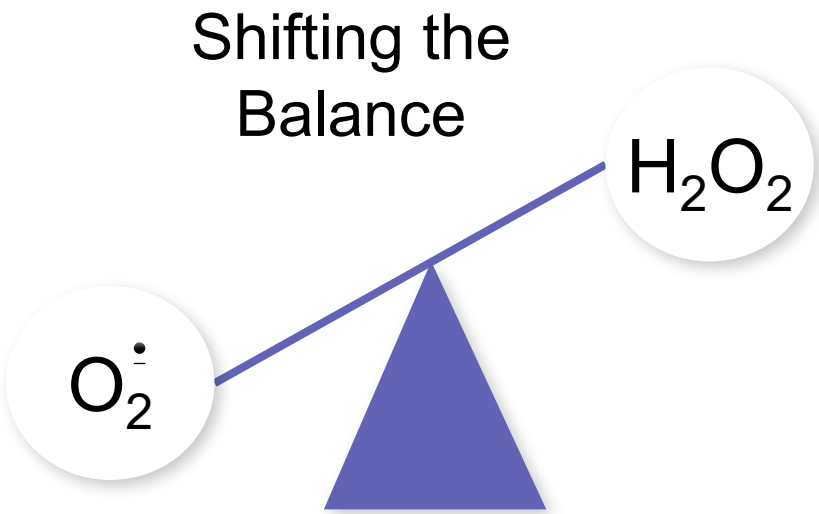
Differential Effect of Dismutase Mimetics

Conversion of superoxide to hydrogen peroxide leverages inherent tissue differences

Superoxide ($O_2^{\bullet-}$) is more damaging to normal cells than cancer cells[1]

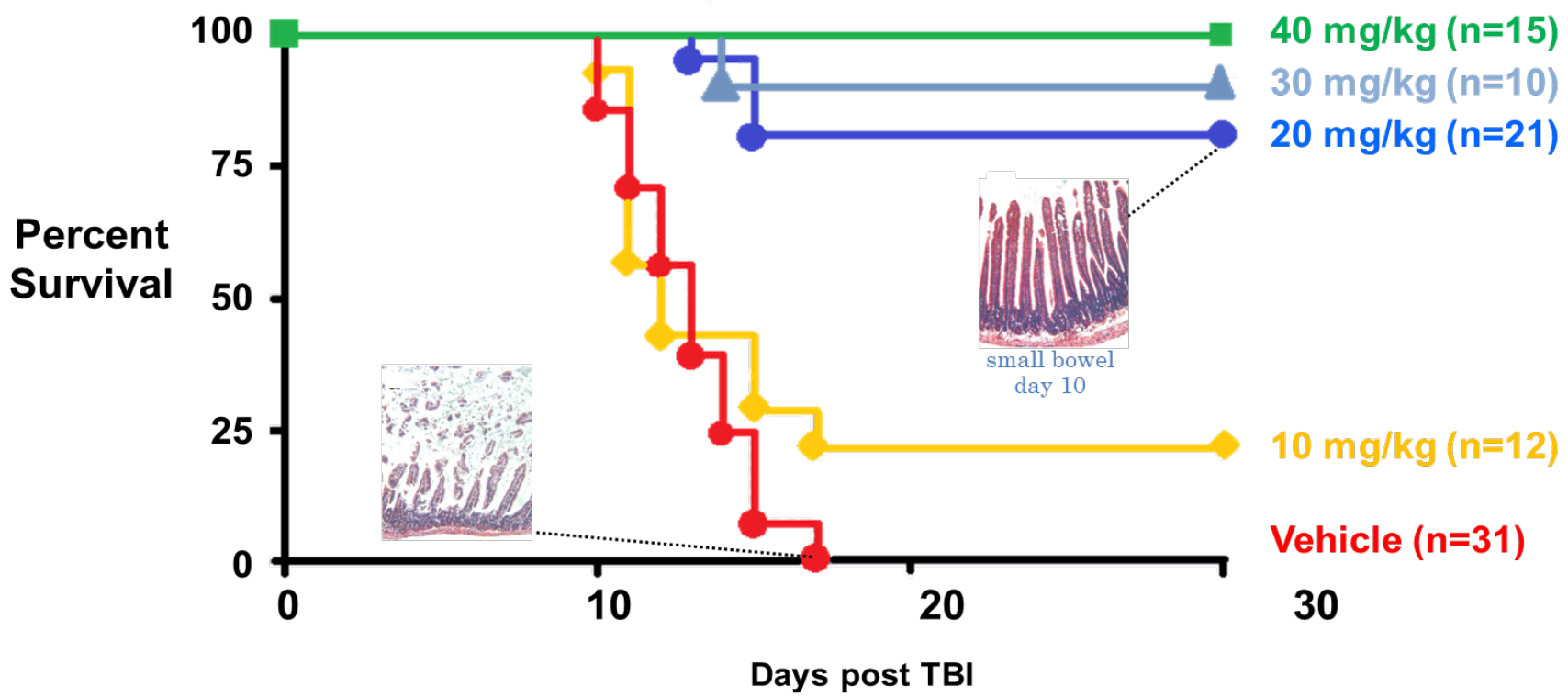


Hydrogen Peroxide (H_2O_2) is more toxic to cancer cells than normal cells[2]

[1]Sonis S. Drug Design, Development and Therapy 2021:15 1021–1029
[2]Park WH: Oncol Rep 40: 1787-1794, 2018

Protection from Lethal Radiation Exposure

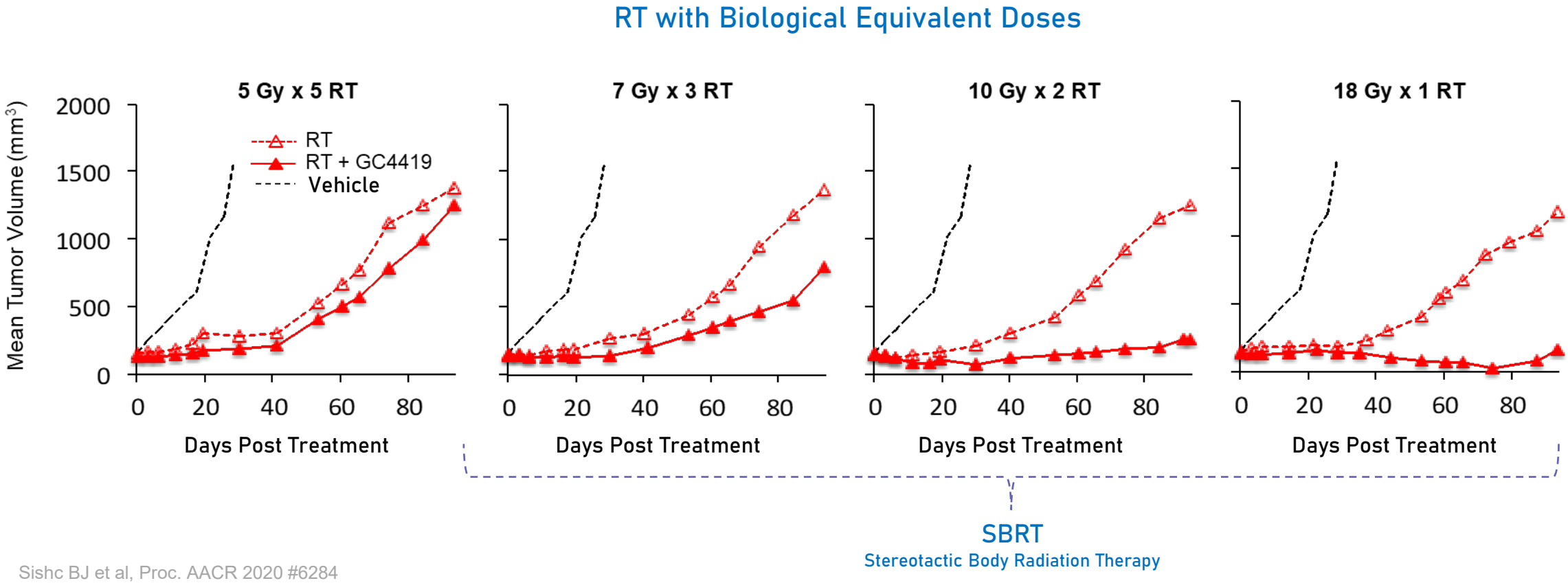
Observed in Preclinical Studies – Total Body Irradiation (8.5 Gy) to Mice



Thompson, et al., Free Radical Research, 44(5):529-540, 2010

Synergy with High-Dose RT (SBRT)

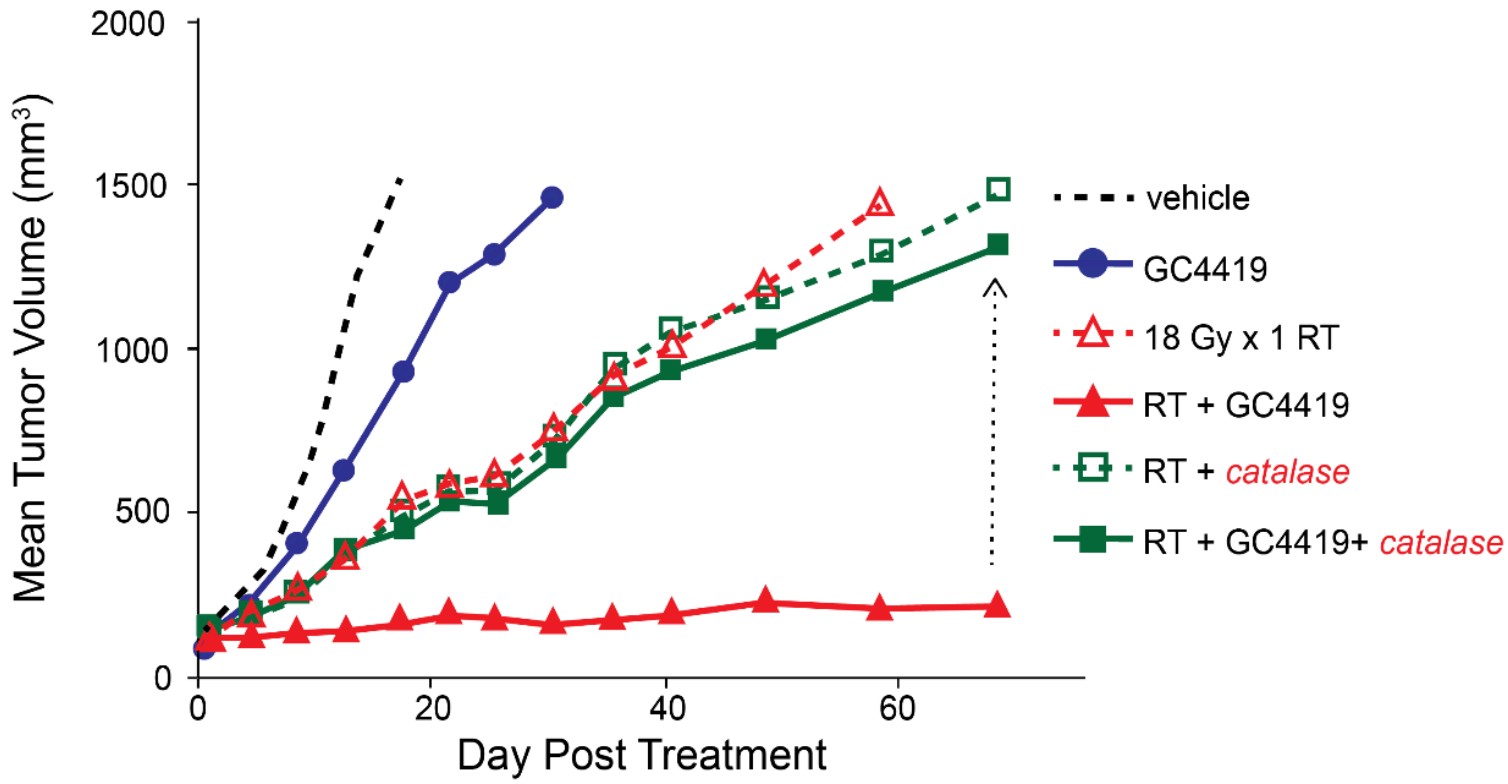
High-fraction focal irradiation of human tumor xenografts (H1299 NSCLC) in mice



Sishc BJ et al, Proc. AACR 2020 #6284

H_2O_2 build-up in Cancer Cell → Synergy with SBRT

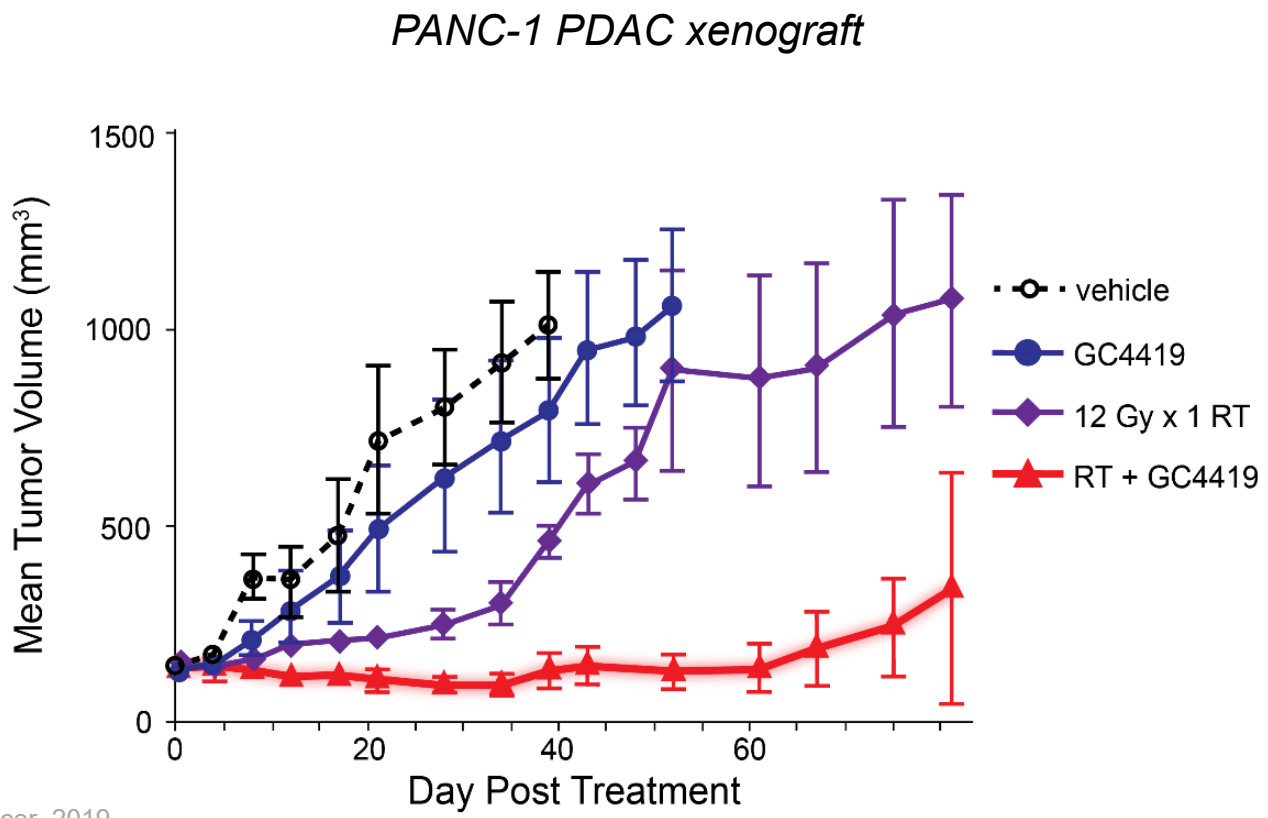
Synergy abrogated with doxycycline-induced catalase in genetically modified $H1299^{CAT}$ cells



Sishc BJ et al, AACR, 2018

Pancreatic Tumor Model → Synergy with SBRT

Marked synergy of Dismutase Mimetic with 12 Gray Radiotherapy

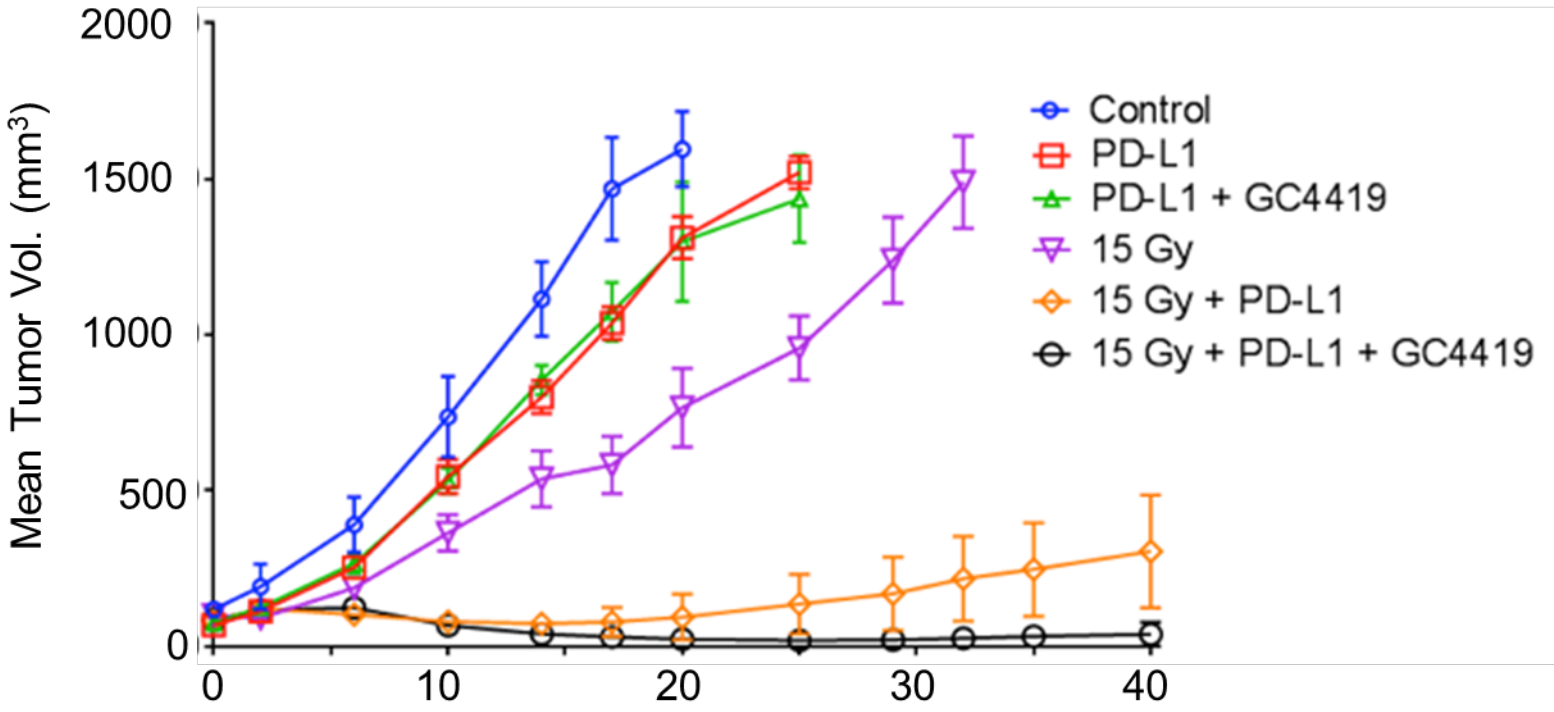


Sishc BJ et al, AACR Pancreatic Cancer, 2019

Enhanced Checkpoint Inhibitor Activity in Vivo

GC4419 enhanced tumor response to SBRT + anti-PD-L1, PD-1 or CTLA-4 – within and outside RT field

LLC syngeneic lung tumor model



Galera Data on file