

Transforming **radiotherapy** for patients with cancer

September 2021



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.

Radiation Therapy – Key Role in Cancer Treatment

Over 50% of all cancer patients receive radiation therapy as part of their treatment

IMRT

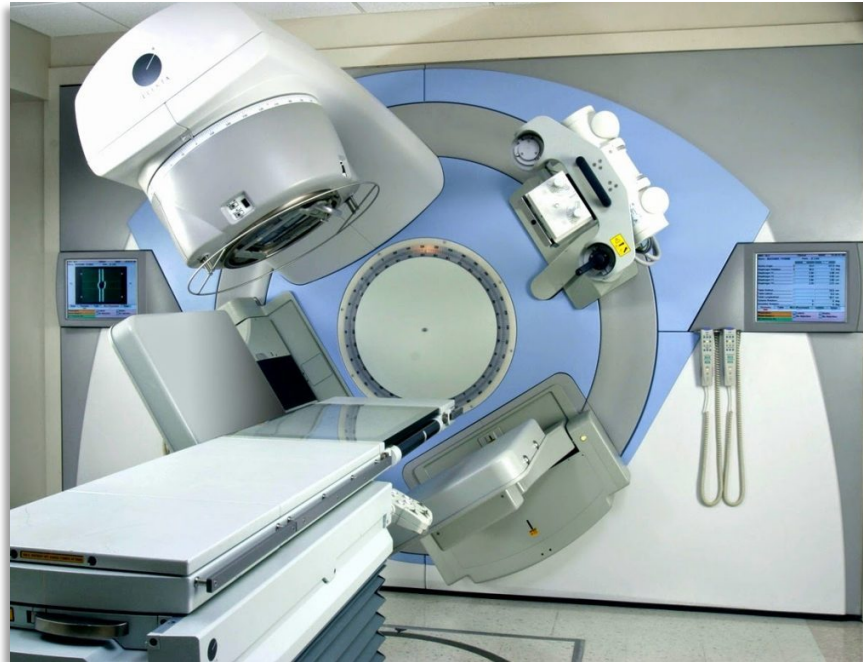
Intensity Modulated Radiation Therapy

Low doses for weeks
(~2 Gy/day)

Most used form of external beam RT

Toxicity

Galera's Goal
Radioprotection



SBRT

Stereotactic Body Radiation Therapy

High doses for days
(>5 Gy/day)

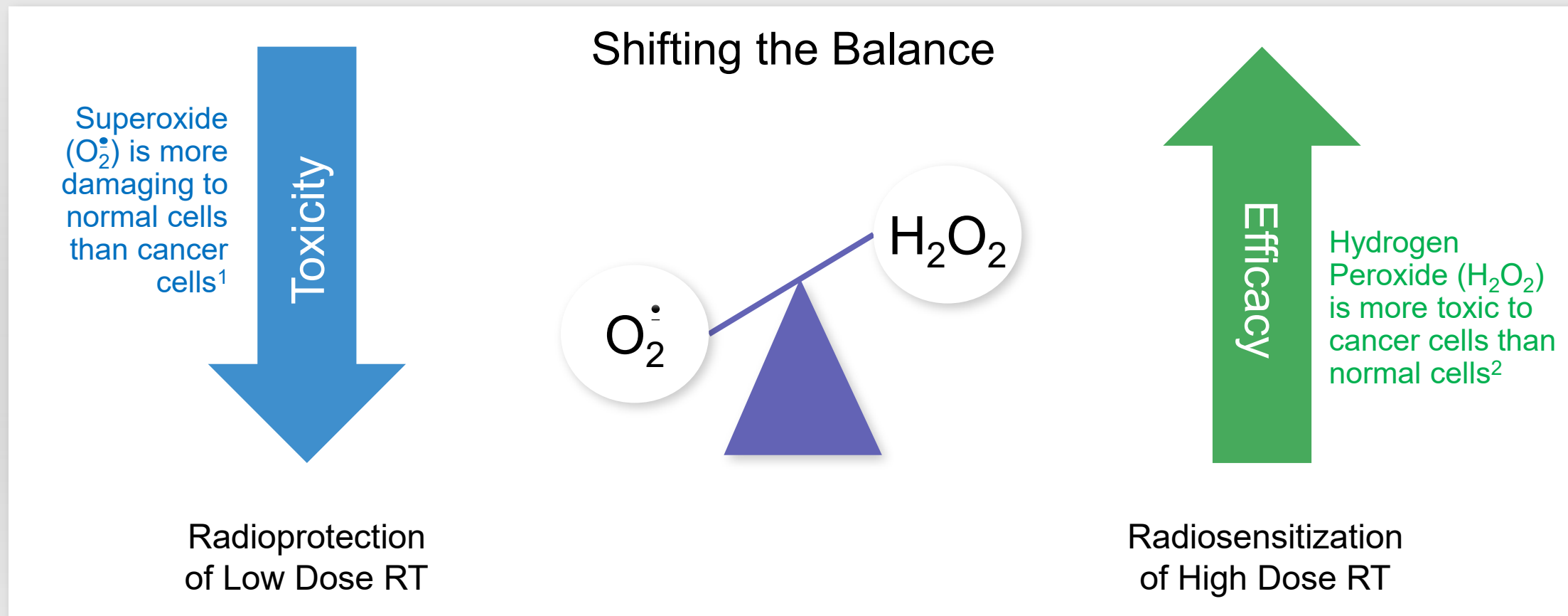
Cutting edge form of external beam RT

Efficacy

Galera's Goal
Radiosensitization

Galera's Technology: Dismutase Mimetics

Mechanism of action is to convert RT-induced burst of Superoxide to Hydrogen Peroxide



¹Sonis S. Drug Design, Development and Therapy 2021;15 1021–1029

²Park WH: Oncol Rep 40: 1787-1794, 2018

Transforming Radiotherapy

Avasopasem **Reducing** **IMRT Toxicity**

Breakthrough Therapy
with Phase 3 Fully Enrolled

Severe Oral Mucositis
In Head & Neck Cancer

Esophagitis
in Lung Cancer

GC4711 **Increasing** **SBRT Efficacy**

Encouraging Survival Data
in Pancreatic Cancer Trial¹

Pancreatic Cancer
Locally Advanced

Lung Cancer
Locally Advanced

Large Markets **with High** **Unmet Need**

18 Million New Cancers in
World in 2020² (1.9M in US)

Radiotherapy needed by over
half of patients with cancer

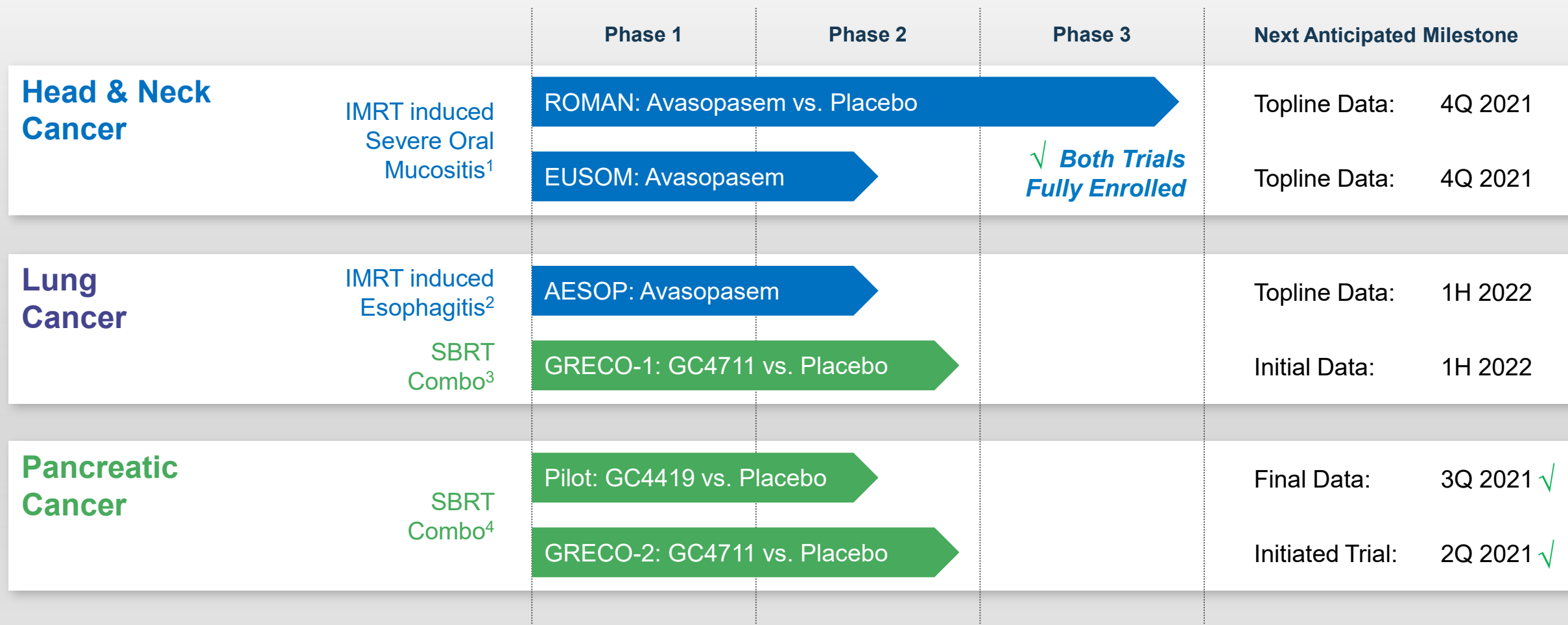
Galera building US commercial
team for Avasopasem Launch

¹The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

²Global Cancer Statistics. Sung H et al. CA Cancer J Clin 2021;0:1–41 (excluding nonmelanoma skin cancer)

³US Cancer Statistics Siegel RL et al. CA Cancer J Clin 2021;71:7–33

Robust Pipeline



¹EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe

²Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC

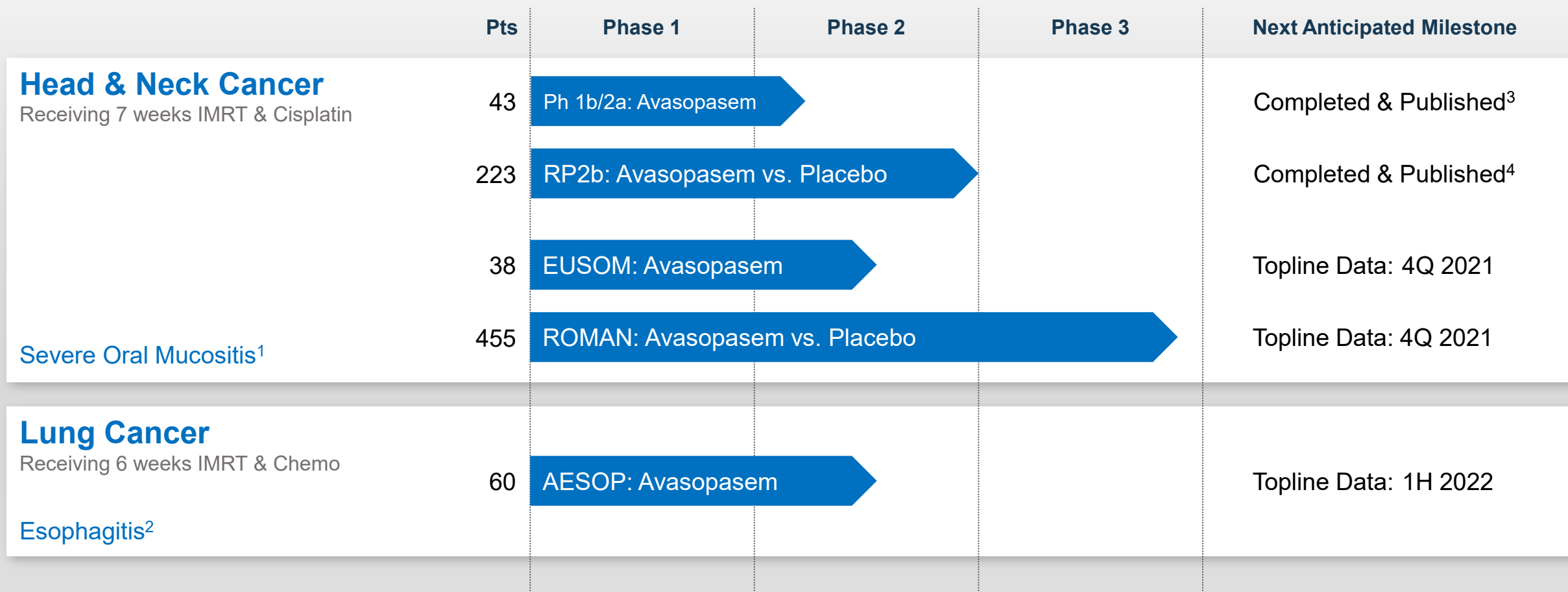
³Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711

⁴The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

Reducing IMRT Toxicity



Radioprotection Programs



¹EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe

²Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC

³Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435

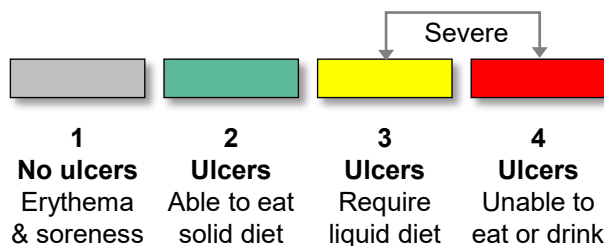
⁴Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.

Severe Oral Mucositis in Head & Neck Cancer

The most burdensome toxicity of standard-of-care chemoradiotherapy (radiotherapy & cisplatin)

70% Patients Get SOM (Grade 3 or 4 OM)

WHO Grading System



Current Approaches Lack Efficacy

MASCC Guidelines focus only on symptoms¹

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

Physicians Consider Topicals Ineffective

Market Research with 150 Radiation Oncologists²

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

¹Elad S et al, MASCC/ISOO Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. Cancer 2020;126:4423-4431

²Galera Market Research

455 Patient ROMAN Phase 3 Trial – Results this Year

Fully Enrolled Randomized Placebo-Controlled Severe Oral Mucositis Trial



Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks
- 70% expected to get SOM



Treatment

R

Avasopasem 90mg x 7 weeks

Randomized 3:2

Placebo x 7 weeks

- 60-minute IV infusion just before IMRT
- Multicenter (North America)



Endpoints

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

Avasopasem: First-to-Market Potential

Avasopasem Prevents RT Injury

Patients get avasopasem
before each RT dose

Blocks initiating injury in normal
cells from RT burst of superoxide

Does not interfere with RT
anti-cancer efficacy

Avasopasem has BTB for Oral Mucositis

FDA Breakthrough Therapy
Designation

BTB granted for oral mucositis in
February 2018

Based on robust Phase 2b data
in 223 patients

455 Patient ROMAN Phase 3 Trial

Data anticipated 4Q 2021

Enrollment complete

Single Phase 3 sufficient for NDA
with Phase 2b as supportive

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
- 70% expected to get SOM



Treatment

- R**
- Avasopasem 90mg x 7 weeks
 - Avasopasem 30mg x 7 weeks
 - Placebo x 7 weeks
- 60-minute IV infusion just before IMRT
 - Multicenter (North America)

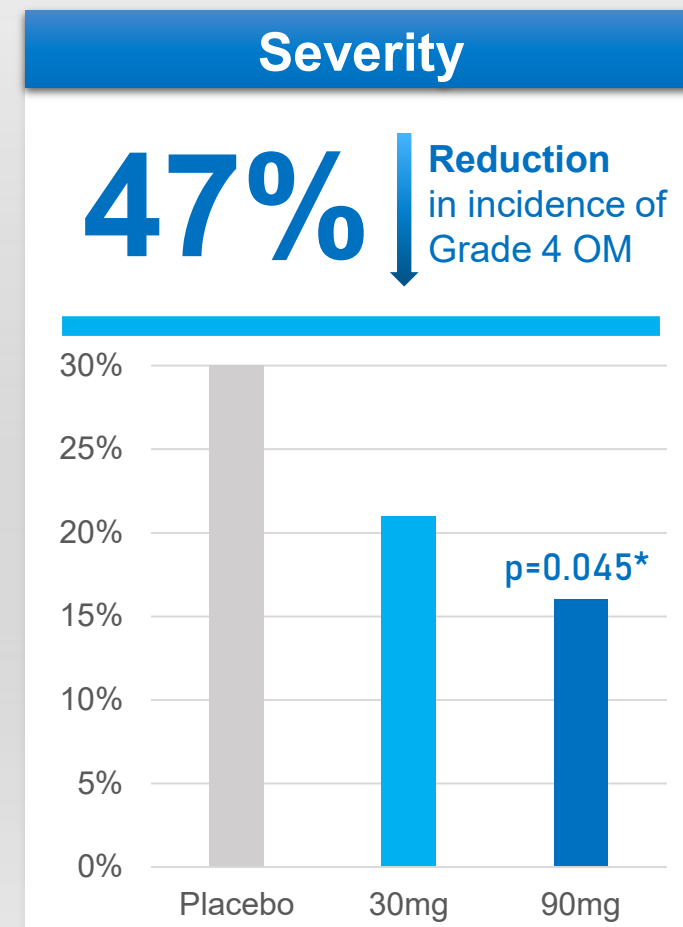
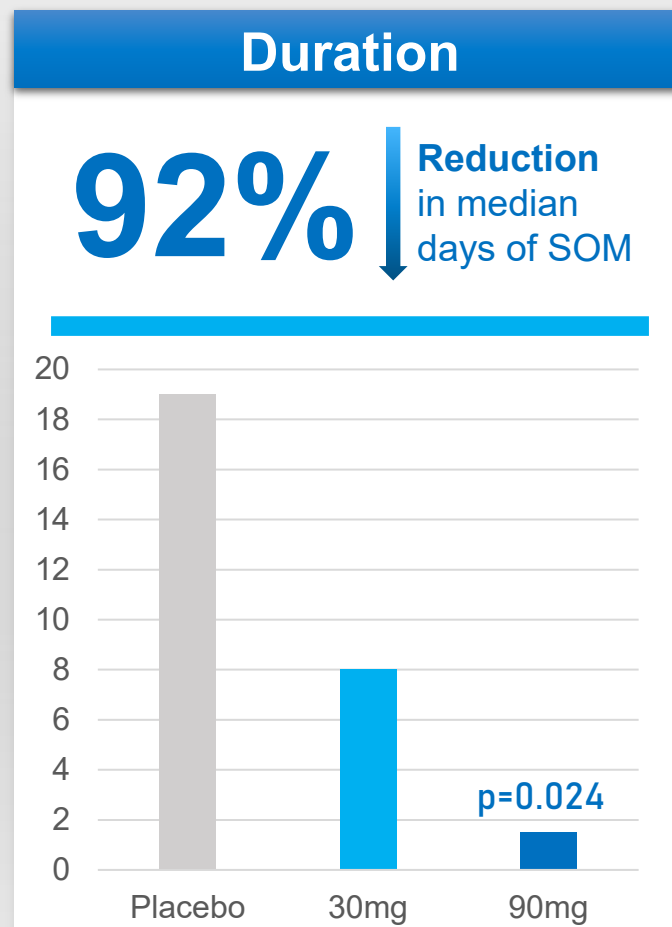
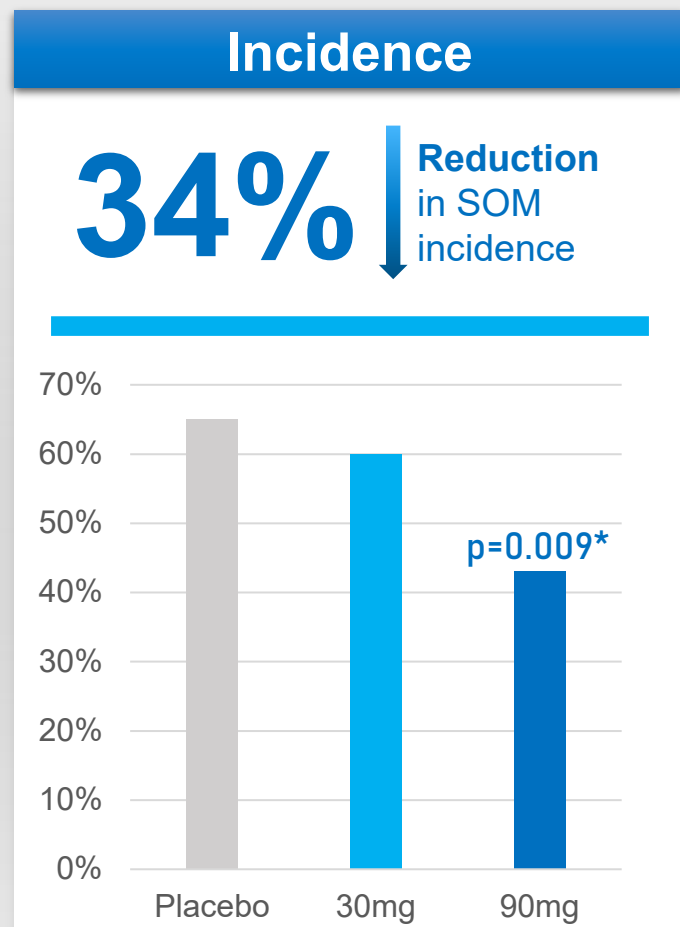


Endpoints

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

Consistent and Encouraging Results

Across SOM Endpoints



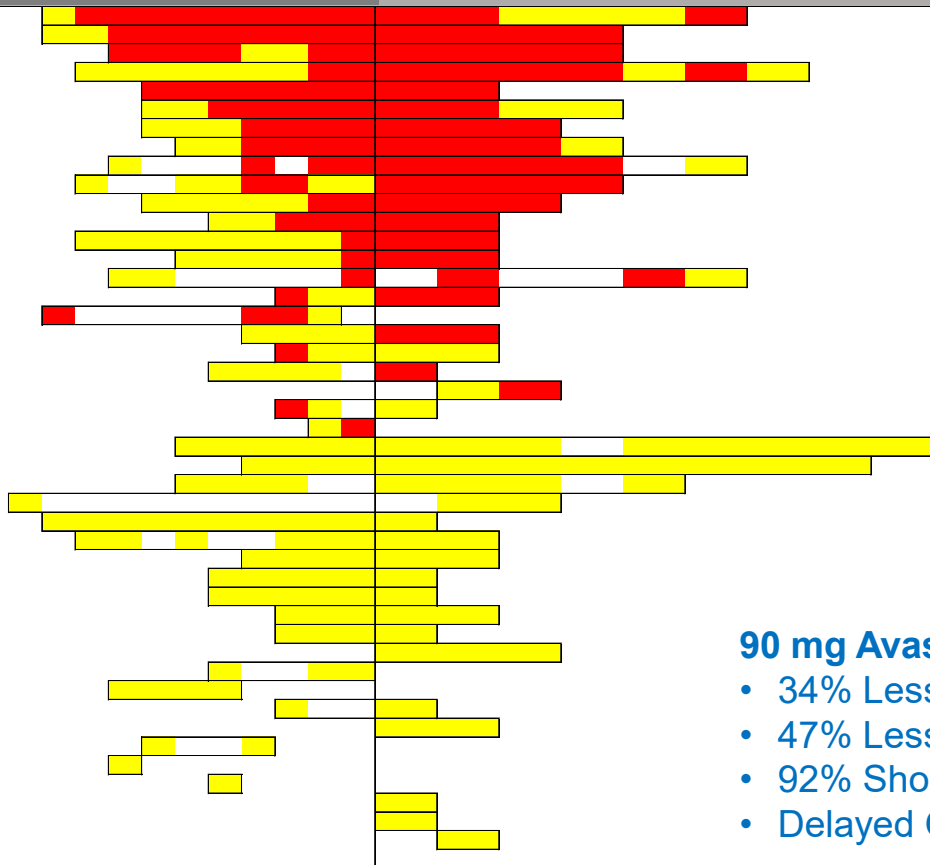
Anderson CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265

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

Avasopasem Efficacy Significantly Better than Placebo

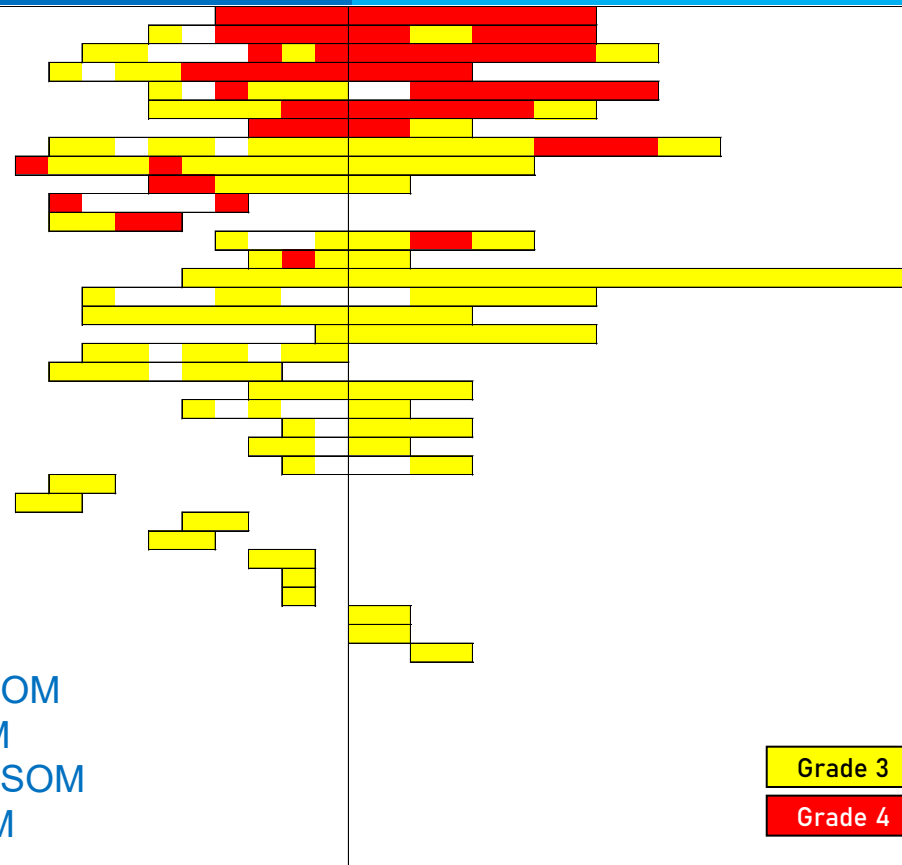
PLACEBO Arm (45 of 74 Pts had ≥ 1 visit with SOM)

RADIOTHERAPY TREATMENT PERIOD FOLLOW UP POST THERAPY



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

RADIOTHERAPY TREATMENT PERIOD FOLLOW UP POST THERAPY



90 mg Avasopasem

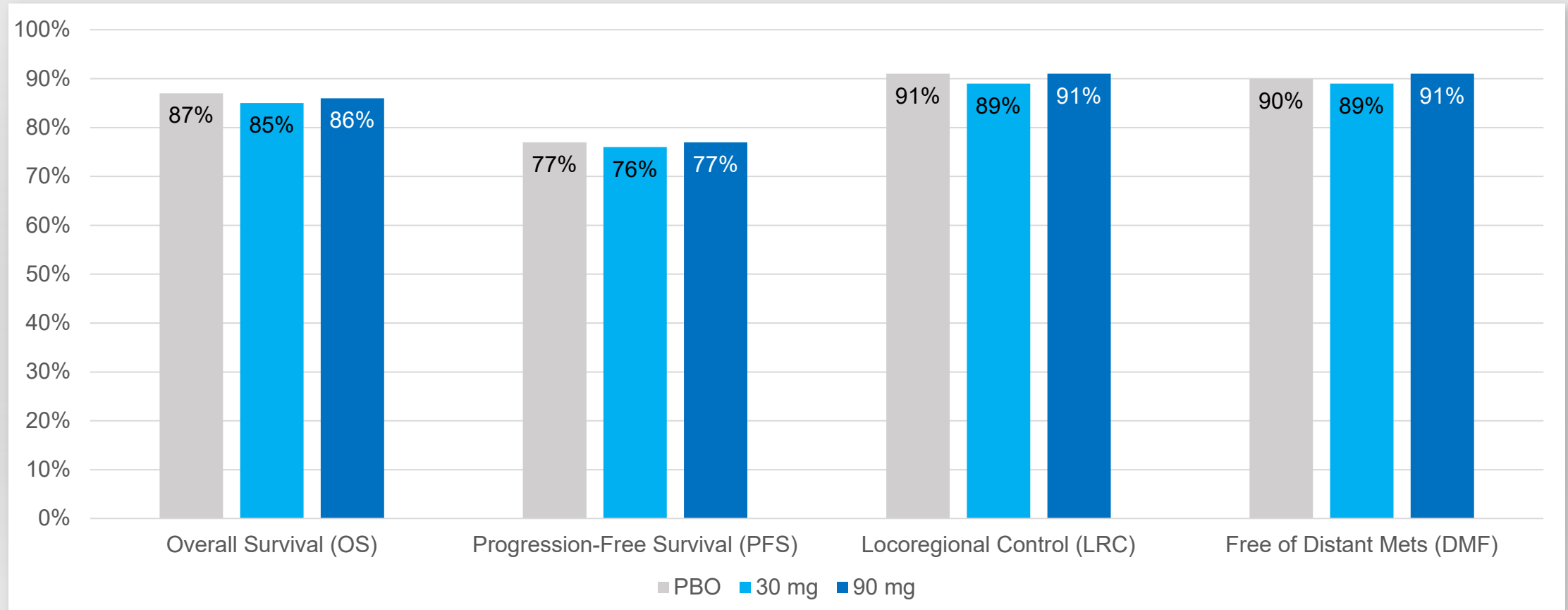
- 34% Less Incidence SOM
- 47% Less Grade 4 OM
- 92% Shorter Duration SOM
- Delayed Onset of SOM

Grade 3

Grade 4

Anderson CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265

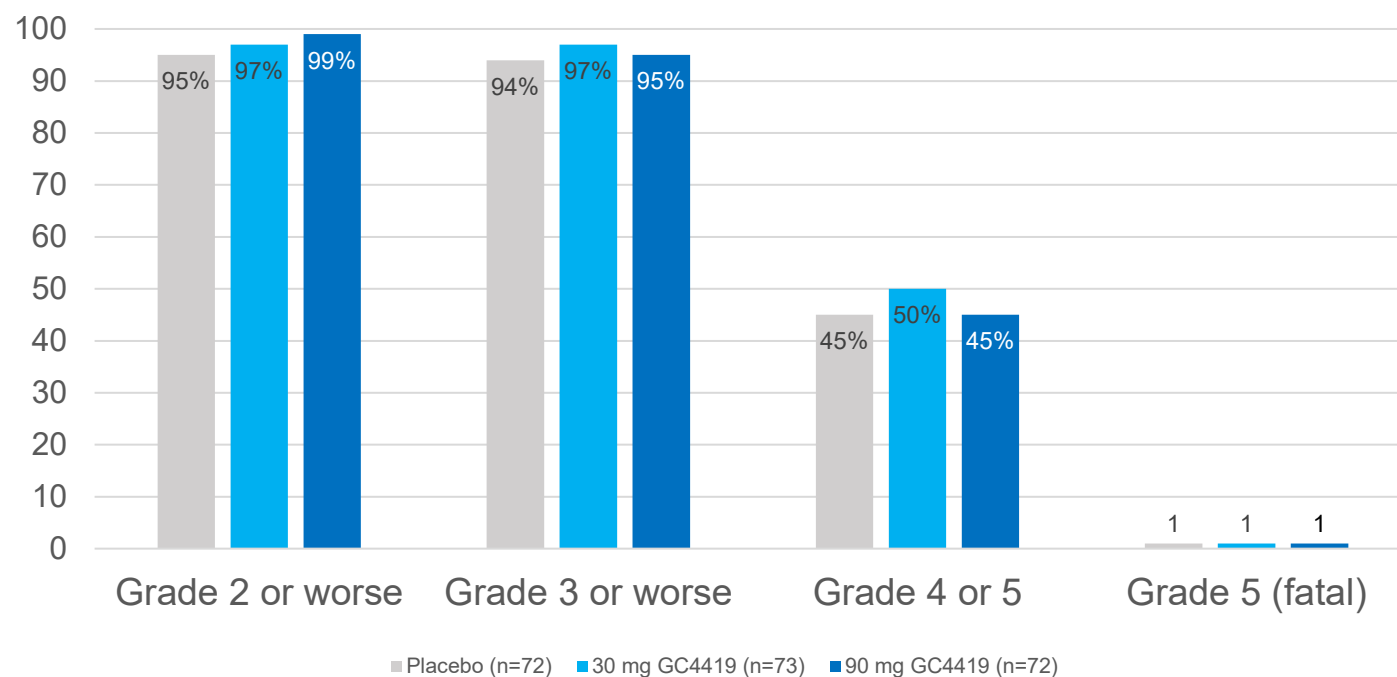
Radiotherapy Efficacy Maintained Over Two Years



Final ITT Analysis

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%

Anderson CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265

SOM Market Opportunity



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

Initial
Target
Population



Locally advanced HNC is 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

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

Initial
Sales
Focus

72%

Sites with Existing
Infusion Capability¹

64%

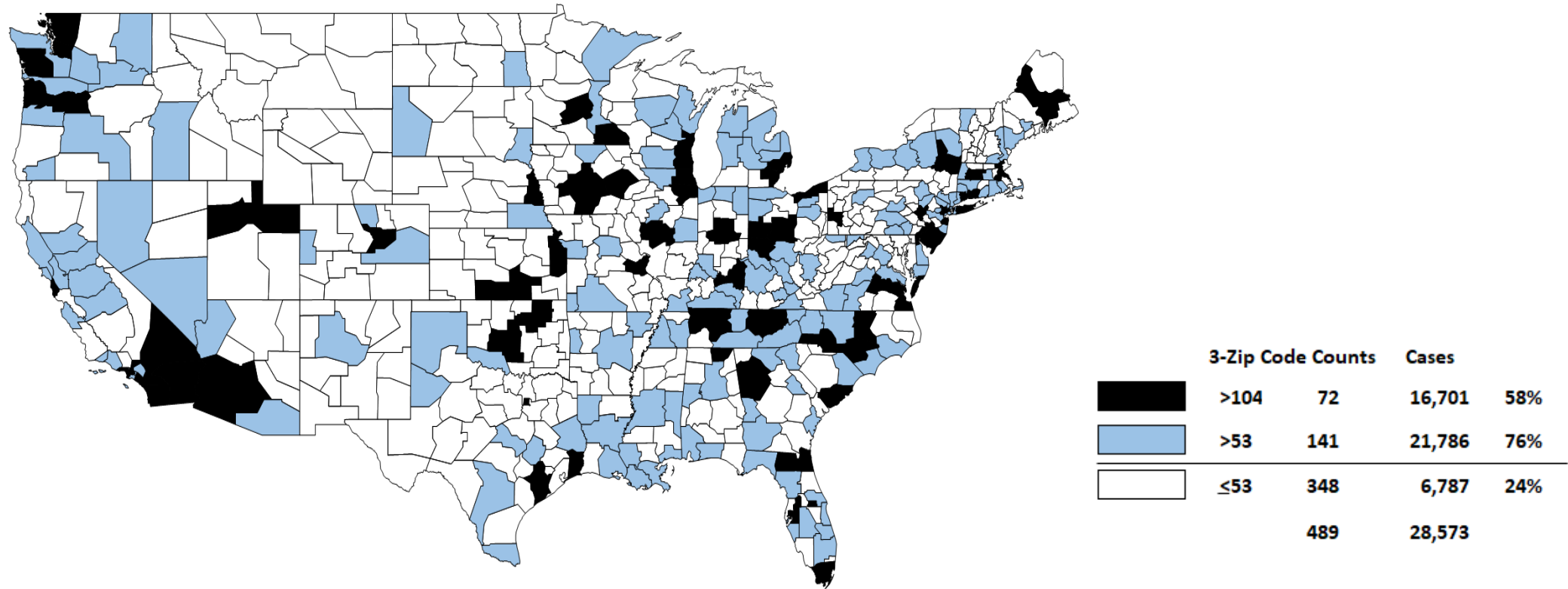
Market Patient Share

38% IMRT centers currently infuse drugs¹
34% more coordinate with medical oncology to infuse patients
Additional 17% can add capabilities to infuse patients

¹Primary 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



Galera Market Research (122 Zip Codes are 0)

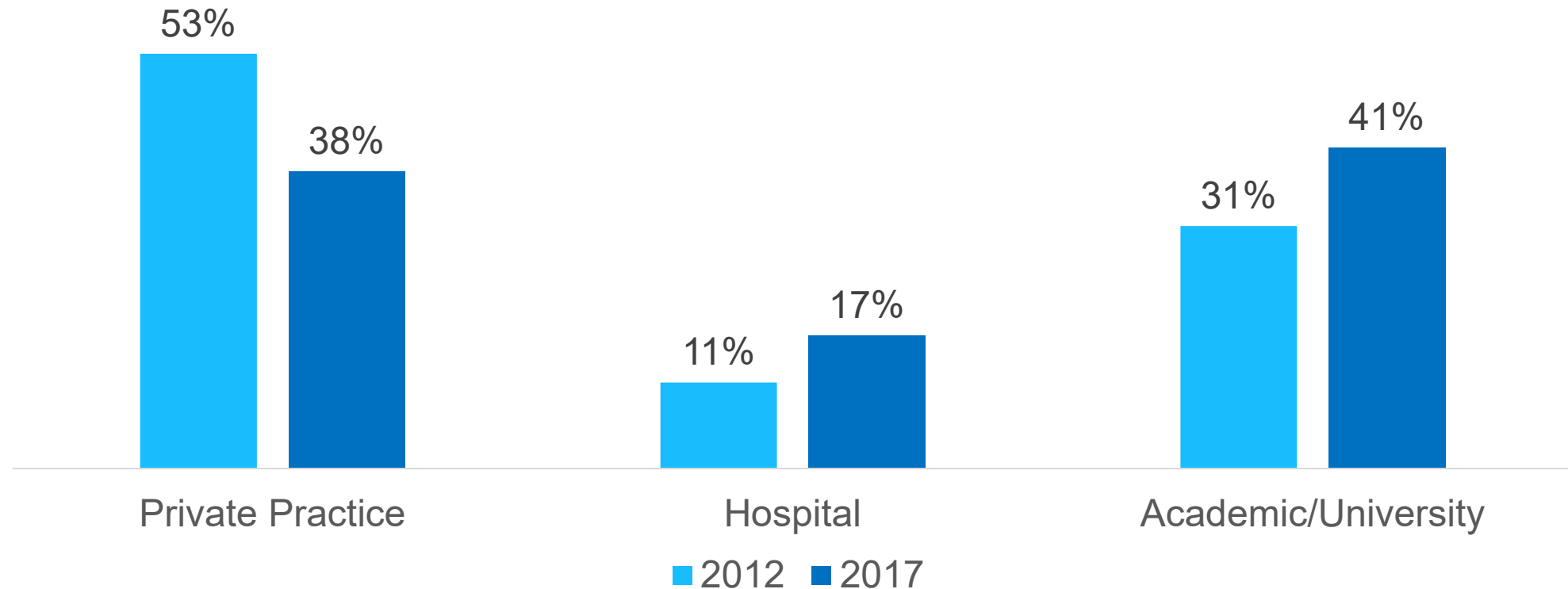
Most Centers Have Ability to Infuse Today

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
Total % Sample Distribution	38%	34%	17%	11%
Avasopasem Infusion Owner	Rad Onc	Med Onc	Rad Onc	-
Ease of Coordination Today	High	High	Low	Low
Likelihood of Prescribing Avasopasem	High	High	High	Low

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

US Radiation Oncologists Trending Away from Private Practice



¹Data 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

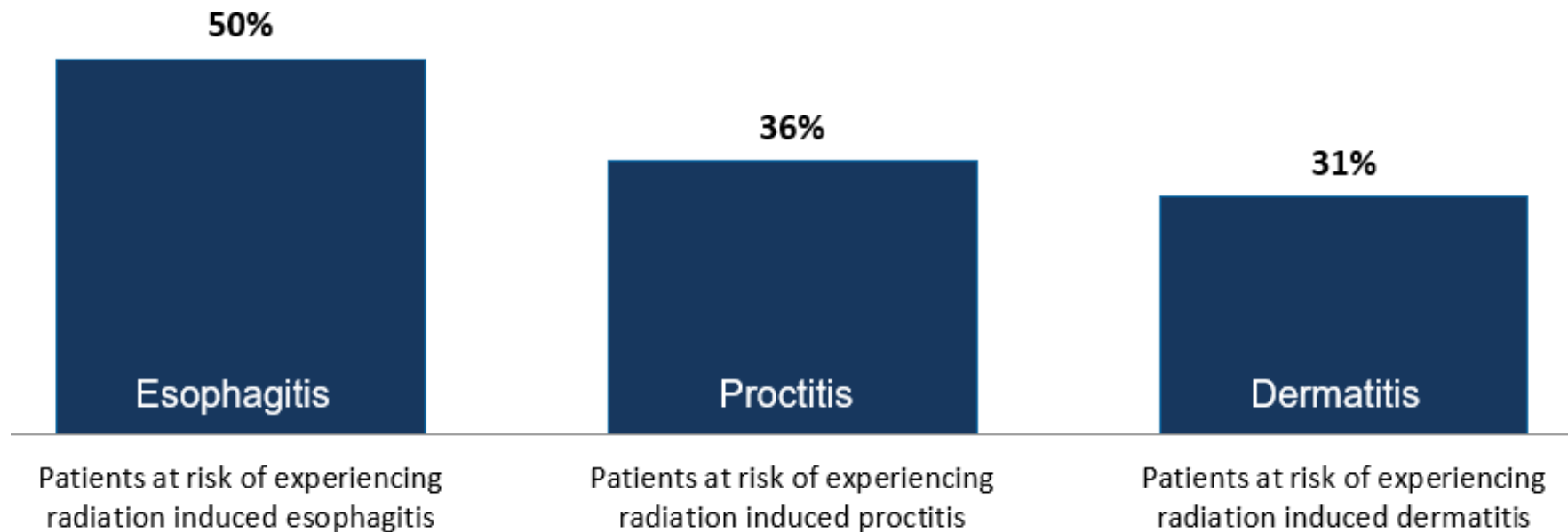
Head and neck cancer not a focus for cost control measure

Step Edits Unlikely

High unmet need with limited treatment options

Beyond Oral Mucositis: Other RT-Related Toxicities

Physicians view oral mucositis data as potentially applicable to other radiation-related toxicities



150 Rad Oncs were asked the following: *Given the demonstrated ability of Product X to prevent radiation-induced toxicities in the oral mucosa, please indicate how you might use (maximum %) Product X for the following radiation associated conditions?*

Galera primary research with 150 Radiation Oncologists

Esophagitis in Lung Cancer

2,500,000

Global NSCLC Incidence

175,000

US Patients Diagnosed each year

50,000

US Patients at Risk for RT-related Esophagitis

Initial
Target
Population

Locally advanced NSCLC frequently treated
with IMRT and chemotherapy

Esophagitis: Major Unmet Need in Lung Cancer

Common Side Effect of Chemoradiotherapy (IMRT x 6 weeks)

50% Patients Get Grade 2+ Esophagitis

RTOG Grading System

-
- 1 Asymptomatic
 - 2 Symptoms & altered eating/swallowing
 - 3 Severely altered eating or swallowing
 - 4 Required urgent operative intervention
 - 5 Results in death

Current Approaches Lack Efficacy

No established drug therapy

Supportive care measures:

- Soft bland diet
- Prophylactic antifungals
- Dilation if stricture develops

AESOP Trial Design

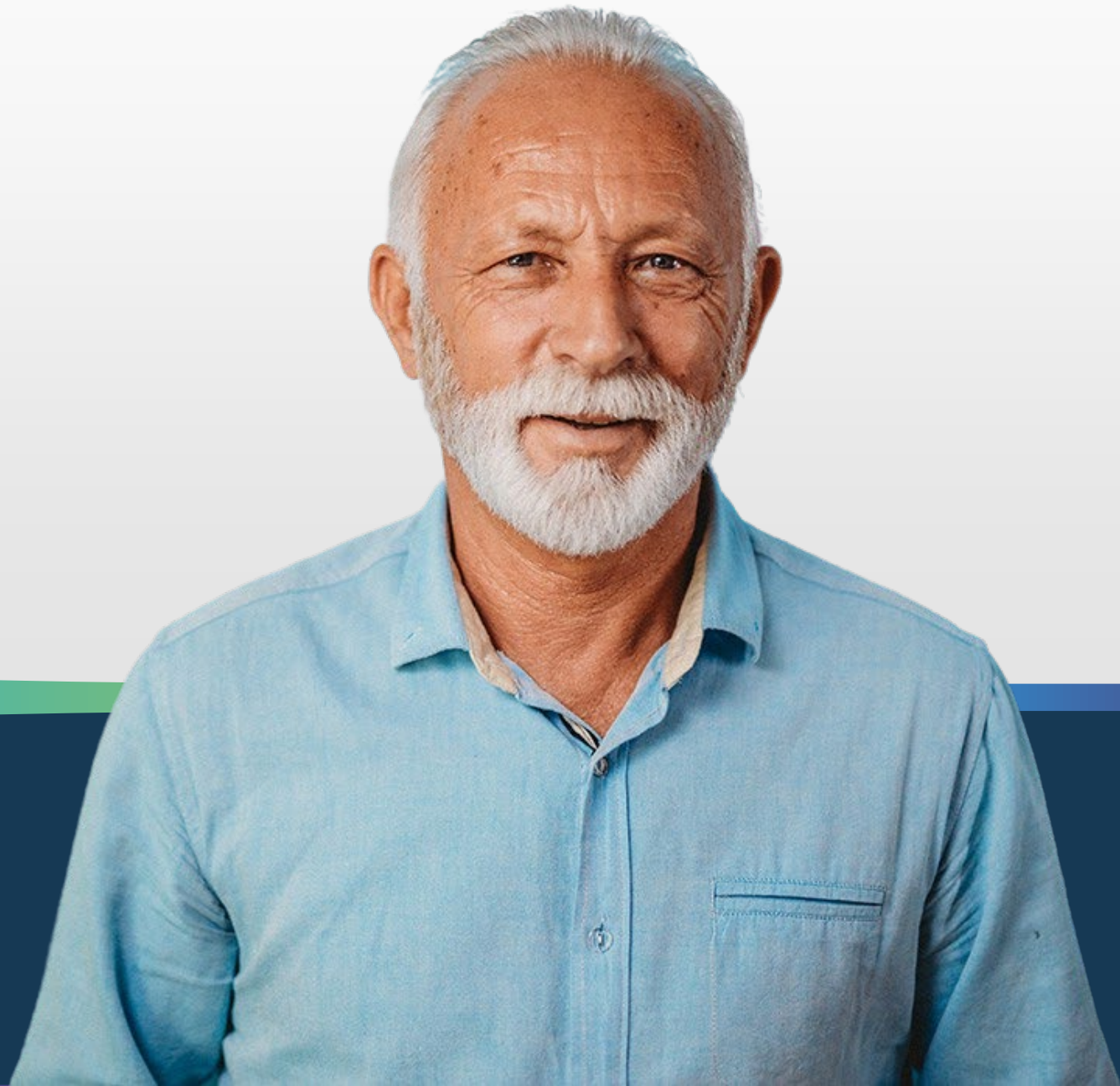
Phase 2 Trial (n=60)

-
- 6 weeks of standard IMRT to ≥ 5 cm of esophagus



- Will compare esophagitis rate with historical data

Increasing SBRT Efficacy



Radiosensitizer Programs

	Pts	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone
Pancreatic Cancer¹ Locally Advanced Receiving 5 days SBRT after 4-6 months chemo	42	Pilot: GC4419 vs. Placebo			Final Data: 3Q 2021 ✓
	160	GRECO-2: GC4711 vs. Placebo			Initiated Trial: 2Q 2021 ✓
Lung Cancer² Locally Advanced Receiving 5 days SBRT	71	GRECO-1: GC4711 vs. Placebo			Initial Data: 1H 2022

¹First SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

²Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711

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

**Initial
Target
Population**



5-year survival rate is only ~10%

SBRT use increasing for locoregional control of pancreatic cancer

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, Munsters' Fred Gwynne, Columnist William Safire, Michal Landon

Proof of Concept Trial in Pancreatic Cancer

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

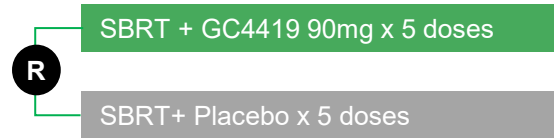


Population

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



Treatment



- 60-minute IV infusion before SBRT
- 4 Centers: MDA, Moffitt, Duke, UTSW



Endpoints

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

Proof of Concept Trial in Pancreatic Cancer – Final Analysis

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

- SBRT and SBRT+GC combination generally well tolerated
- Improvements observed across all evaluated efficacy endpoints
 - HR < 0.5 for Overall & Progression-Free Survival
 - HR < 0.4 for Local & Distant Tumor Control
- Results reinforce the rationale for ongoing GRECO-2 trial

Final Analysis of Safety & Efficacy

Minimum of One Year Follow-up on All Patients

Baseline Characteristics	Placebo (n=18)	GC4419 (n=24)
Median age (range), yrs	68 (48–82)	72 (41–83)
Male / Female	39% / 61%	67% / 33%
Borderline resectable / Unresectable	11% / 89%	29% / 71%
ECOG Performance status 0/1/2	50% / 50% / 0%	50% / 46% / 4%
Prior chemo, duration median (range), wks	22 (12.0–36.3)	18 (9.1–67.1)
CA19-9 at randomization, median (range)	71 (0.5–5505)	31 (0.3–719)
Smokers/Nonsmokers	17% / 83%	8% / 92%

CA 19-9 = Carbohydrate Antigen 19-9 is a tumor marker for pancreatic cancer
ECOG = Eastern Cooperative Oncology Group Performance Status Criteria

Final Safety Analysis - Regimen Generally Well Tolerated

12-Month Safety Follow-up (% of Patients)

Similar SBRT Toxicity Across Arms

AEs Considered related by Investigator to SBRT		SBRT + PBO	SBRT + GC
≤90 days after SBRT	Any AE	67%	46%
	GI AE	44%	42%
	Severe AE	0%	0%
>90 days after SBRT	Any AE	22%	25%
	GI AE	17%	21%
	Severe AE	11%	8%

- *No bleeding ulcers by 12-week endoscopy*

No Early or Late Toxicity Signal for GC

AEs Considered related by Investigator to GC/PBO		SBRT + PBO	SBRT + GC
≤90 days after SBRT	Any AE	67%	46%
	GI AE	44%	42%
	Severe AE	0%	0%
>90 days after SBRT	Any AE	17%	21%
	GI AE	17%	17%
	Severe AE	11%	4%

AE = Adverse Event, GI AE = Gastrointestinal AE

Final Efficacy Analysis – Improvements Across All Parameters

Encouraging hazard ratios across all endpoints

Hazard Ratios Below 0.5 Overall & Progression-Free Survival

Survival

Median	OS	PFS (mos)
GC	17.0	11.2
PBO	13.3	7.1

Survival	OS	PFS
Hazard Ratio	0.48	0.46

Hazard Ratios Below 0.4 Local & Distant Tumor Control

Tumor Control

Median	LRC	DMC (mos)
GC	NR	13.9
PBO	9.6	7.0

Tumor Control	LRC	DMC
Hazard Ratio	0.30	0.39

2.5-fold Increase in Response Rate

Response

Partial Response Rate	
GC	29%
PBO	11%

Surgery	GC	PBO
R0*	5	1

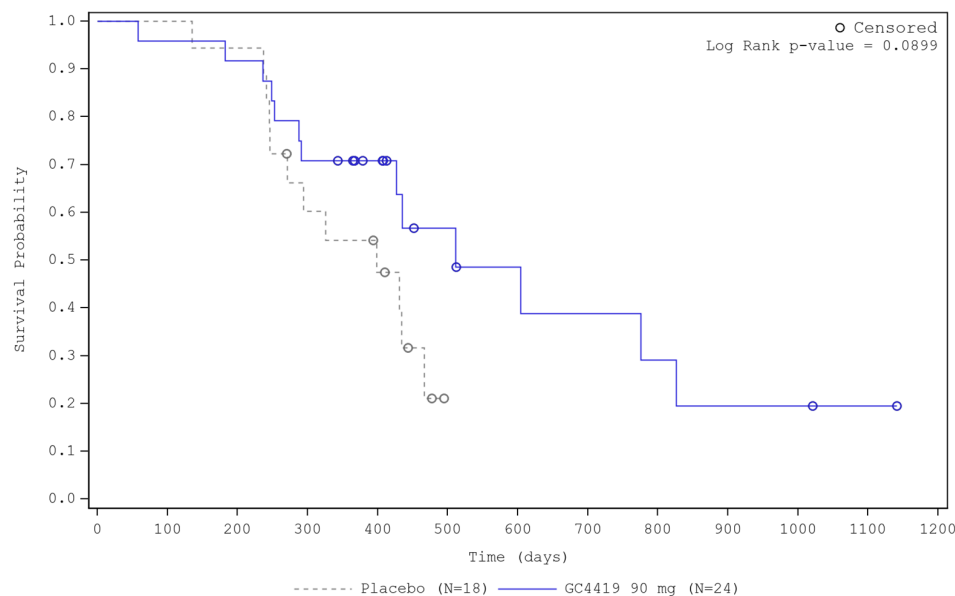
*R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)

LRC = Locoregional Control; DMC = Control of Distant Metastases; PFS = Progression-Free Survival; OS = Overall Survival; NR = Not Reached

Improved Overall and Progression-Free Survival

46% (11/24) alive on GC arm at last follow up compared to 33% (6/18) on placebo

Overall Survival (OS)



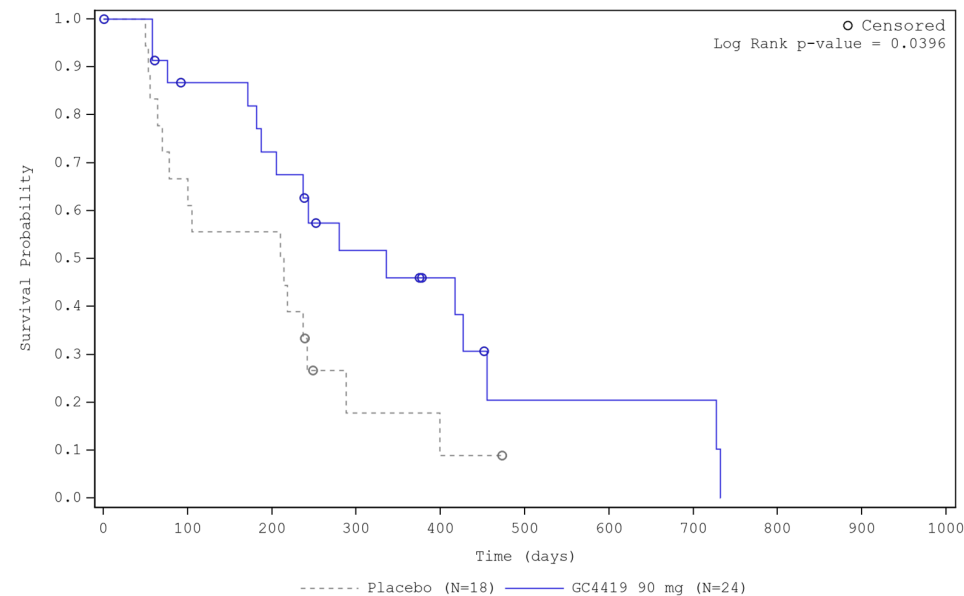
Number of Patients at Risk

Placebo	18	18	17	10	7	0	0	0	0	0	0	0
GC4419 90 mg	24	23	22	17	13	7	5	4	3	2	1	0

P-value = 0.0899

Hazard Ratio = 0.48

Progression-Free Survival (PFS)



Number of Patients at Risk

Placebo	18	12	10	2	1	0	0	0	0	0	0
GC4419 90 mg	24	18	15	9	6	2	2	2	0	0	0

P-value = 0.0396

Hazard Ratio = 0.46

Minimum 12-month follow-up on all patients,

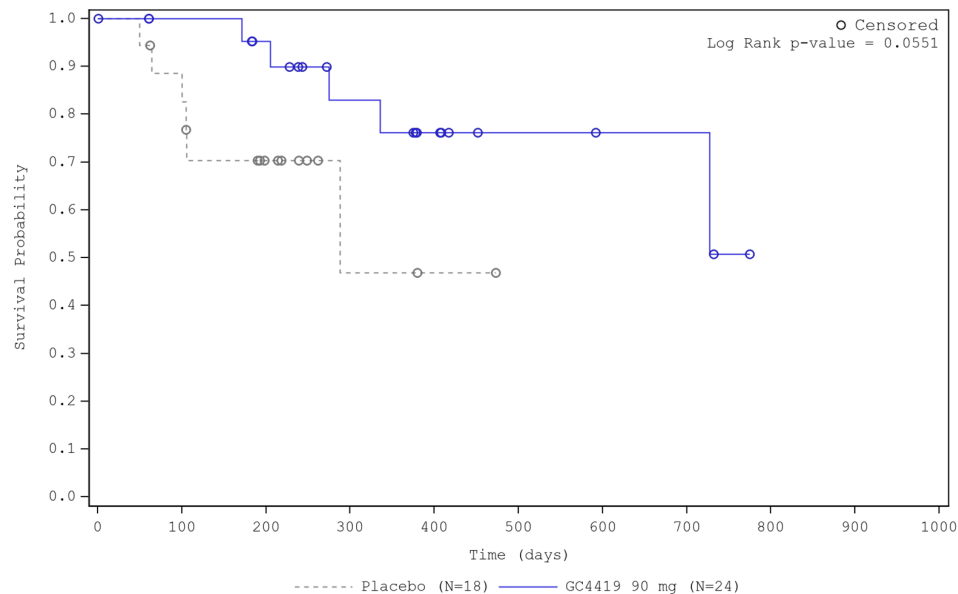
PFS defined as local progression or distant metastasis, not censored for treatment post SBRT

Improved Control of Both Local and Distant Disease

Median LRC on GC arm not yet reached at data cut-off; Increased median DMC by 100%

Locoregional Control (LRC)

– within RT Field



Number of Patients at Risk

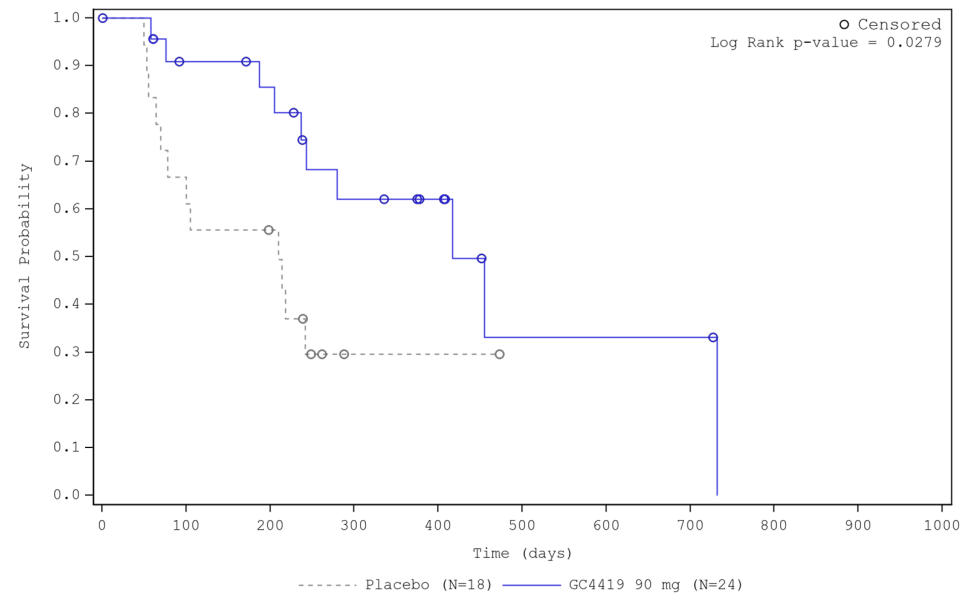
Placebo	18	15	8	2	1	0	0	0	0	0
GC4419 90 mg	24	21	18	12	8	4	3	3	0	0

P-value = 0.0551

Hazard Ratio = 0.30

Distant Metastases Control

– outside RT Field



Number of Patients at Risk

Placebo	18	12	9	1	1	0	0	0	0	0
GC4419 90 mg	24	18	16	10	7	2	2	2	0	0

P-value = 0.0279

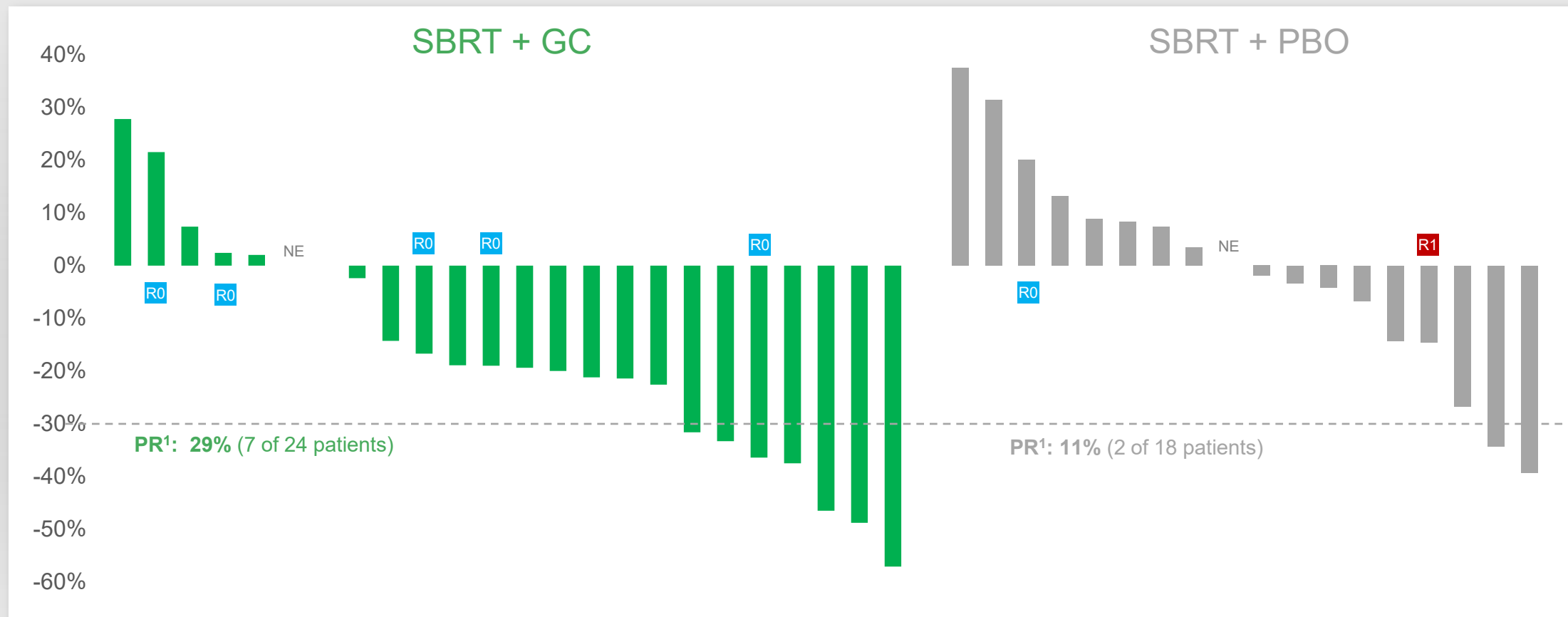
Hazard Ratio = 0.39

Minimum 12-month follow-up on all patients, HR = Hazard Ratio

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

Partial Response Rate Increased 2.5-fold

Best Local Response with follow-up of at least 12 months on all patients (ITT, n=42)



¹Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)

R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)

NE = not evaluable (scans not performed post SBRT)

R1 = positive tumor margins at surgery

Galera's Radiosensitization Trials

Galera Radiotherapy Efficacy Cancer Optimization

GRECO-1 in Lung Cancer



- 71 Patients
- Placebo-controlled multicenter trial
- Locally Advanced NSC Lung Cancer
- Large & central tumors
- Status: Open & recruiting patients

GRECO-2 in Pancreatic Cancer



- 160 Patients
- Placebo-controlled multicenter trial
- Locally Advanced Pancreatic Cancer
- Following 4 months chemotherapy
- Status: Open & recruiting patients

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

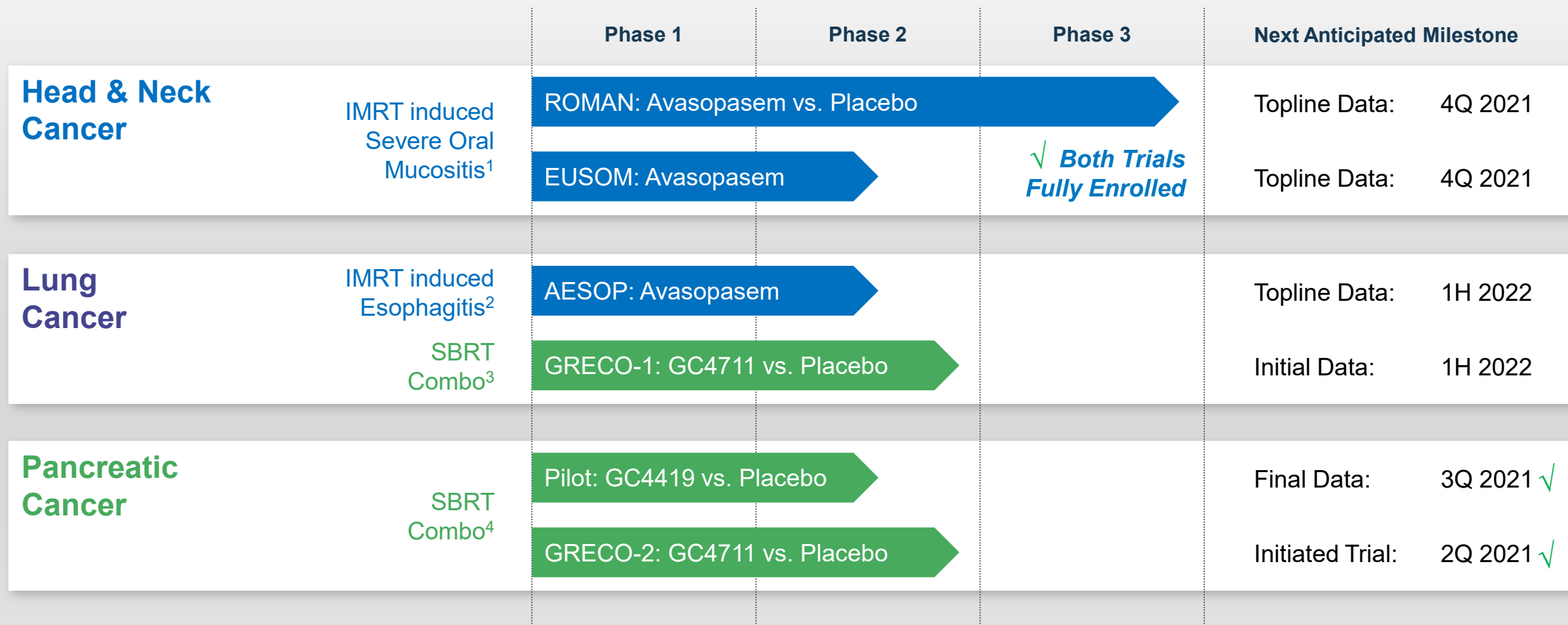


All SBRT	14,600	12,120	15,430
Node-Negative NSCLC	Peripheral Tumor >3cm	Central Tumor <3cm	Central Tumor >3cm
Surgery ONLY	16%	30%	12%
SBRT (+/- other modalities)	81%	67%	85%
Other	3%	2%	4%

Corporate Highlights



Robust Pipeline



¹EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe

²Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC

³Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711

⁴The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

Thank you.



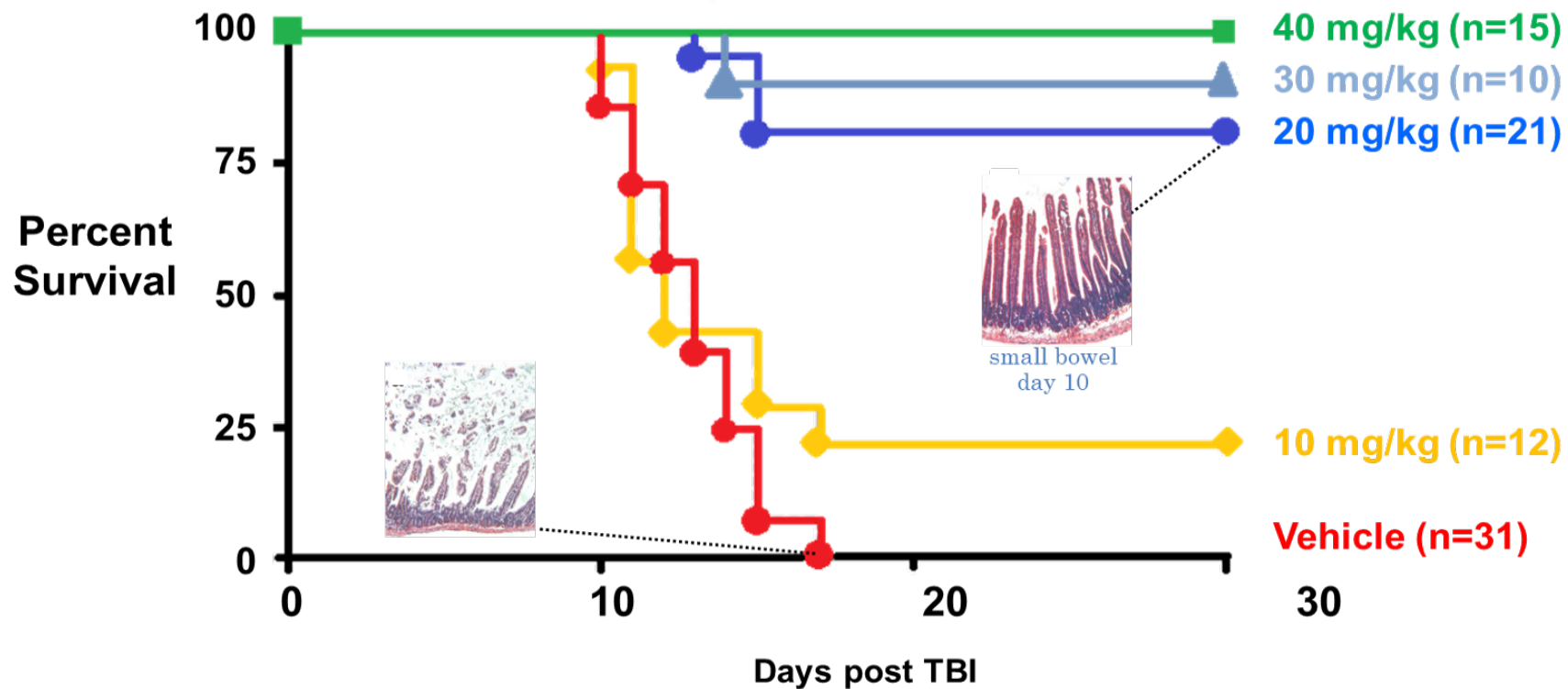
Back-up Slides

Mechanistic and Preclinical Data



Protection from Lethal Radiation Exposure

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

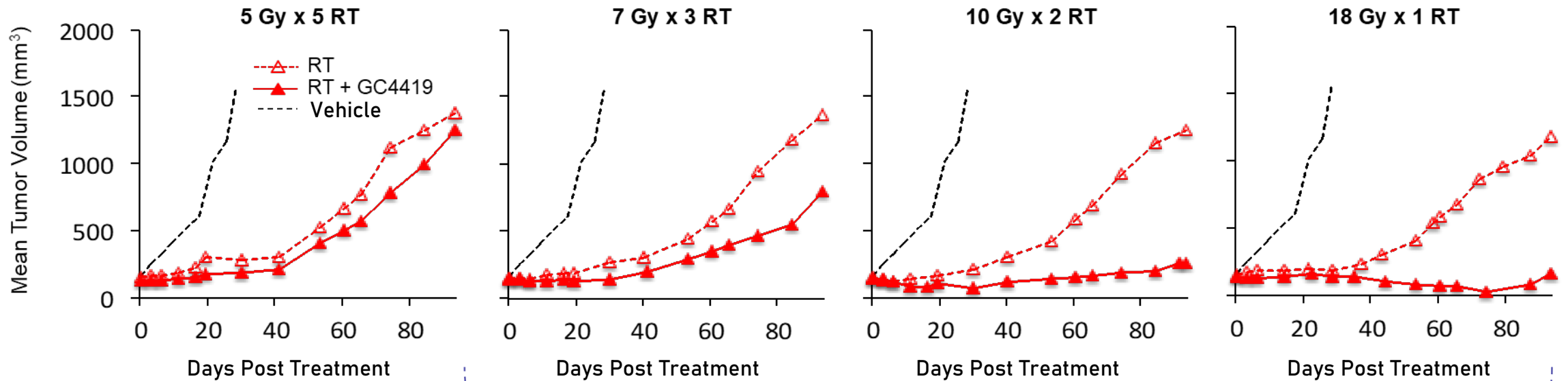


Thompson, et al., Free Radical Research, 44(5):529-540, 2010

Synergy with High-Dose RT (SBRT)

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

RT with Biological Equivalent Doses



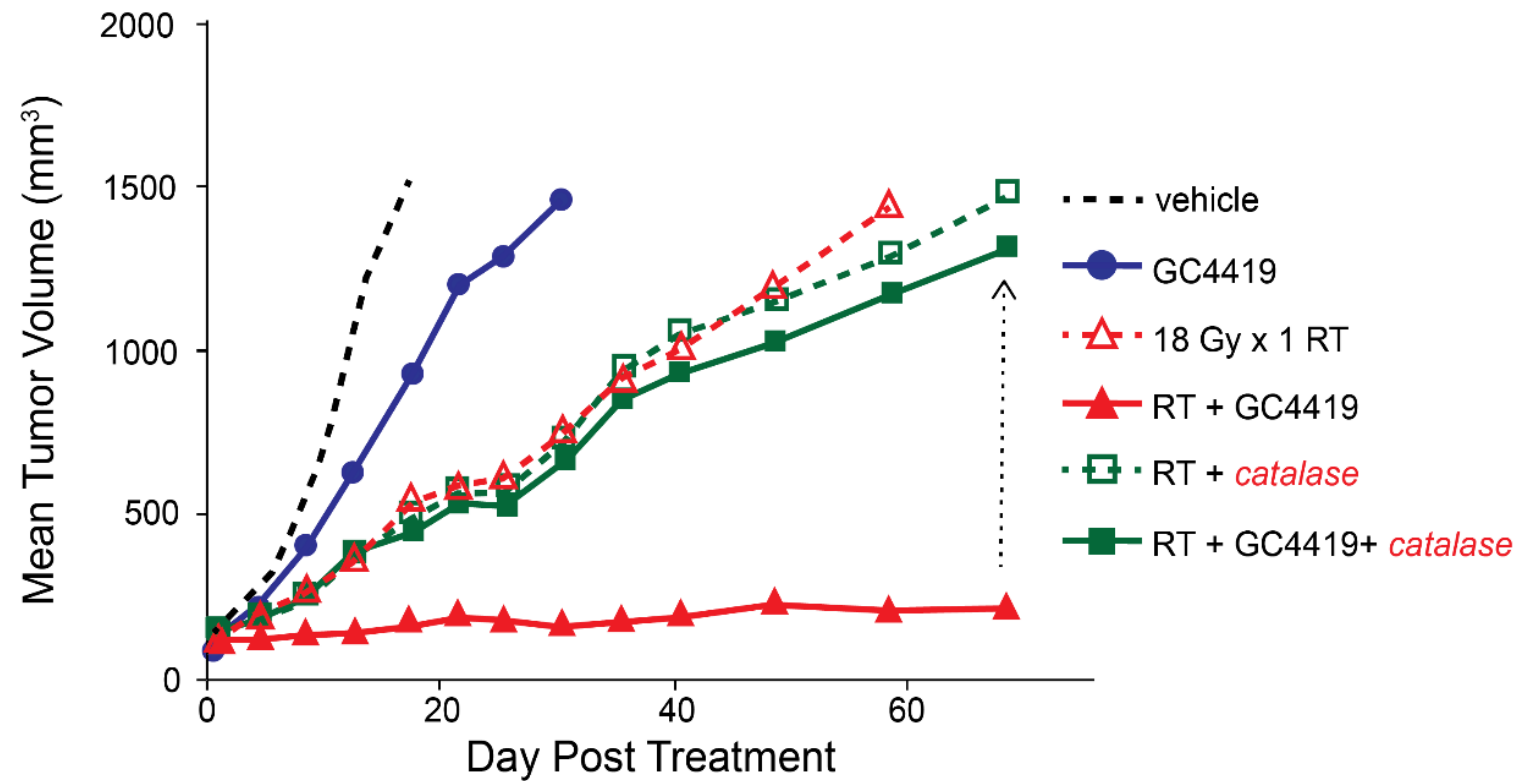
SBRT

Stereotactic Body Radiation Therapy

Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

H₂O₂ build-up in Cancer Cell → Synergy with SBRT

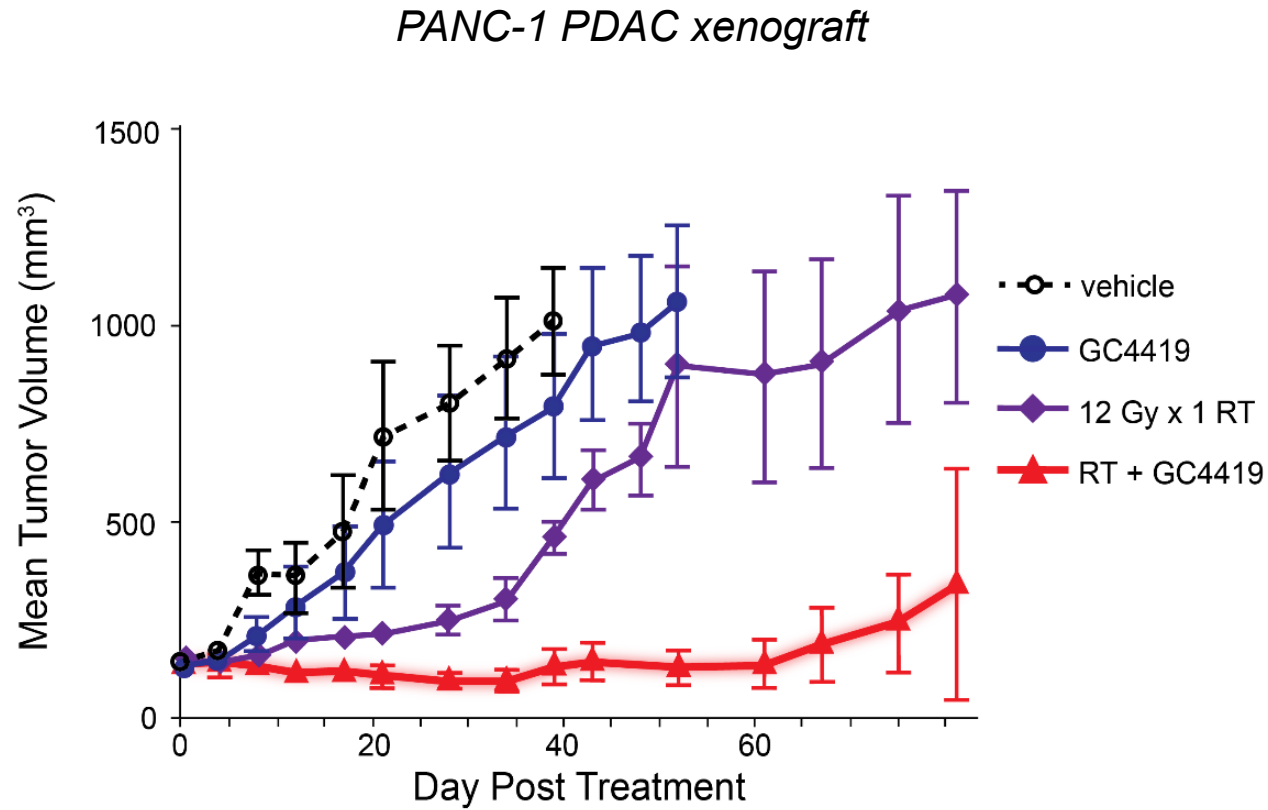
Synergy abrogated with doxycycline-induced catalase in genetically modified H1299^{CAT} cells



Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

Pancreatic Tumor Model → Synergy with SBRT

Marked synergy of Dismutase Mimetic with 12 Gray Radiotherapy

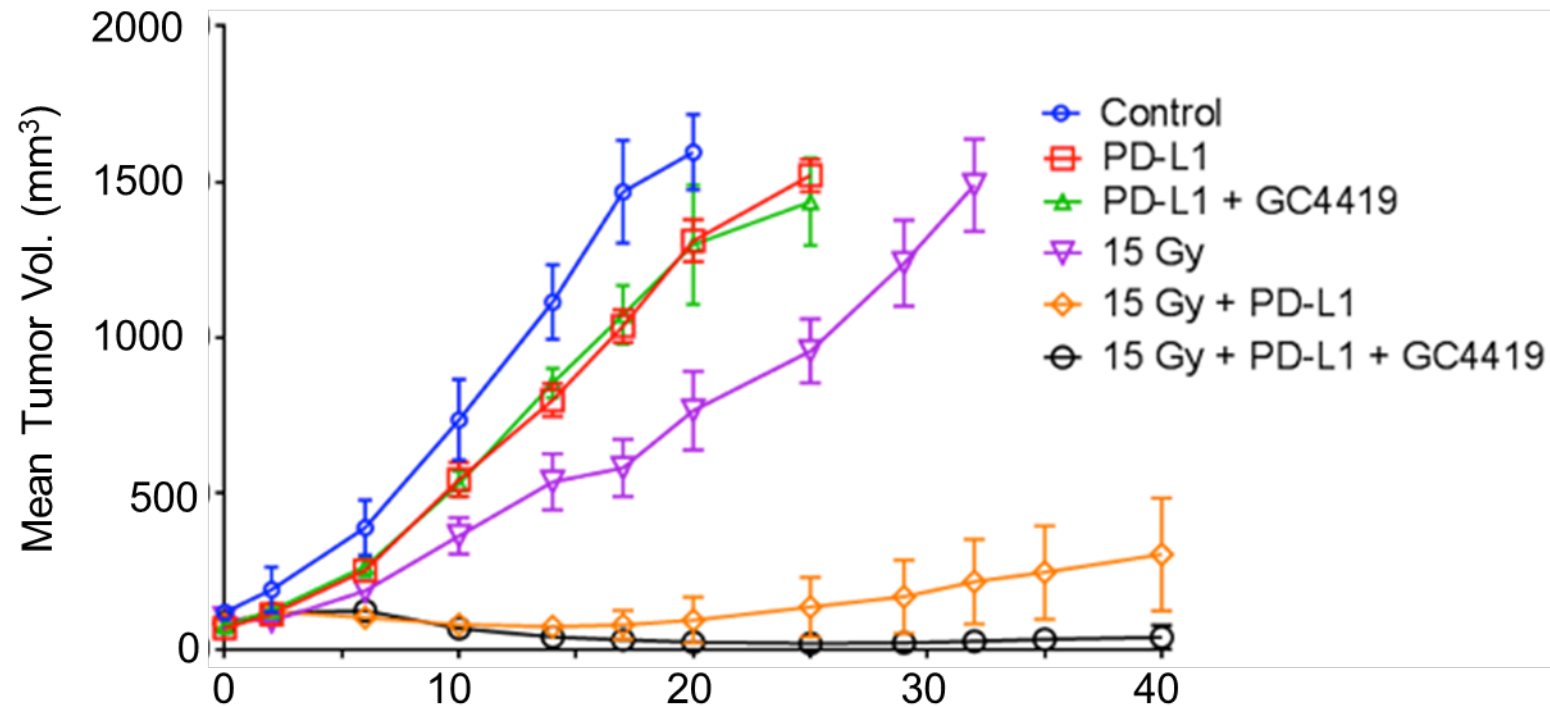


Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

Enhanced Checkpoint Inhibitor Activity in Vivo

GC4419 enhances 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