Transforming **radiotherapy** for patients with cancer

August 2023

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.

Radiation Therapy – Key Role in Cancer Treatment

Two million new cancers annually[1] in US; over 50% of patients receive radiation therapy as part of their treatment

IMRT

Intensity Modulated Radiation Therapy

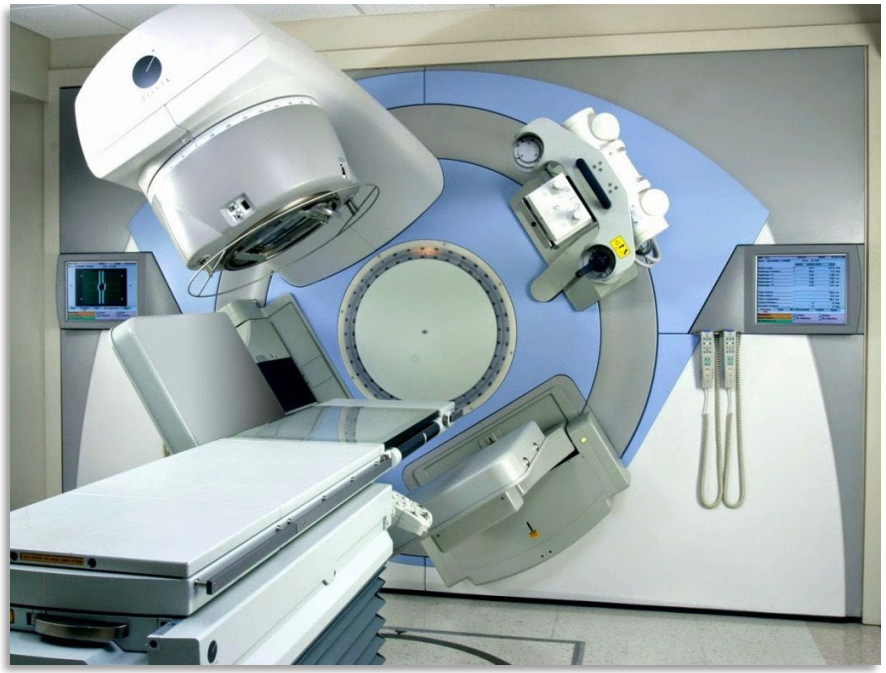
Low doses for weeks
(~2 Gy/day)

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

Galera's Goal

Radiosensitization

Efficacy

[1]US SEER Data in CA Cancer J Clin 2023

Galera's Technology: Dismutase Mimetics

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

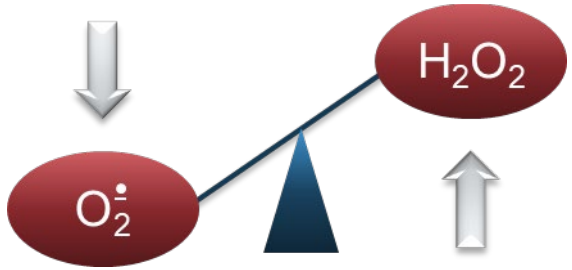
Avasopasem (GC4419)

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

Toxicity

Radioprotection of Low Dose RT

Shifts balance in normal & cancer cells from superoxide to hydrogen peroxide



Rucosopasem (GC4711)

Efficacy

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

Radiosensitization of High Dose RT

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

Transforming Radiotherapy for Patients with Cancer

Potential to improve both sides of the therapeutic index

Rucosopasem
Increasing SBRT Efficacy

➢ **Locally Advanced Pancreatic Cancer (LAPC)**

Encouraging survival data in pancreatic cancer trial[1]

Rucosopasem + SBRT x 5 fractions
- GRECO-2 in LAPC (n=220)
- GRECO-1 in NSCLC (up to 66 pts)

Data-readout for both by end 2024

Avasopasem
Reducing IMRT Toxicity

➢ **Severe Oral Mucositis in Head & Neck Cancer (HNC)**

Positive placebo-controlled HNC trials
- GT-201 Phase 2b (n=223)
- ROMAN Phase 3 (n=455)

Breakthrough Therapy Designation

Received CRL in August 2023 and plan to meet with FDA on next steps

Avasopasem
Reducing Cisplatin Toxicity

➢ **Cisplatin-induced Chronic Kidney Disease (CKD)**

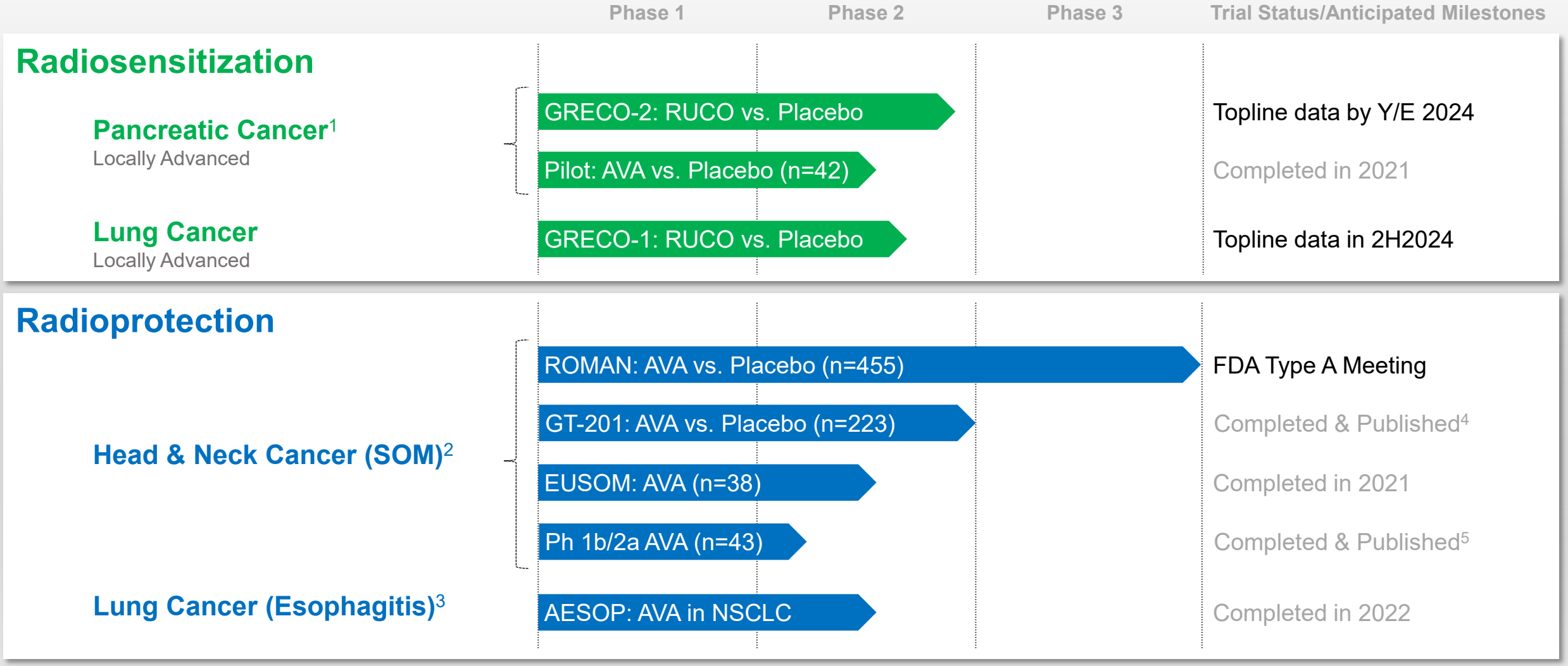
CKD halved at 1 year after cisplatin
- 10% on AVA vs. 20% on PBO
- Prospectively defined endpoint in ROMAN trial (n=351 at 1 year)

Superoxide drives cisplatin nephrotoxicity, independent of RT

CRL = Complete Response Letter; FDA=U.S. Food and Drug Administration; AVA = avasopasem manganese; PBO = placebo

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

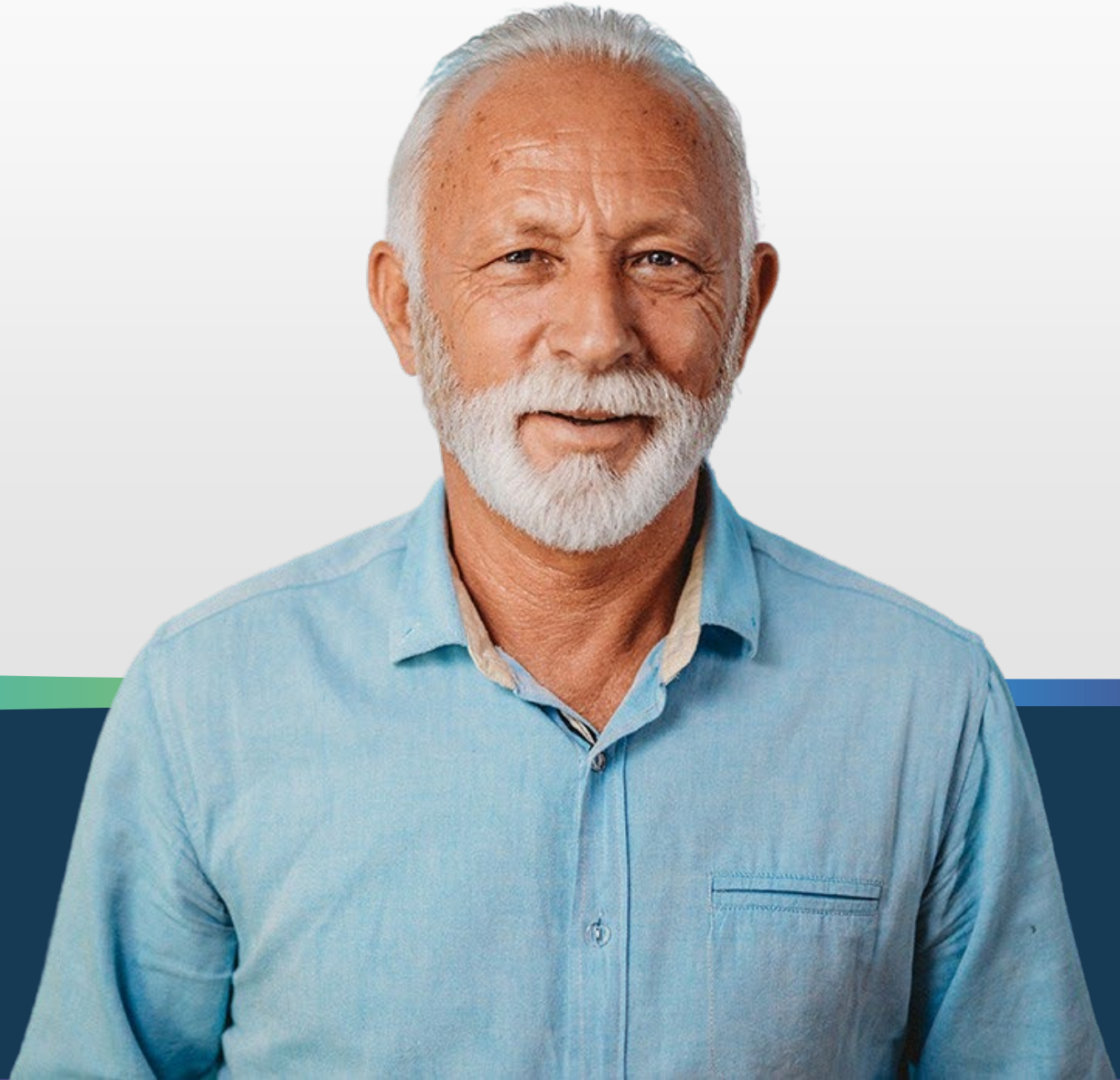
Clinical Stage Pipeline



[1]First SBRT combination trial was a pilot & used avasopasem (AVA). Subsequent SBRT trials combine rucosopasem (RUCO) with SBRT.
[2]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[3]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[4]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[5]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Rucosopasem = RUCO
Avasopasem = AVA
Severe Oral Mucositis = SOM
U.S. Food & Drug Administration = FDA

Increasing SBRT Efficacy



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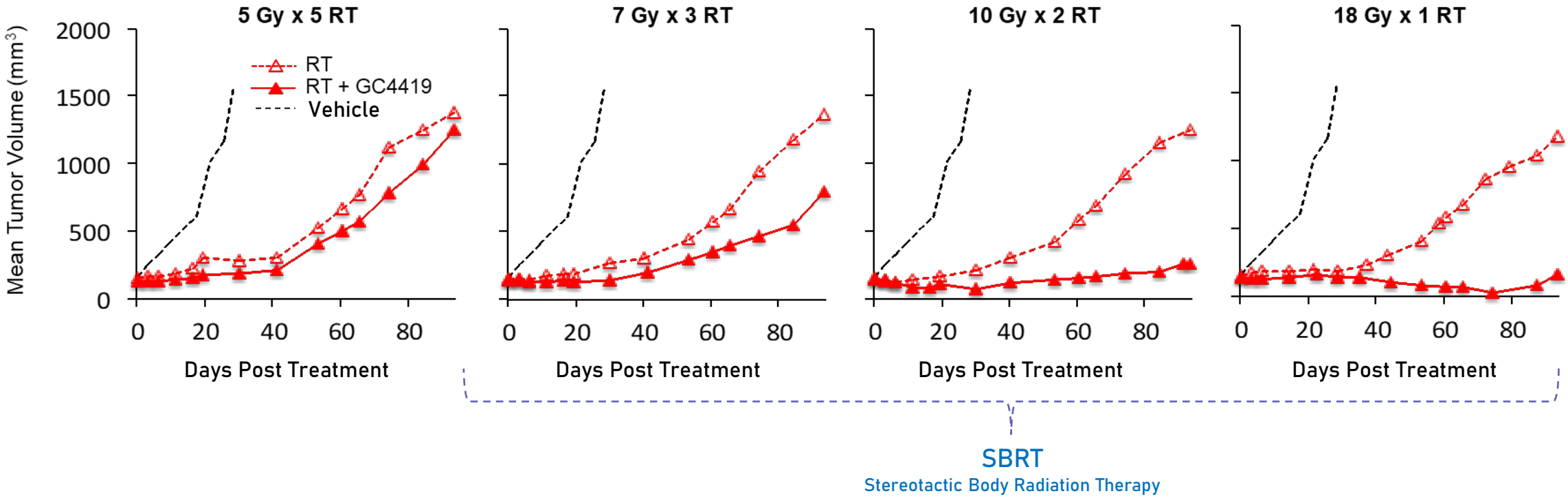
Synergy with High-Dose RT (SBRT)

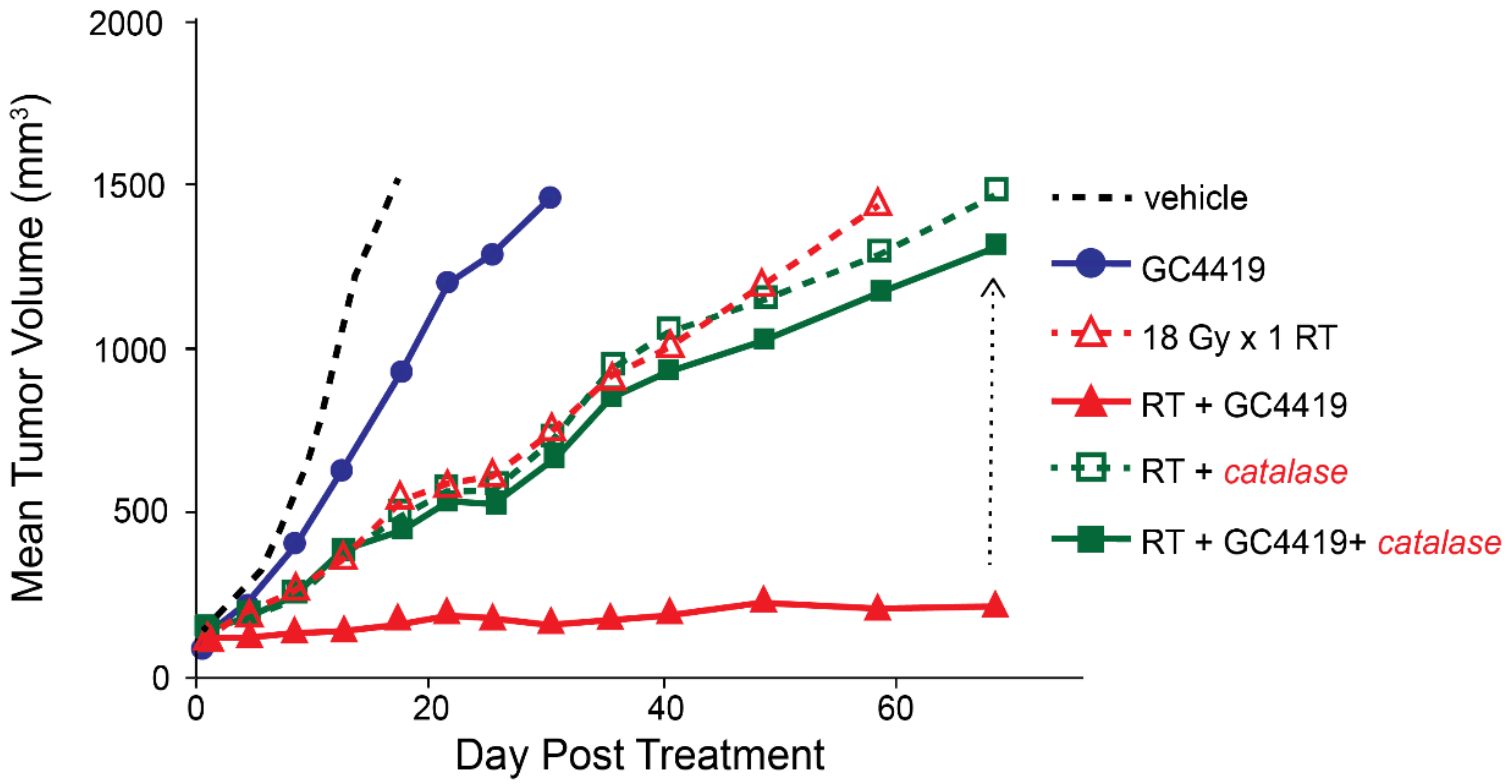
High-fraction focal irradiation of human tumor xenografts (H1299 NSCLC) in mice



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

H_2O_2 build-up in Cancer Cell → Synergy with SBRT

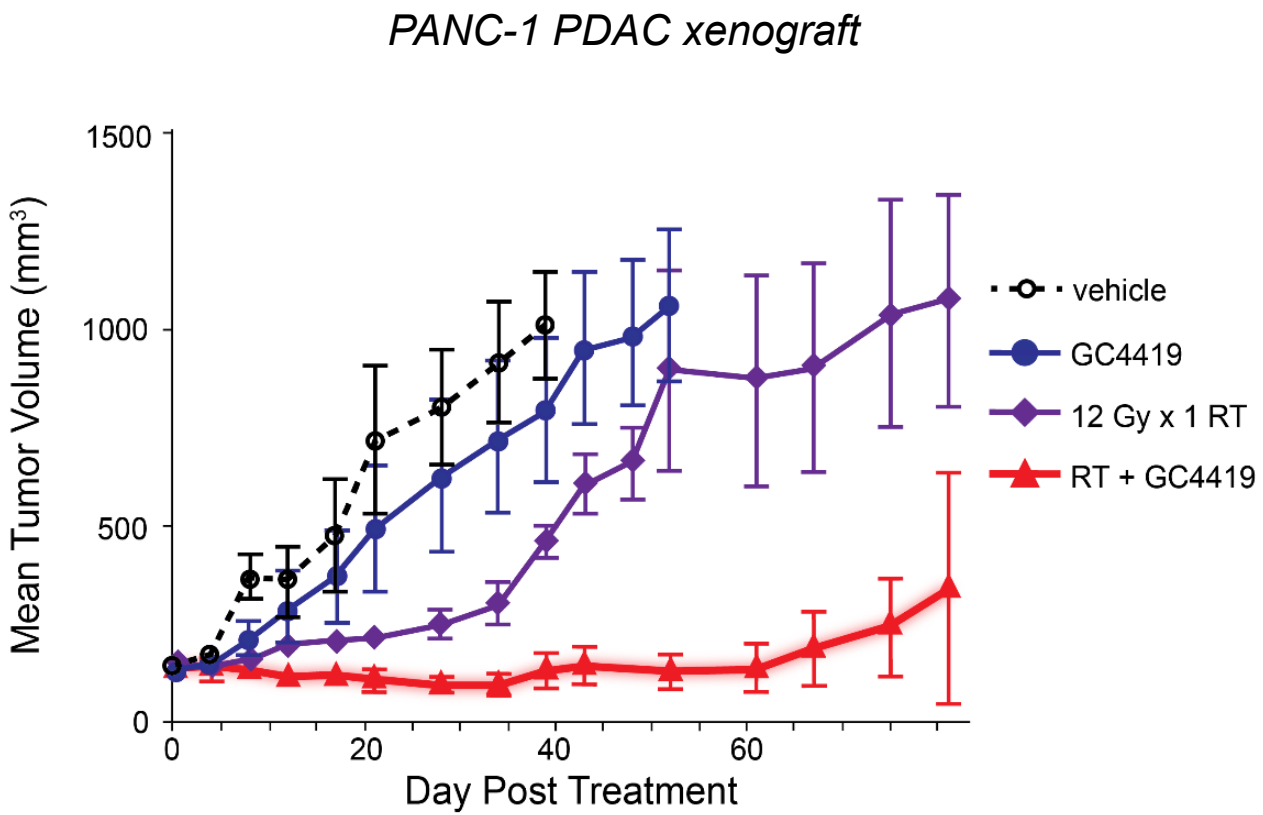
Synergy eliminated with doxycycline-induced catalase in genetically modified $H1299^{CAT}$ cells



Preclinical results; 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



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

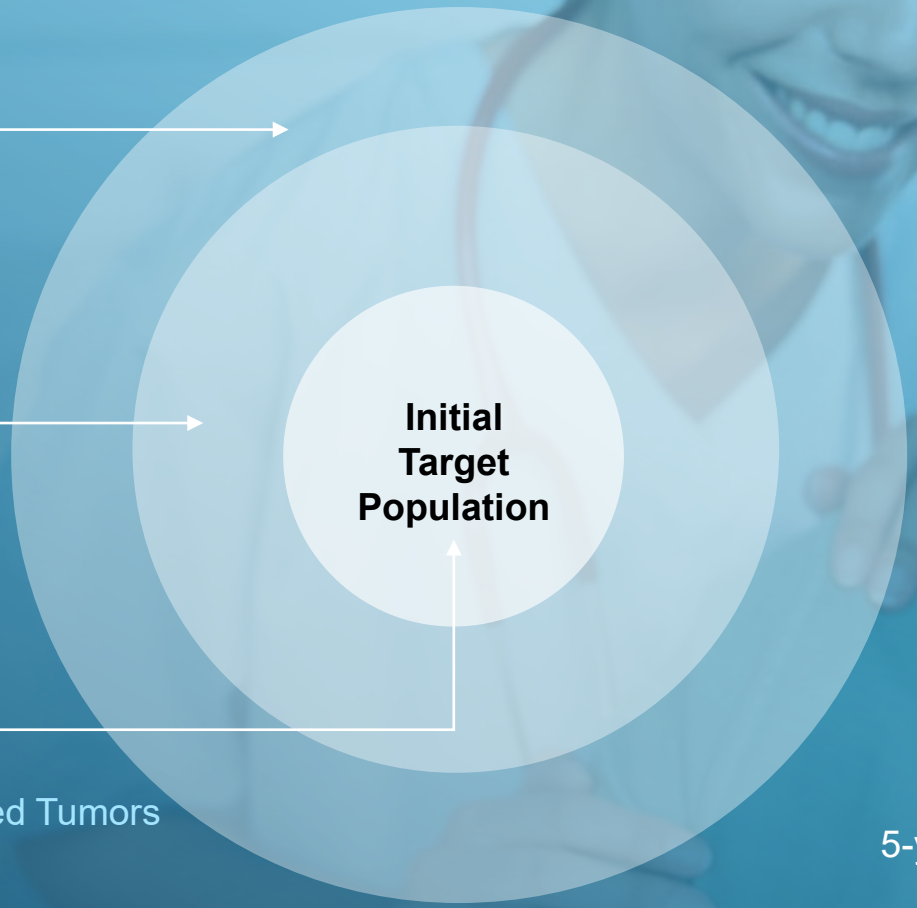
Pancreatic Cancer

High Unmet Medical Need With Limited Therapeutic Options

500,000
Global Incidence

64,000
US Patients Diagnosed each year

18,000
Patients with Unresectable Locally Advanced Tumors



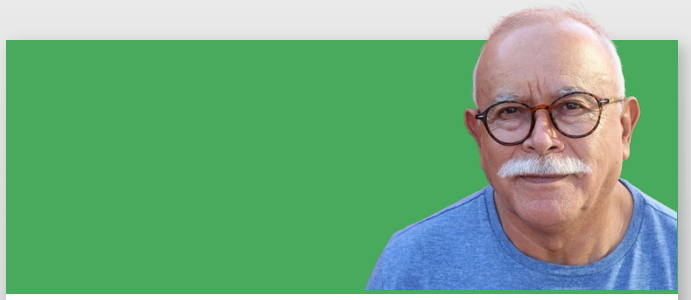
5-year survival rate is only ~10%

SBRT use increasing for locoregional control of pancreatic cancer

Source: Globocan 2020 and US SEER Data in CA Cancer J Clin 2023

Proof of Concept Trial in Pancreatic Cancer

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



Population

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

Treatment

R

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

- 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

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*

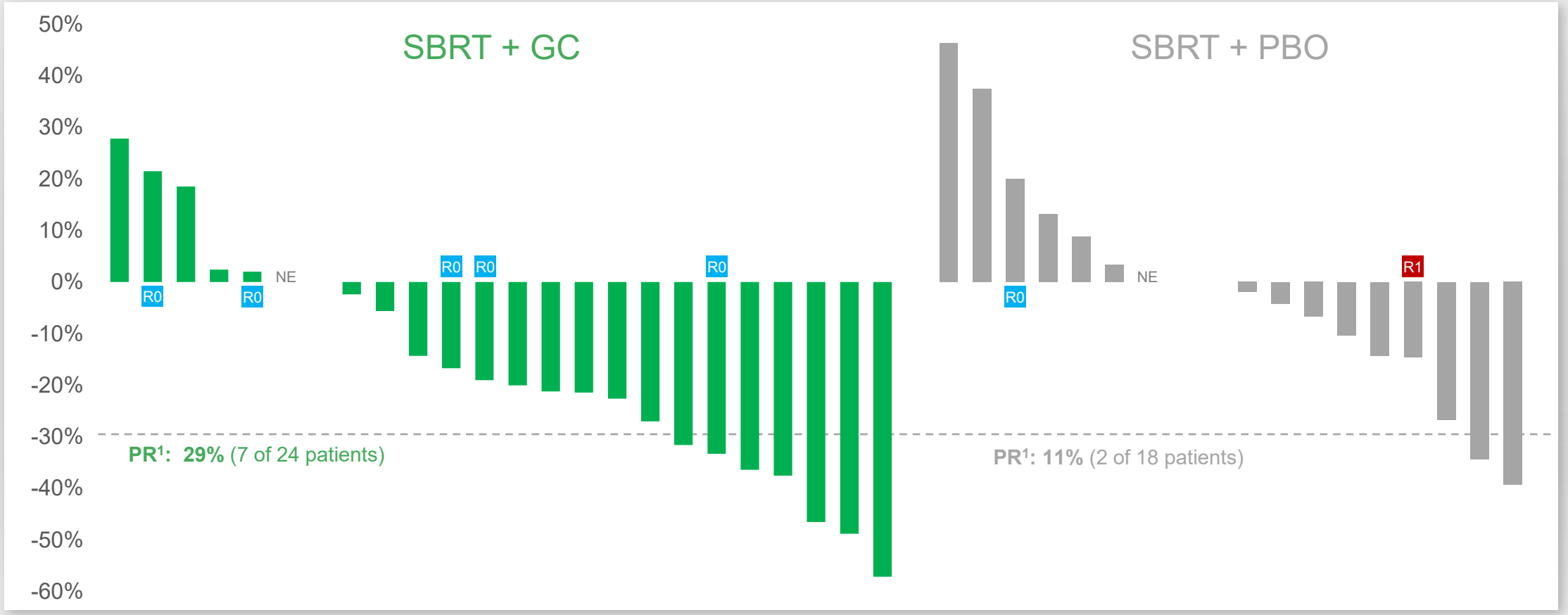
No Early or Late Toxicity Signal for GC

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

Partial Response Rate Increased 2.5-fold

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



[1]Partial 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)
Censored for surgery, treatment post SBRT and new malignancy

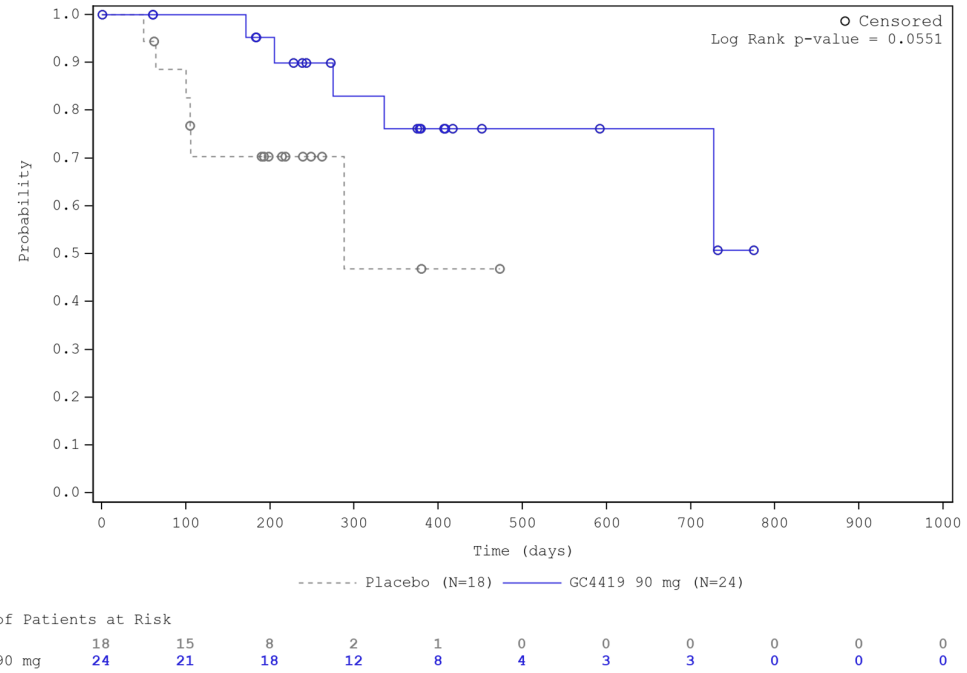
NE = not evaluable (scans not performed post SBRT)
R1 = positive tumor margins at surgery

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% at data cut-off

Locoregional Control (LRC)

– within RT Field



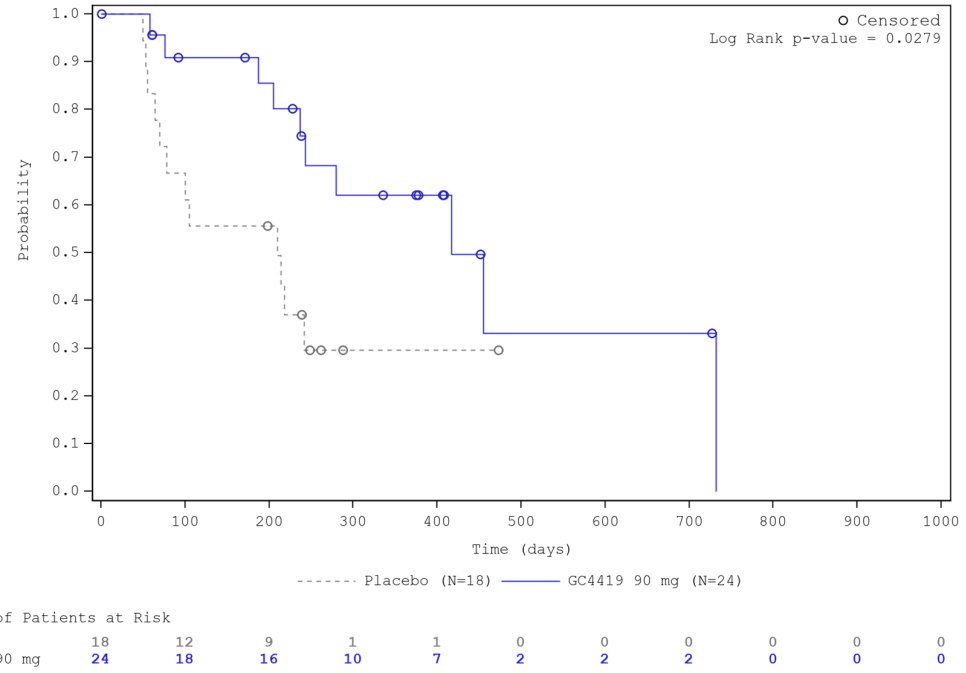
Number of Patients at Risk

Placebo	18	15	8	2	1	0	0	0	0	0	0
GC4419 90 mg	24	21	18	12	8	4	3	3	0	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	0
GC4419 90 mg	24	18	16	10	7	2	2	2	0	0	0

P-value = 0.0279 Hazard Ratio = 0.39

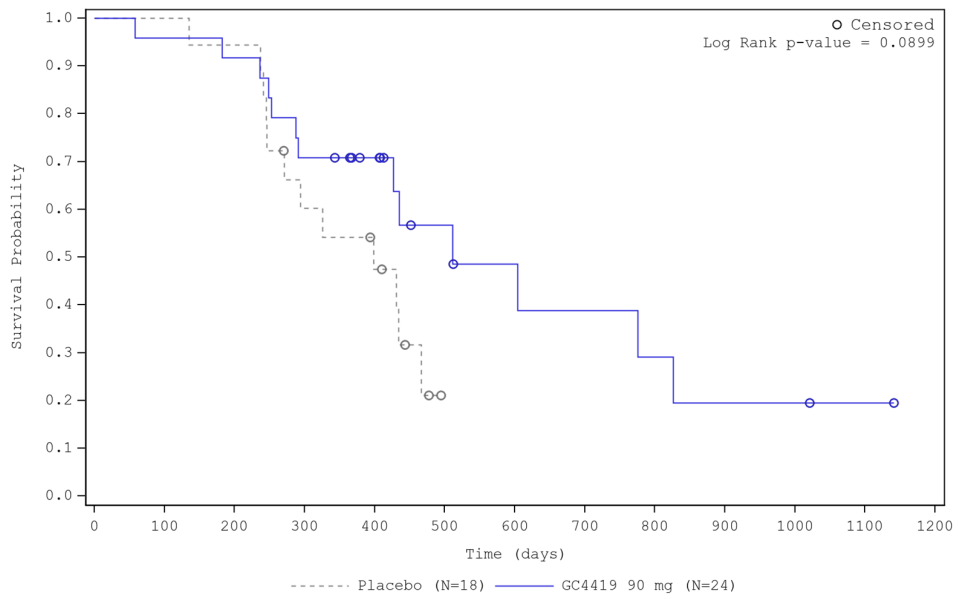
Minimum 12-month follow-up on all patients, HR = Hazard Ratio

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

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)

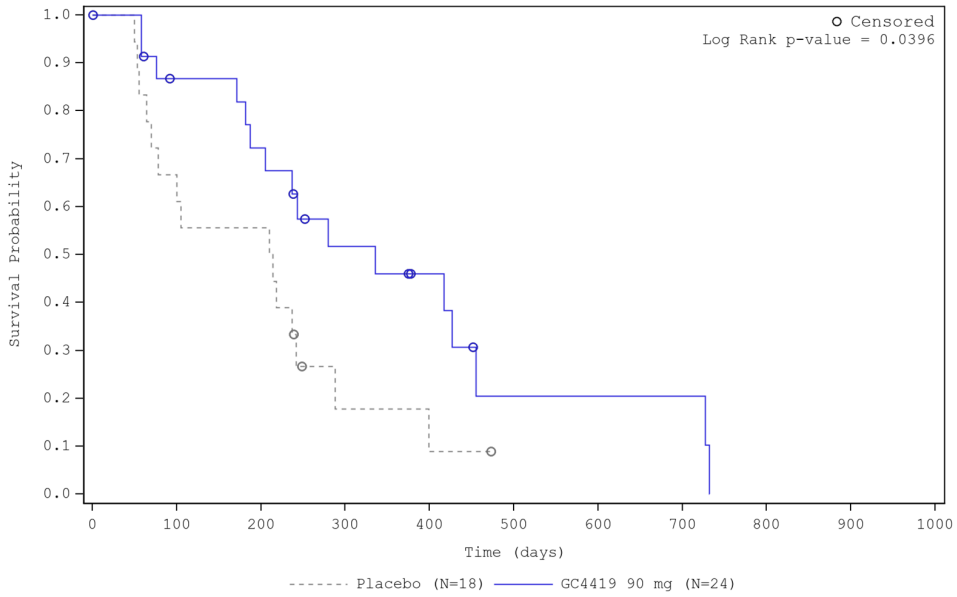


Number of Patients at Risk

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

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

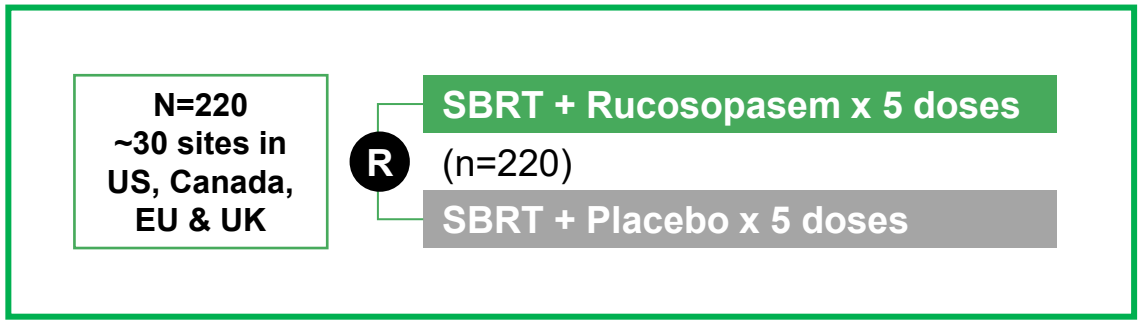
*R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)
LRC = Locoregional Control; DMC = Control of Distant Metastases; PFS = Progression-Free Survival; OS = Overall Survival; NR = Not Reached

GRECO-2 Trial of Rucosopasem + SBRT in LAPC

Galera Radiotherapy Efficacy Cancer Optimization

- Multicenter, double-blinded, placebo-controlled trial
- 220 patients, 1:1 randomization
- Locally Advanced Pancreatic Cancer (LAPC) – unresectable or borderline resectable, non-metastatic
- ECOG Performance 0-2
- Must have 6 weeks or more of chemotherapy (FOLFIRINOX or Gemcitabine doublet regimen)
- Stratified for borderline resectable vs. unresectable

Rucosopasem 100mg IV or placebo administered over 15 mins <3 hrs before SBRT (5 fractions of 10 Gy each)



- Primary Endpoint: Overall Survival
- Secondary Endpoints: PFS, LRC, TDM, surgical resection, in-field response rate, acute & late toxicity

PFS = Progression-Free Survival; LRC = Locoregional Control; TDM = Time to Distant Metastasis

SBRT for Non-Small Cell Lung Cancer

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

1,800,000
Global NSCLC Incidence

195,000
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%

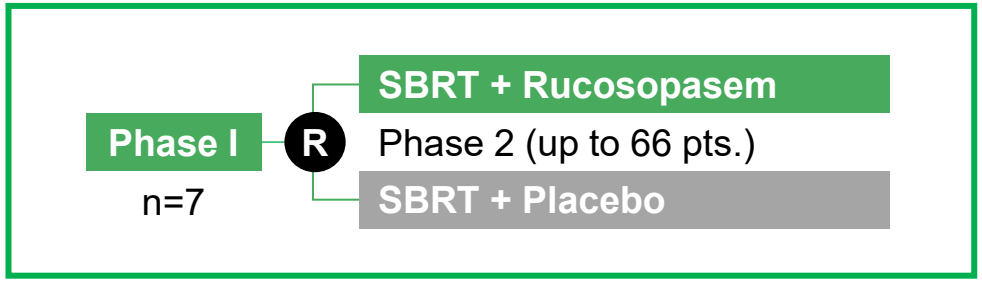
Source: Globocan 2020 and US SEER Data in CA Cancer J Clin 2023; Decision Resources Market Sizing Report, Oct 2020

GRECO-1 Trial of Rucosopasem + SBRT in NSCLC

Galera Radiotherapy Efficacy Cancer Optimization

GRECO-1 Trial

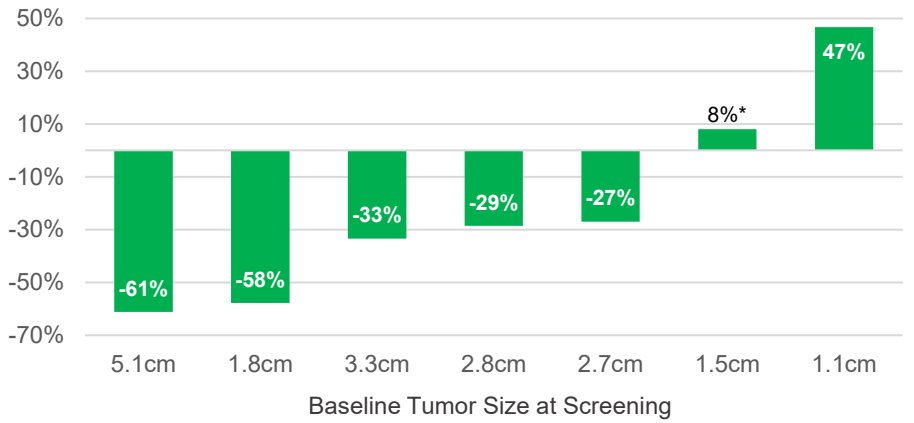
Rucosopasem 100mg IV or placebo over 15 mins before each SBRT fraction



- Patients with central and/or large NSCLC tumors
- Single-arm open label Phase 1 stage complete
- Multicenter, double-blinded, placebo-controlled Phase 2 stage actively enrolling; anticipate topline data in 2H2024
- SBRT Dose Schedule:
  - Phase 1: 5 fractions x 10 Gy
  - Phase 2: 5 x 10 Gy or 3 x 18 Gy

Phase 1 Results

- Rucosopasem + SBRT was well tolerated in Phase 1 with fatigue, cough & nausea most frequent adverse events (common in patients receiving RT)
- Pulmonary function preserved:
  - No Grade 2-4 declines in DLCO[1] (RTOG scale) with rucosopasem
  - Historical expectation 7-12% in prospective trial[2] evaluating effect of lung SBRT on pulmonary function (4-5 fractions, n=127)
- Target tumor volume at 6 months post SBRT + Rucosopasem, as follows:



* Measurement at 3 months, target lesion unevaluable at 6 months; progressed out of RT field at 6 months; only patient with prior chemotherapy

[1]DLCO is the diffusing capacity of the lung for carbon monoxide, a measurement of the lung's ability to transfer gas from inspired air to the bloodstream.
[2]Stone B, Mangona VS, Johnson MD et.al. Changes in pulmonary function following image-guided stereotactic lung radiotherapy. J Thorac Oncol. 2015;10: 1762–1769

RTOG=Radiation Therapy Oncology Group

Rucosopasem

Potential to increase anti-cancer efficacy of stereotactic body radiation therapy

- **Rucosopasem shows strong potential as anti-cancer agent in combination with SBRT**
  - Clinical pilot trial demonstrated meaningful improvements in multiple cancer endpoints[1]
  - Preclinical data illustrate potent mechanism-of-action
- **Large market opportunities with little competition and composition-of-matter patent to 2038**
  - Locally-advanced pancreatic cancer ~18k patients
  - Early-stage lung cancer ~55k patients
- **Rucosopasem anti-cancer trials enrolling with topline data expected in 2024**
  - GRECO-1 topline in NSCLC in 2H 2024
  - GRECO-2 topline in LAPC by Y/E 2024

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

Reducing
IMRT Toxicity

Galera® Therapeutics, Inc

Avasopasem NDA Update

Complete Response Letter (CRL) received in August 2023; plan to meet with FDA on next steps

- No FDA-approved drugs for radiotherapy-induced SOM in HNC
- Avasopasem has Breakthrough Therapy and Fast Track Designations
- NDA was submitted in December 2022 based on statistically significant, clinically meaningful data from two placebo-controlled randomized trials: ROMAN and GT-201
- NDA was granted priority review by FDA with August 9th PDUFA Date
- Received CRL in August 2023; FDA stated results from an additional clinical trial will be required for resubmission
- Intend to request Type A meeting with FDA to discuss next steps

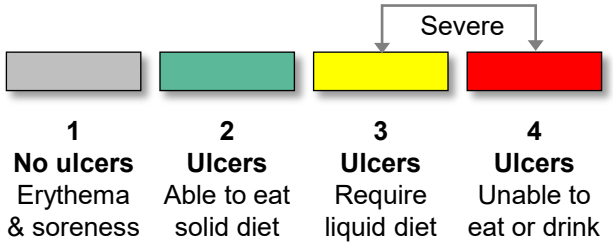
NDA=New Drug Application; FDA=U.S. Food and Drug Administration; PDUFA=Prescription Drug User Fee Act

Severe Oral Mucositis in Head & Neck Cancer

The most burdensome toxicity of standard-of-care chemoradiotherapy (radiotherapy & cisplatin)[1]

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

WHO Scale Criteria for Oral Mucositis



Current Approaches Lack Efficacy

MASCC Guidelines focus principally on symptoms[2]

- Basic oral care
- Opioids, anesthetics
- Coating agents
- Benzydamine
- Anti-inflammatories
- Laser and other light therapy

Physicians Consider Topicals Ineffective

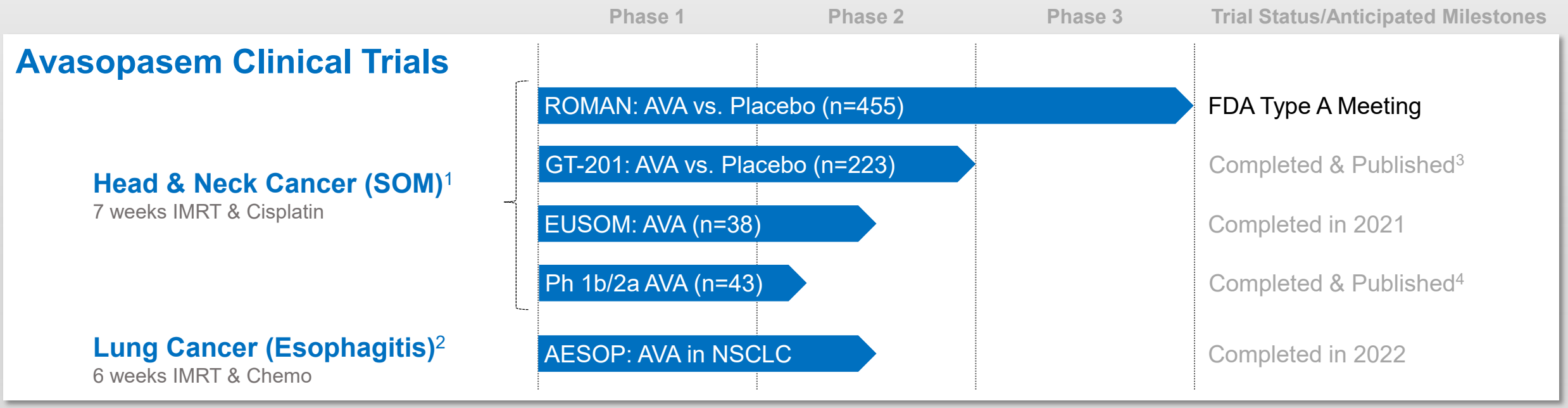
Market Research with 150 Radiation Oncologists[1]

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

[1]Galera Market Research
[2]Elad S et al, MASCC/ISOO Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. Cancer 2020;126:4423-4431
MASCC=Multinational Association of Supportive Care in Cancer

Avasopasem: First-to-Market Potential for Severe Oral Mucositis

Achieved statistical significance in two randomized trials in patients with head and neck cancer



Avasopasem has FDA Breakthrough Therapy Designation based on GT-201 results

[1]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[2]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[3]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[4]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Comparison of Galera's Two Placebo-Controlled Trials

Both GT-201 and ROMAN were double-blind placebo-controlled randomized trials

GT-201 Phase 2b

N=223

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

Endpoints

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

Similarities

- SoC IMRT + Cisplatin
- 60-minute IV infusion just before IMRT
- WHO Grading
- Multicenter in North America (~90% US)

- Patients with Head & Neck Cancer (locally advanced)
- Same inclusion / exclusion criteria

ROMAN Phase 3

N=455

R
- Avasopasem 90mg x 7 weeks

Randomized 3:2

- Placebo x 7 weeks

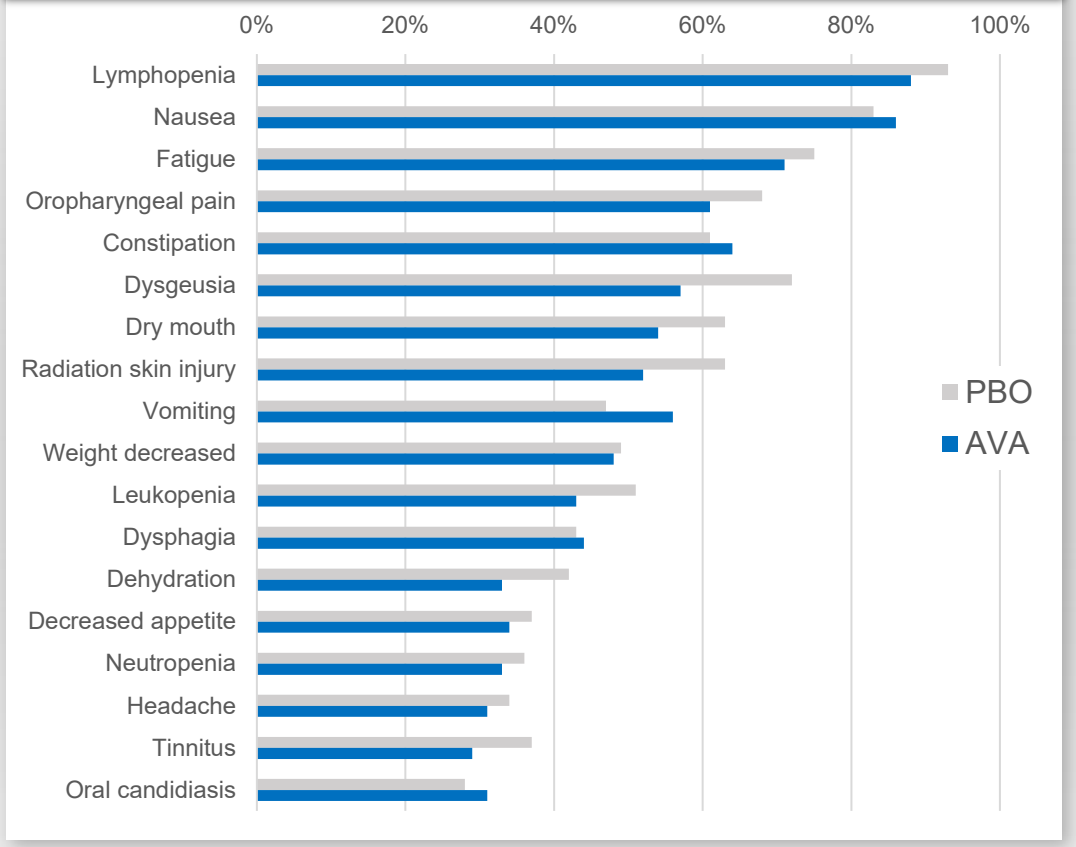
Endpoints

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

Most Frequent Adverse Events on the Two Randomized Trials

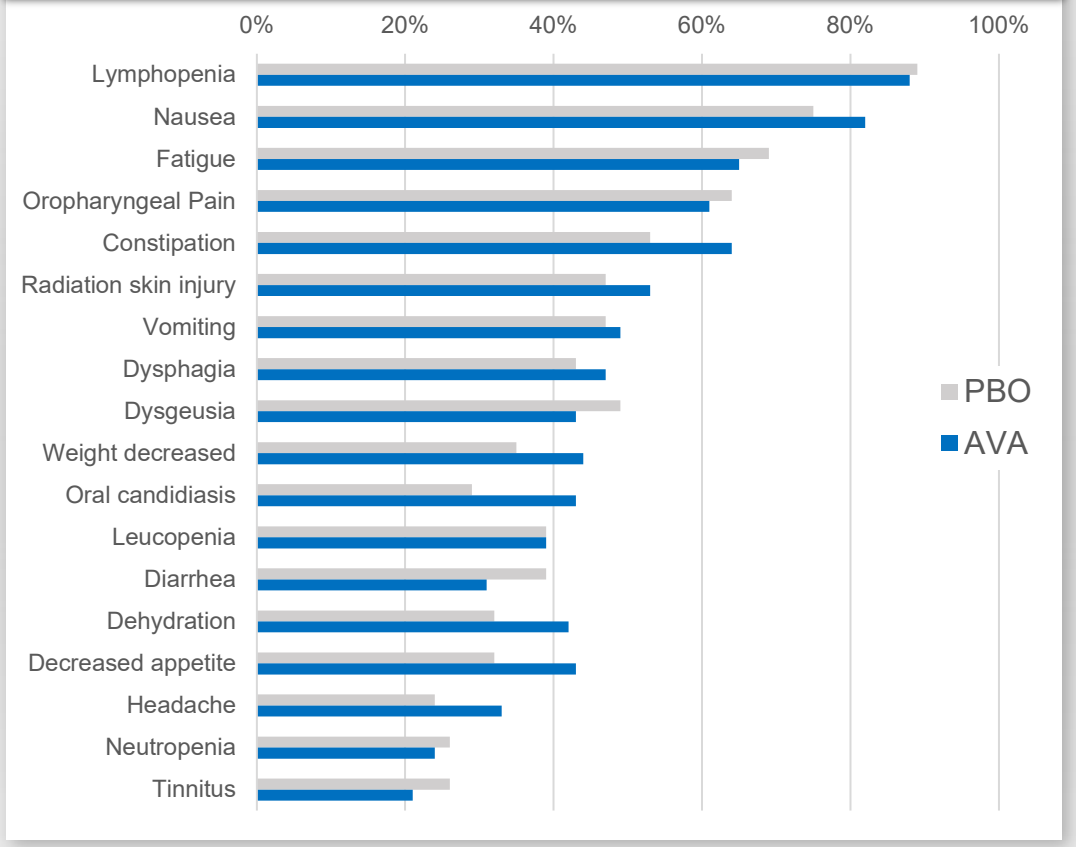
Avasopasem 90mg appears generally well tolerated (all grades and causes)

ROMAN[1]



[1]ITT population: 166 patients on placebo; 241 on 90mg avasopasem

GT-201[2,3]

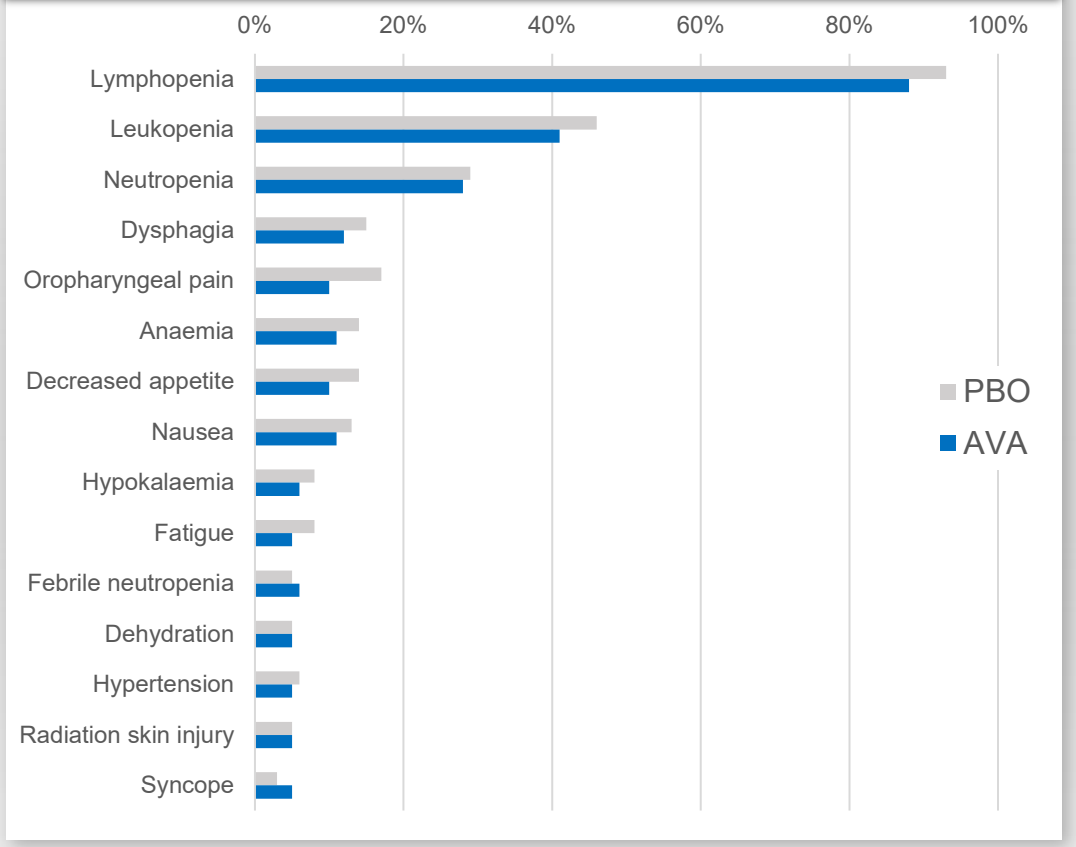


[2]Intent-to-Treat (ITT) population: 72 patients on placebo; 72 patients on 90mg avasopasem
[3]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Most Frequent ≥ Grade 3 AEs on the Two Randomized Trials

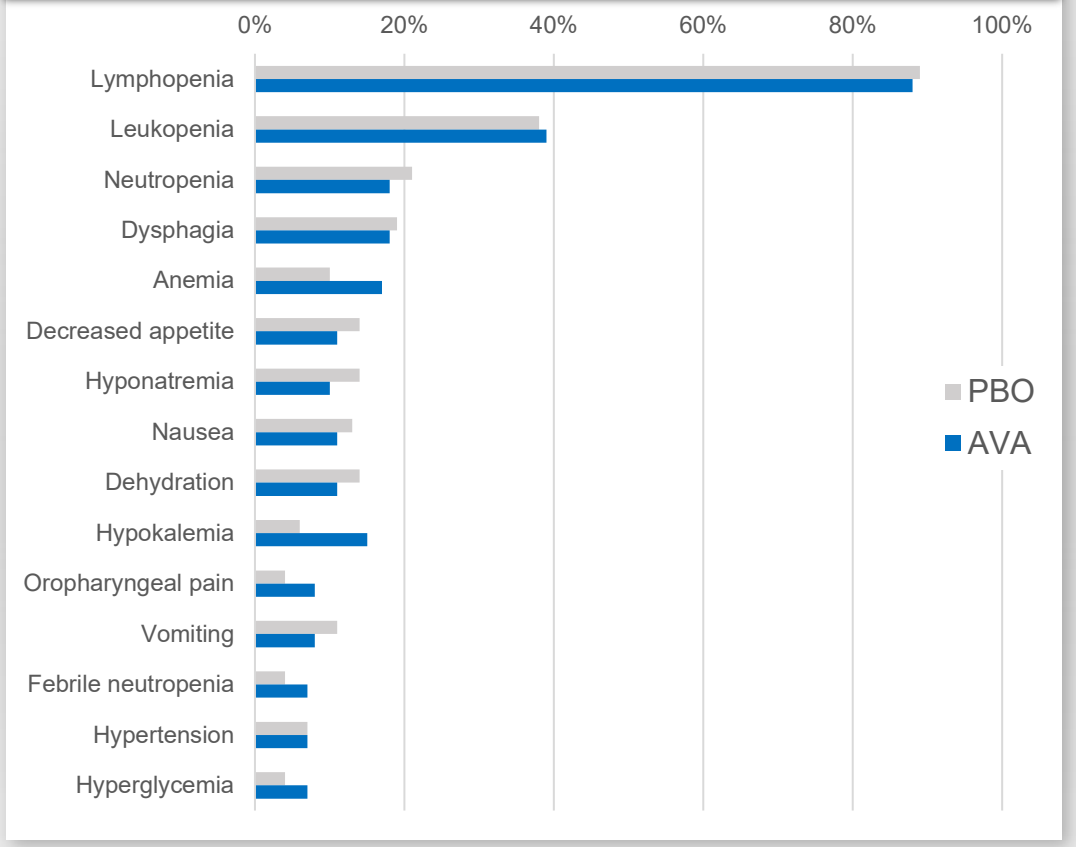
Avasopasem 90mg appears generally well tolerated

ROMAN[1]



[1]ITT population: 166 patients on placebo; 241 on 90mg avasopasem
AE = Adverse Event

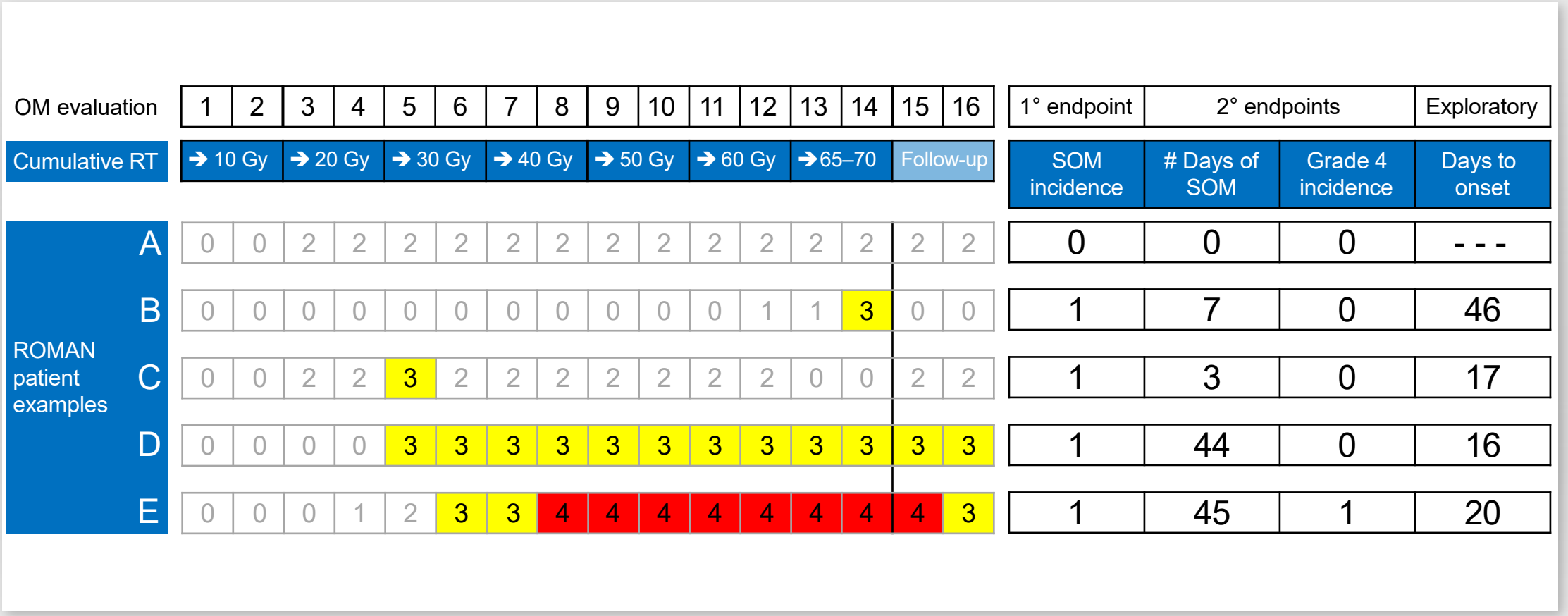
GT-201[2,3]



[2]Intent-to-Treat (ITT) population: 72 patients on placebo; 72 patients on 90mg avasopasem
[3]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Multiple Efficacy Parameters Define the Patient Burden of SOM

Incidence doesn't tell full story; real patient examples from ROMAN



OM=oral mucositis; RT=radiation therapy

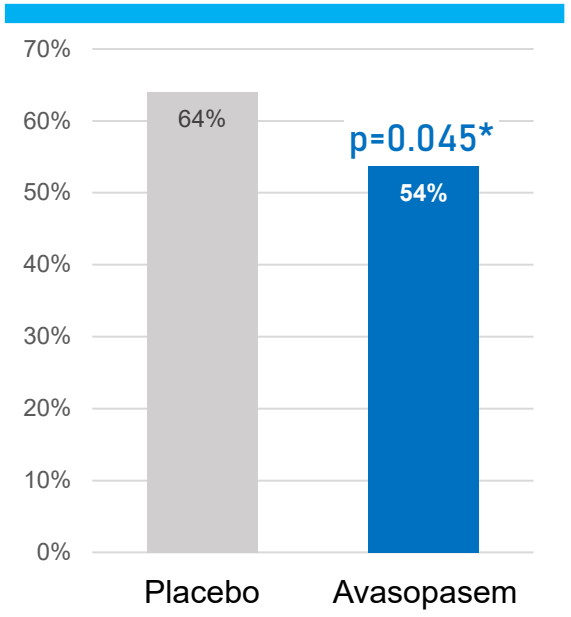
Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

ROMAN Results (ITT n=407)

Reductions across SOM endpoints; statistical significance on the primary & median days SOM secondary endpoint

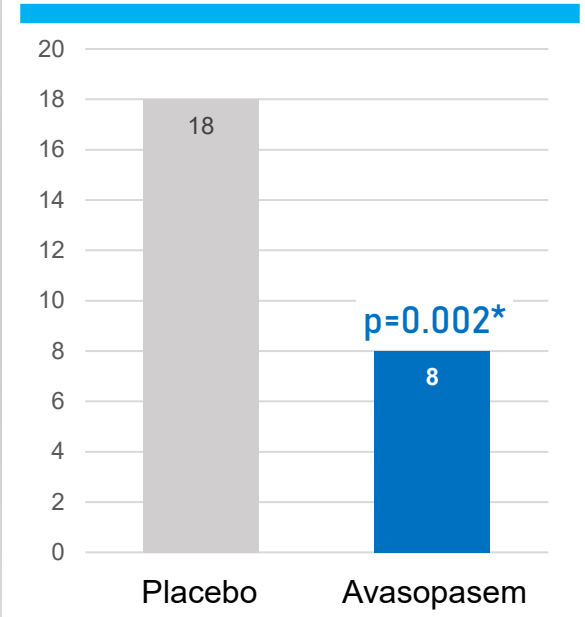
SOM Incidence

16% **Reduction** in SOM incidence



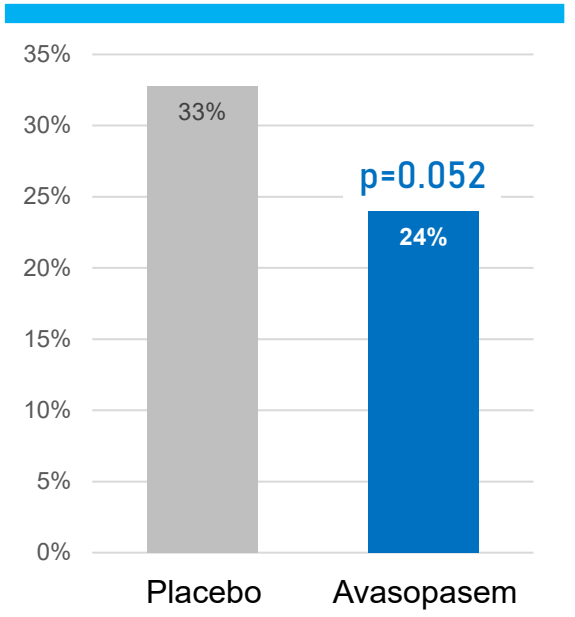
SOM Days

56% **Reduction** in median days of SOM



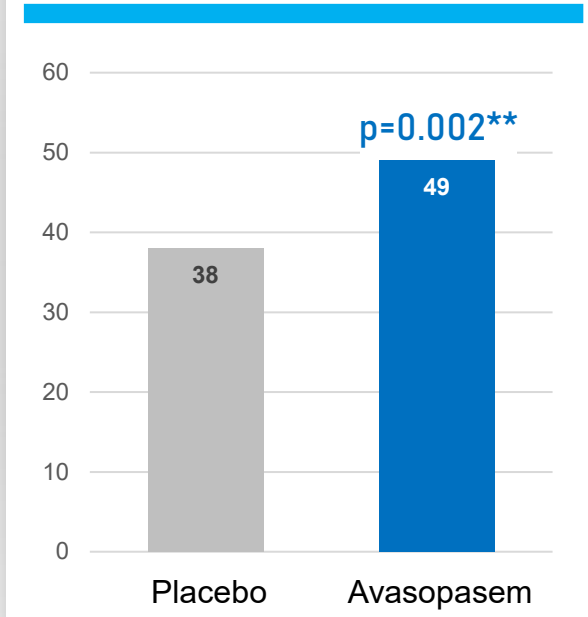
Grade 4 OM Incidence

27% **Reduction** in incidence of Grade 4 OM



SOM Onset

29% **Delay** in median days to 1st SOM

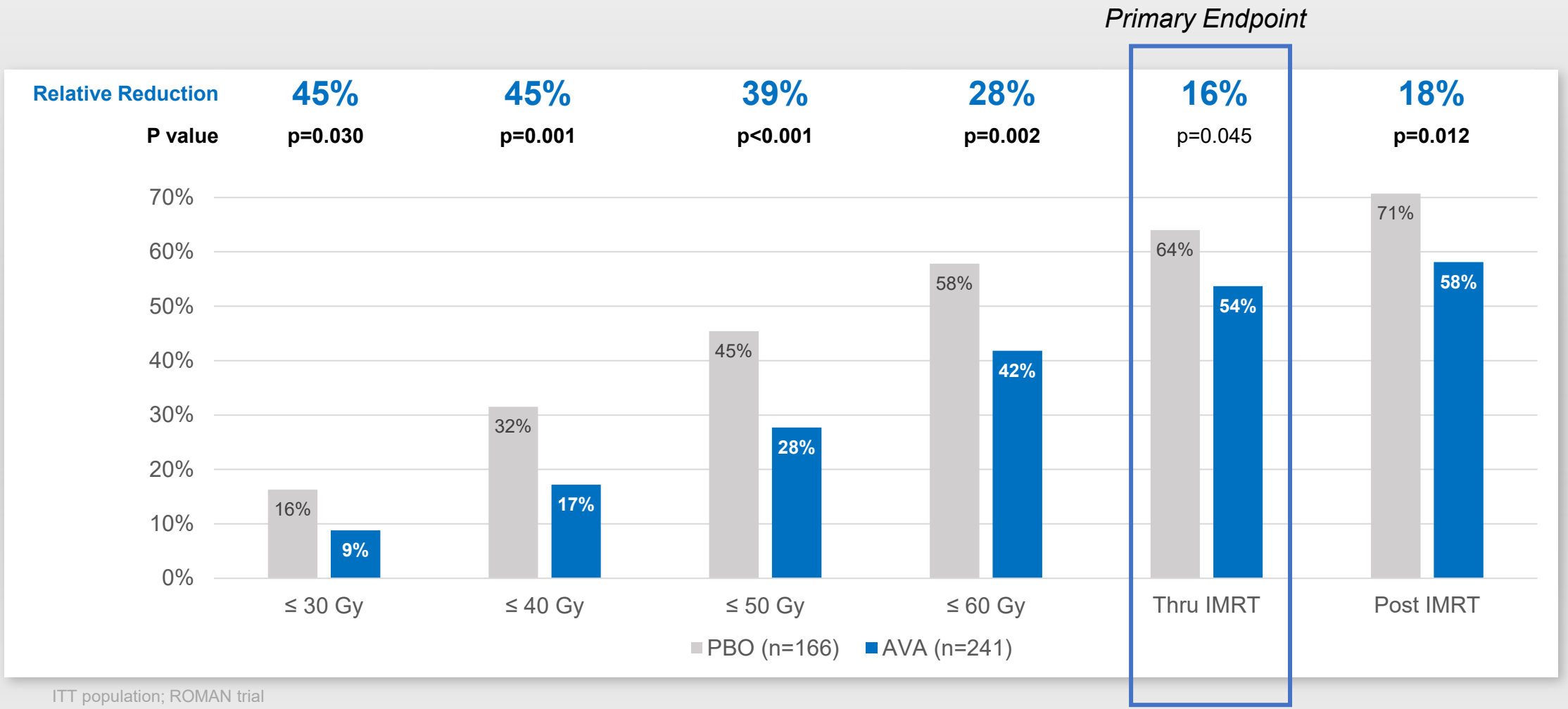


*Statistical significance per statistical analysis plan for this Phase 3 trial
**Time to Onset was an exploratory endpoint

Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

Incidence Reduced at All Landmarks of Radiation Therapy

Both before and after primary endpoint at end of IMRT – ITT population



ITT population; ROMAN trial

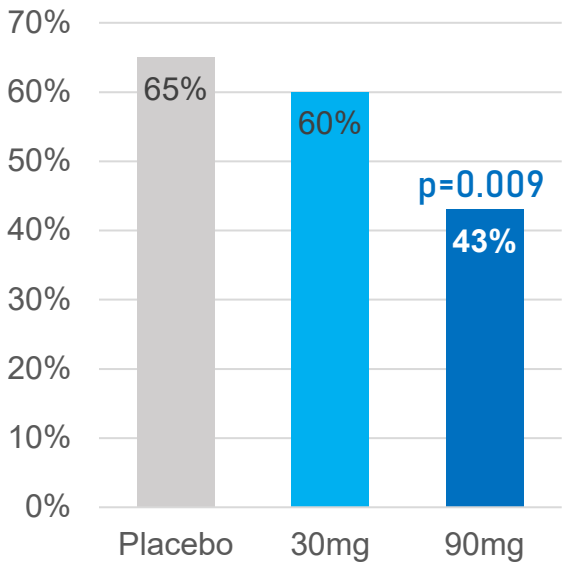
Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

GT-201 Results (n=223)

Consistent and encouraging results across SOM endpoints – ITT Population

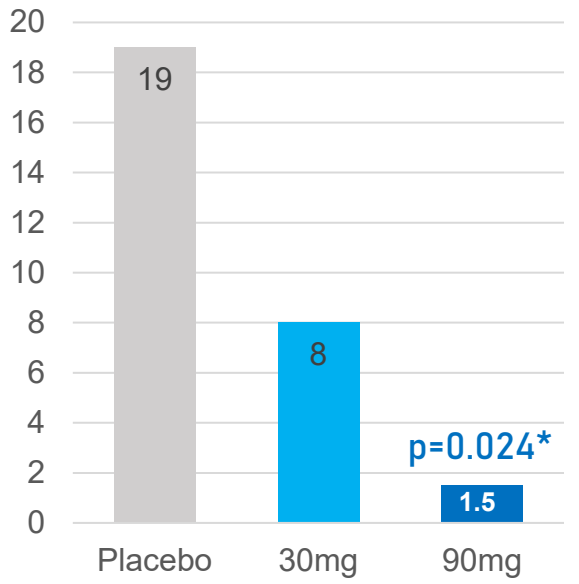
SOM Incidence

34% **Reduction** in SOM incidence



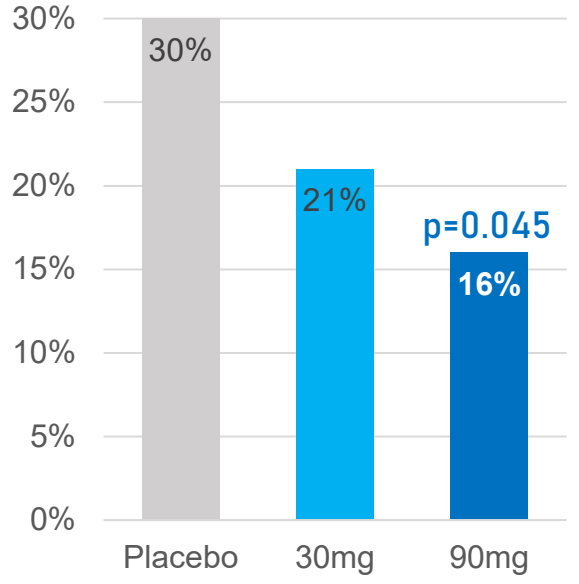
SOM Days

92% **Reduction** in median days of SOM



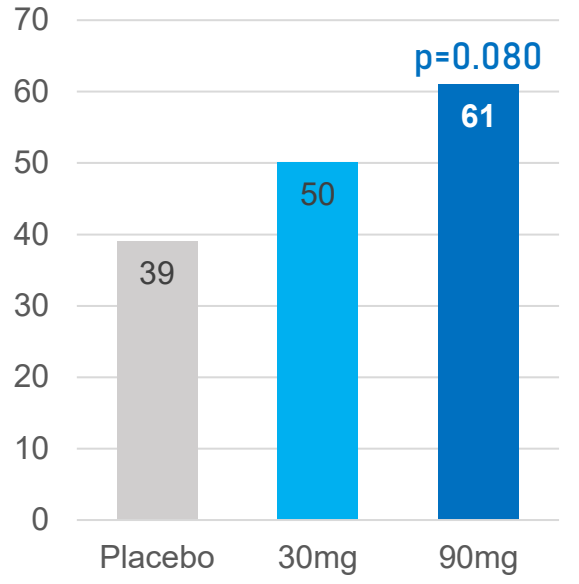
Grade 4 OM Incidence

47% **Reduction** in incidence of Grade 4 OM



SOM Onset

56% **Delay** in median days to 1st SOM



*Statistical significance per statistical analysis plan for this trial

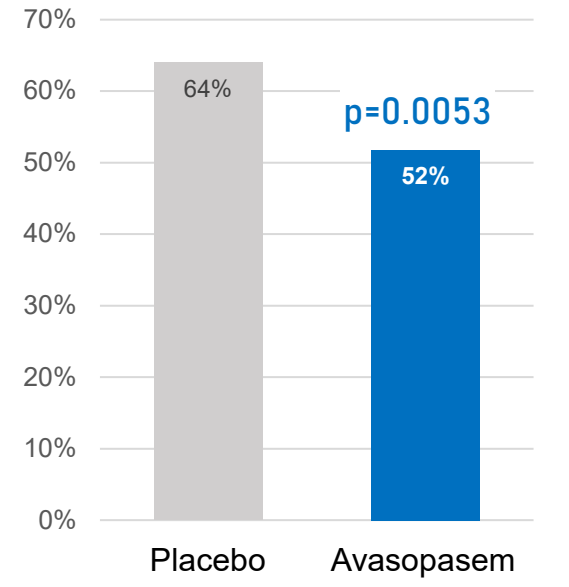
Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Combined Meta-Analysis of the Two Randomized Trials (n=551)

Avasopasem SOM improvement consistent across trials and key parameters

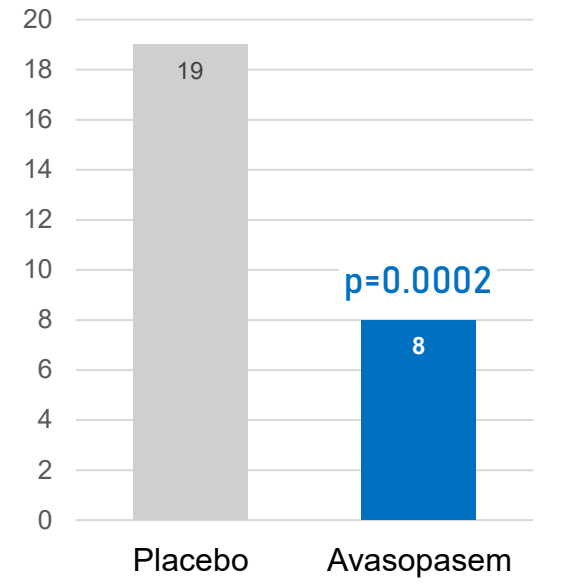
SOM Incidence

19% **Reduction** in SOM incidence



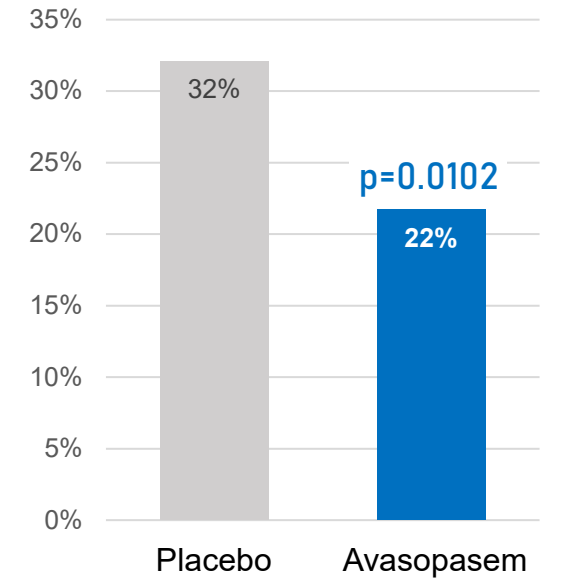
SOM Days

58% **Reduction** in median days of SOM



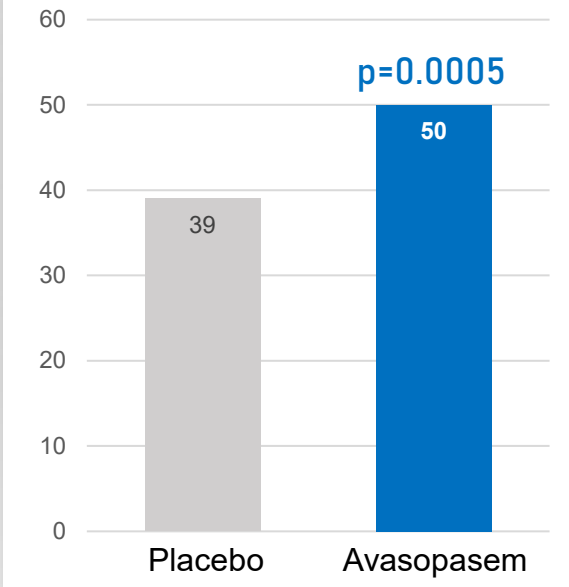
Grade 4 OM Incidence

32% **Reduction** in incidence of Grade 4 OM



SOM Onset

28% **Delay** in median days to 1st SOM



Note: Nominal p values for all endpoints, calculated according to prespecified statistical analysis plan (SAP) for the meta-analysis; 238 patients on placebo; 313 patients on 90mg avasopasem

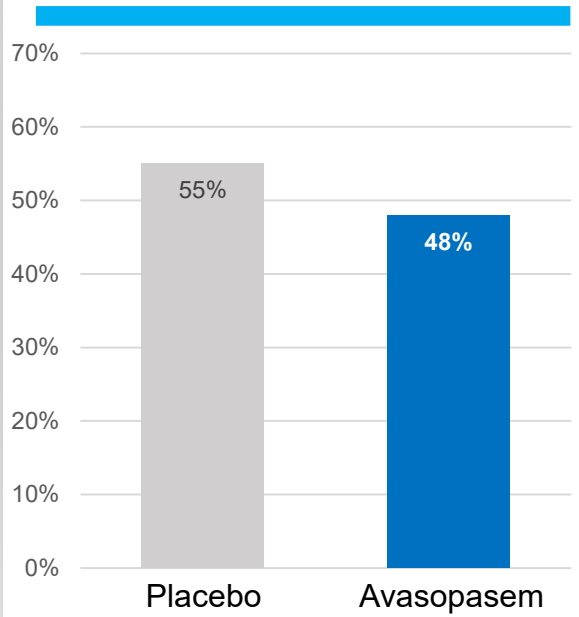
Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

Avasopasem Reduced Narcotic and Feeding Tube Usage

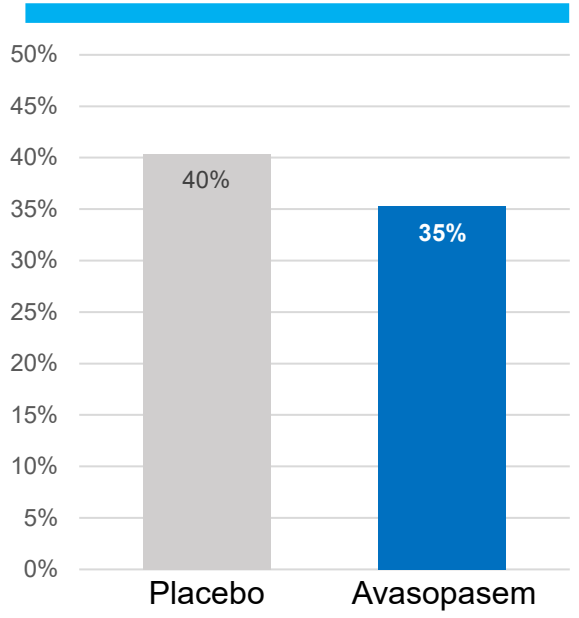
Reductions in SOM with avasopasem appeared to decrease utilization in ROMAN trial

Narcotics

13% **Reduction** in usage after RT start

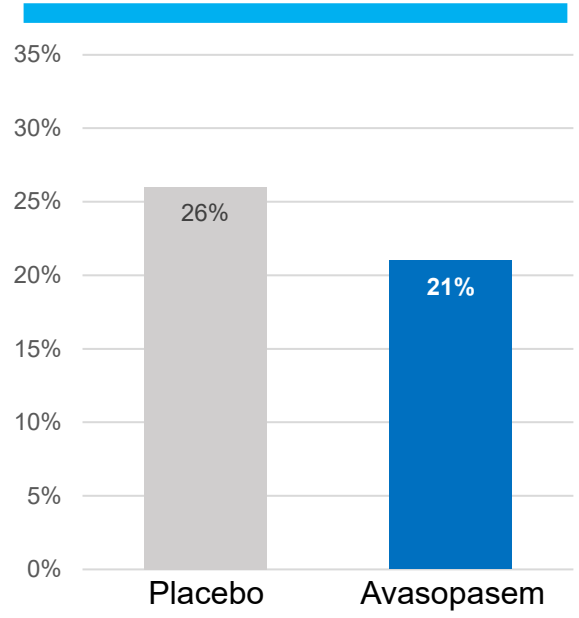


13% **Reduction** in usage for OM pain

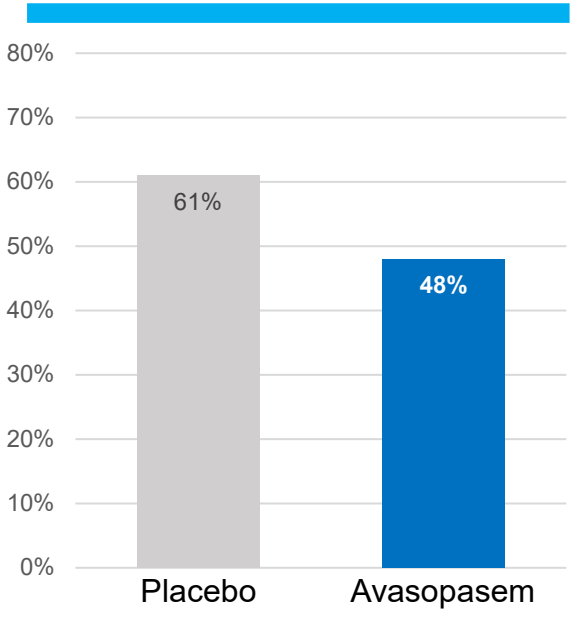


Gastrostomy (Feeding) Tubes

19% **Reduction** in placements after RT start



21% **Reduction** in overall utilization

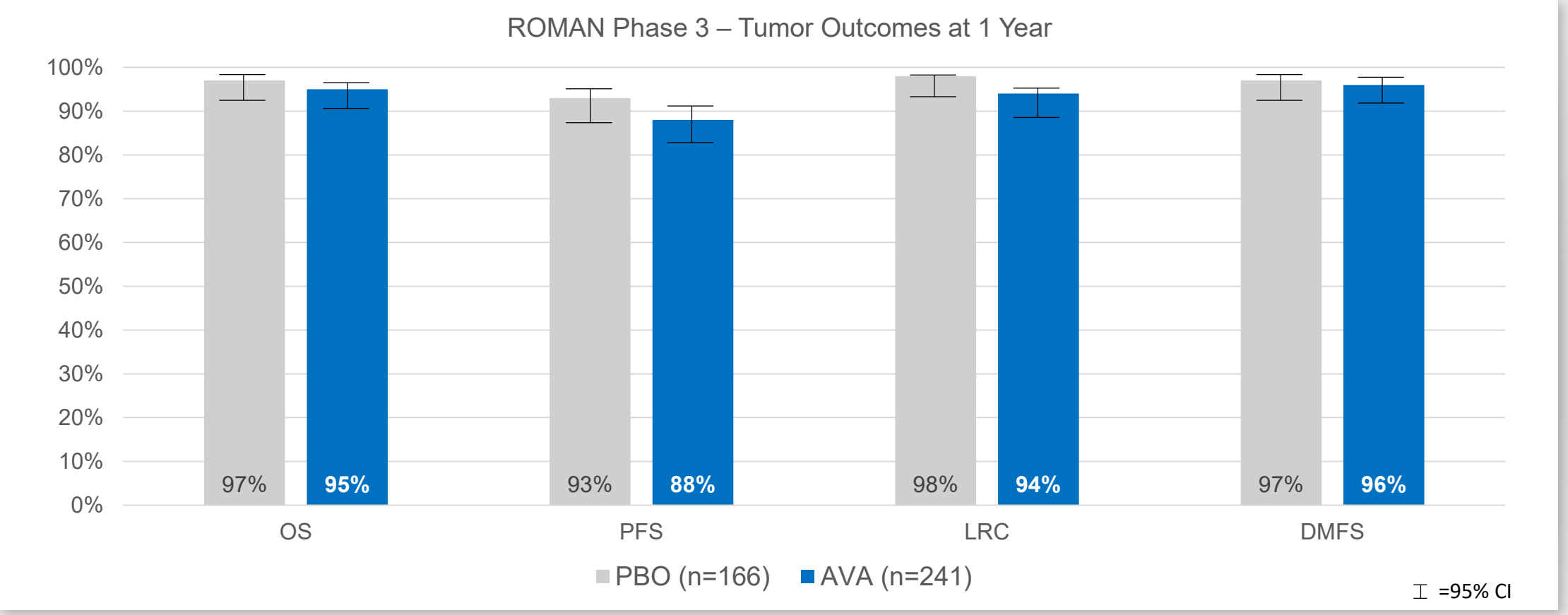


ITT population; ROMAN trial

Saunders D, Lee CM, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem to reduce chemoradiotherapy (CRT)-related severe oral mucositis (SOM) in patients with head and neck cancer (HNC). Presented at Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology Annual Meeting, June 23-25, 2022.

ROMAN Long-term Outcomes: Tumor Control & Survival

Overlapping 95% confidence intervals at 1 year; consistent with GT-201 tumor outcomes[1]



OS = overall survival, PFS = progression-free survival, LRC = locoregional control, DMFS = distant metastasis-free survival. 95% Confidence Intervals for each endpoint.

Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

[1] Anderson CM, Lee CM, Saunders D, et al. Two-year tumor outcomes of Phase 2B, randomized, double-blind trial of avasopasem manganese (GC4419) versus placebo to reduce severe oral mucositis due to concurrent radiation therapy and cisplatin for head and neck cancer. Int J Radiation Oncol Biol Phys. June 17 2022 [online ahead of print].

Reducing
Cisplatin Toxicity

Galera® Therapeutics, Inc

Cisplatin – One of the Most Commonly Used Chemo Drugs

Despite available prevention & treatment measures, renal toxicity is one of the major dose-limiting side effects

- **Cisplatin used to treat many tumor types**
  - Head & neck, lung, ovarian, breast, brain, renal and testicular cancers
- **Cisplatin-induced acute kidney injury occurs in as many as 31.5% of cases[1]**
  - Decline in kidney function continues up to 5 years after treatment
- **Published retrospective study showed 29% of patients had chronic kidney disease at one year following cisplatin treatment compared to 11% at baseline[2,3]**
- **Boxed warning for PLATINOL® (cisplatin)**
  - "Cumulative renal toxicity associated with PLATINOL is severe."

[1]ZhiYu D et al. Therapeutic Advances in Medical Oncology 2020, Vol. 12:1-15
[2]Latcha S et al. Clin J Am Soc Nephrol. 2016 Jul 7; 11(7): 1173-1179.
[3]CKD defined by Nat. Kidney Foundation as eGFR (estimated Glomerular Filtration Rate) < 60 mL/min/1.73 m2 (Grade 3+ according to KDIGO criteria)

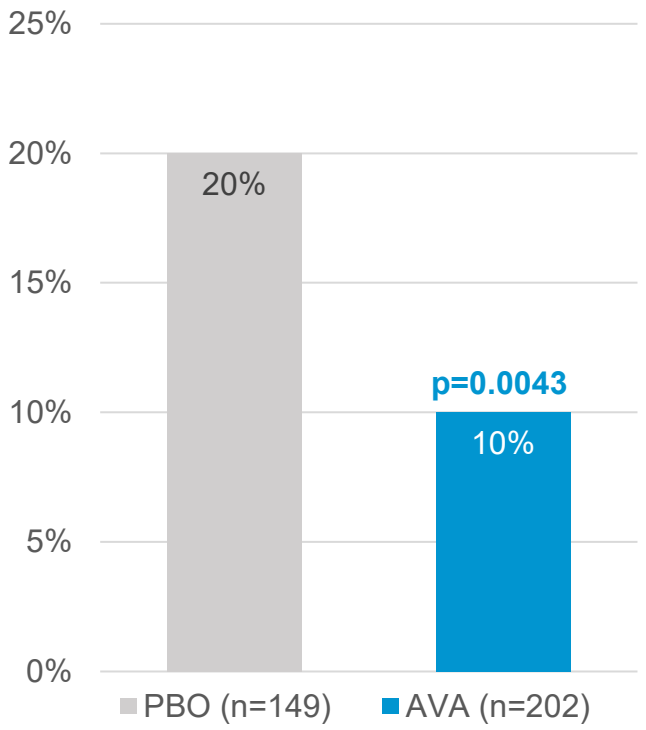
ROMAN Long-Term Outcomes: Cisplatin Renal Endpoints

Avasopasem halved Chronic Kidney Disease (CKD) at 1 year; a prospectively defined endpoint

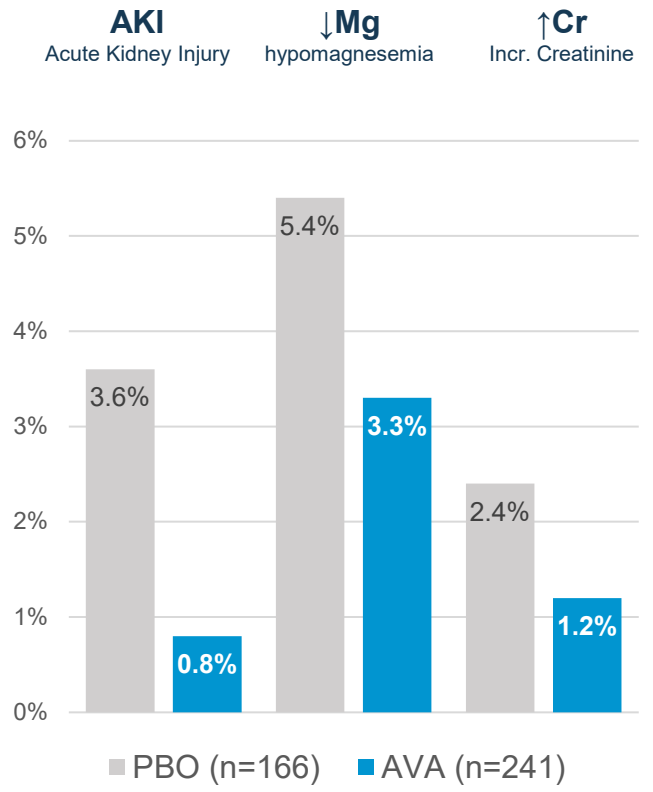
Previous Scientific Data

- Superoxide drives cisplatin nephrotoxicity
  - Mapuskar, *Redox Biol* 2021
- Avasopasem preclinically prevented cisplatin acute kidney injury
  - Mapuskar, *Antioxid* 2018
- Retrospective analysis of Phase 2b patient subset suggested CKD prevention
  - Steinbach, *ASCO* 2020

CKD @ 1 Year on ROMAN



Cisplatin Renal Gr. 3+ AEs

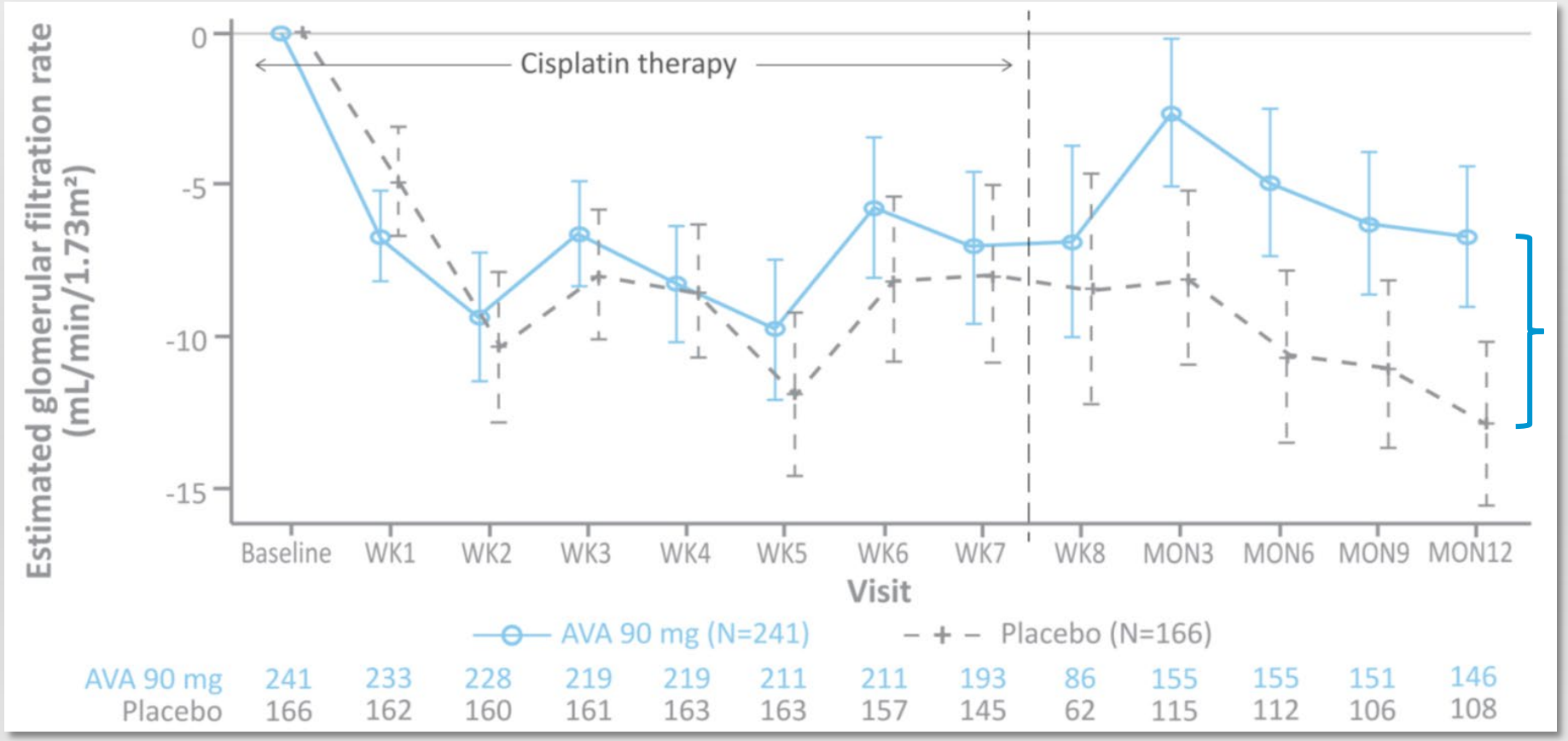


ITT population; CKD defined by Nat. Kidney Foundation as eGFR (estimated Glomerular Filtration Rate) < 60 mL/min/1.73 m2 (approx. the % of normal kidney function that is working)

Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

Significant improvements in preservation of kidney function

Beginning by 3 months through one-year end of follow-up



p = 0.0008

Least squares mean change from baseline were generated using a mixed-effects model repeated measures (MMRM) analysis with parameters treatment, visit, and treatment-by-visit interaction as factors and baseline value as covariate. Error bars represent standard errors. Note: eGFR was calculated using the CKD-EPI equation.

Allen BG, Spitz DR, Mapuskar KA, et al. One-year Reductions in Cisplatin Related Chronic Kidney Disease (CKD) in Patients With Head and Neck (HNC) Cancer Treated With Avasopasem Manganese: A Prespecified Analysis From the Phase 3 ROMAN Trial. Presented at ASCO Annual Meeting, June 5, 2023.

SOM Market Opportunity

Galera® Therapeutics, Inc

Head and Neck Cancer – Large Market Opportunity

Severe Oral Mucositis is >$1.5B total market opportunity in the US[1]

880,000
Global Head & Neck Cancer Incidence

66,900
US Patients Diagnosed each year

43,500
US Patients at Risk for RT-related SOM

Standard-of-care IMRT and cisplatin regimen is highly effective treatment for patients with locally advanced HNC

Source: Globocan 2020 and US SEER Data in CA Cancer J Clin 2023

[1] Based on 43,500 US patients and branded supportive care price analogs

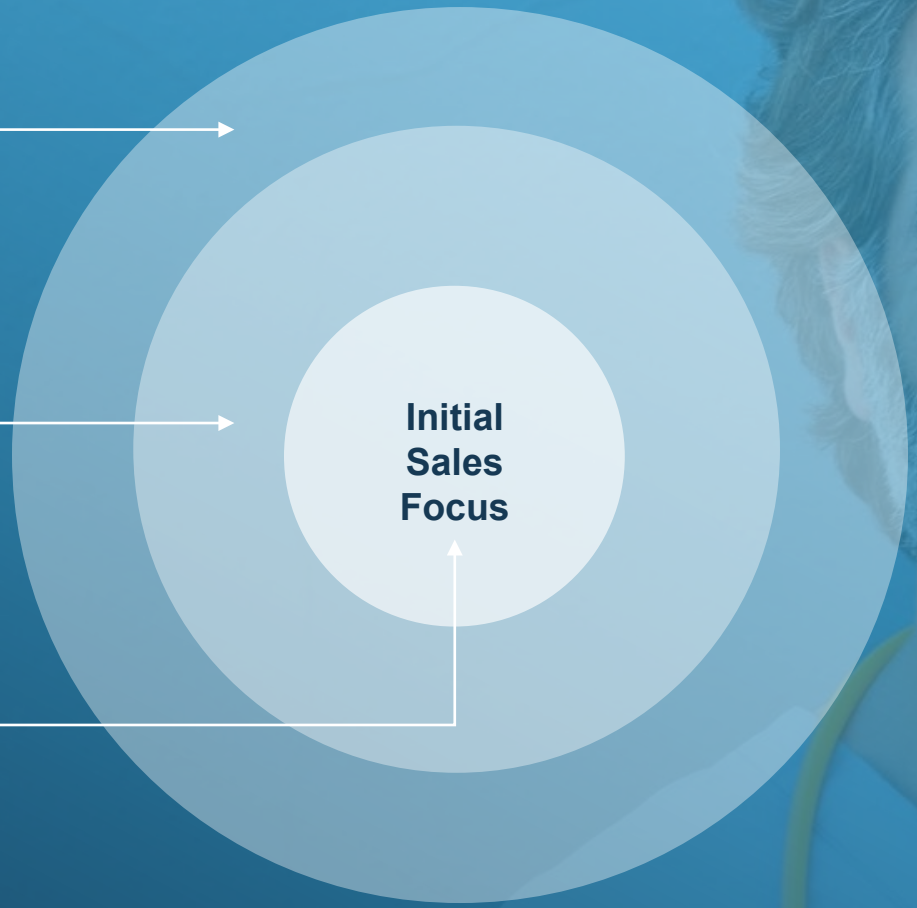
Concentrated Physician Population

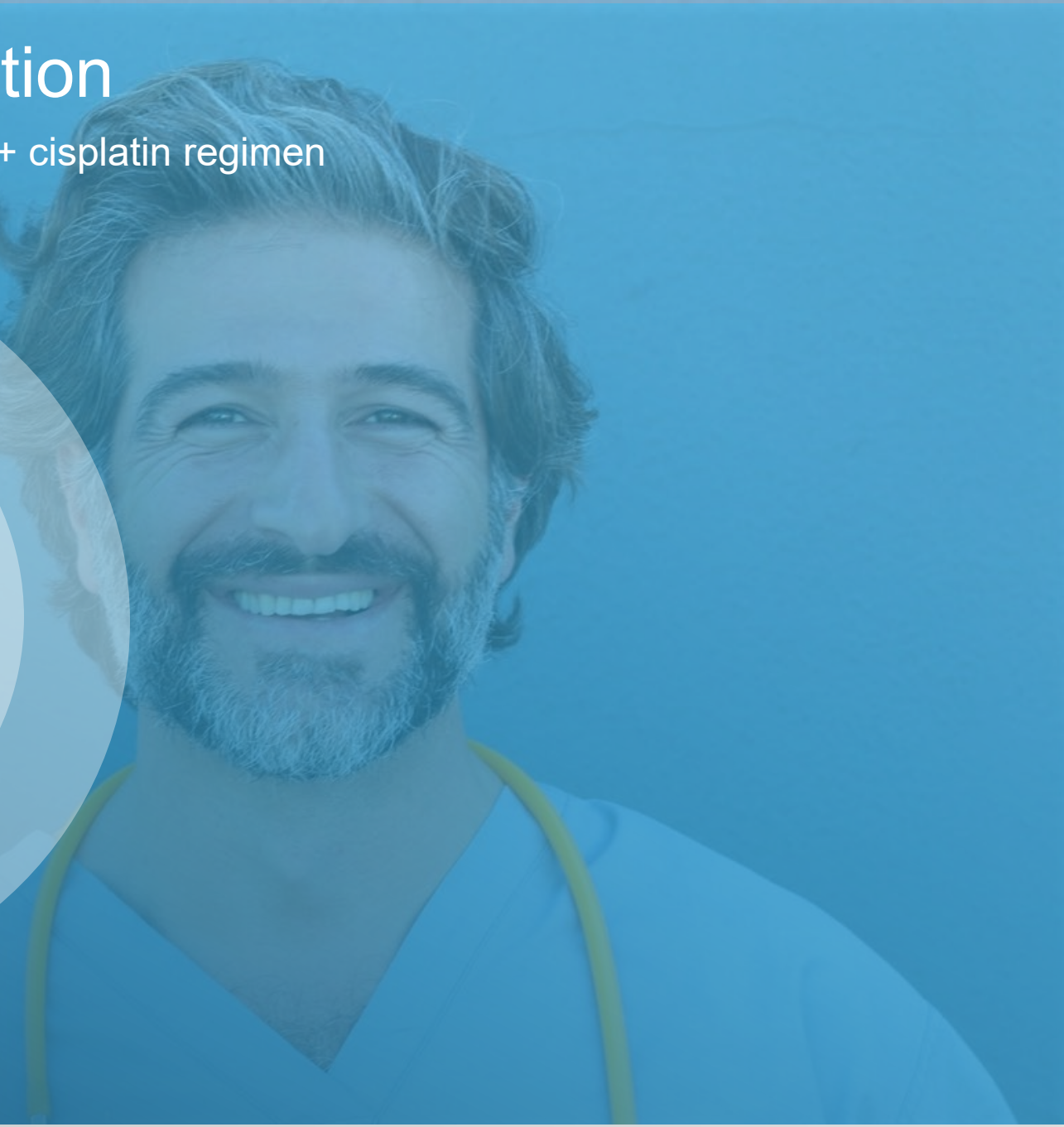
SOM is most burdensome side effect of curative IMRT + cisplatin regimen

5,000
Radiation Oncologists in US

2,500
Radiotherapy Treatment Sites

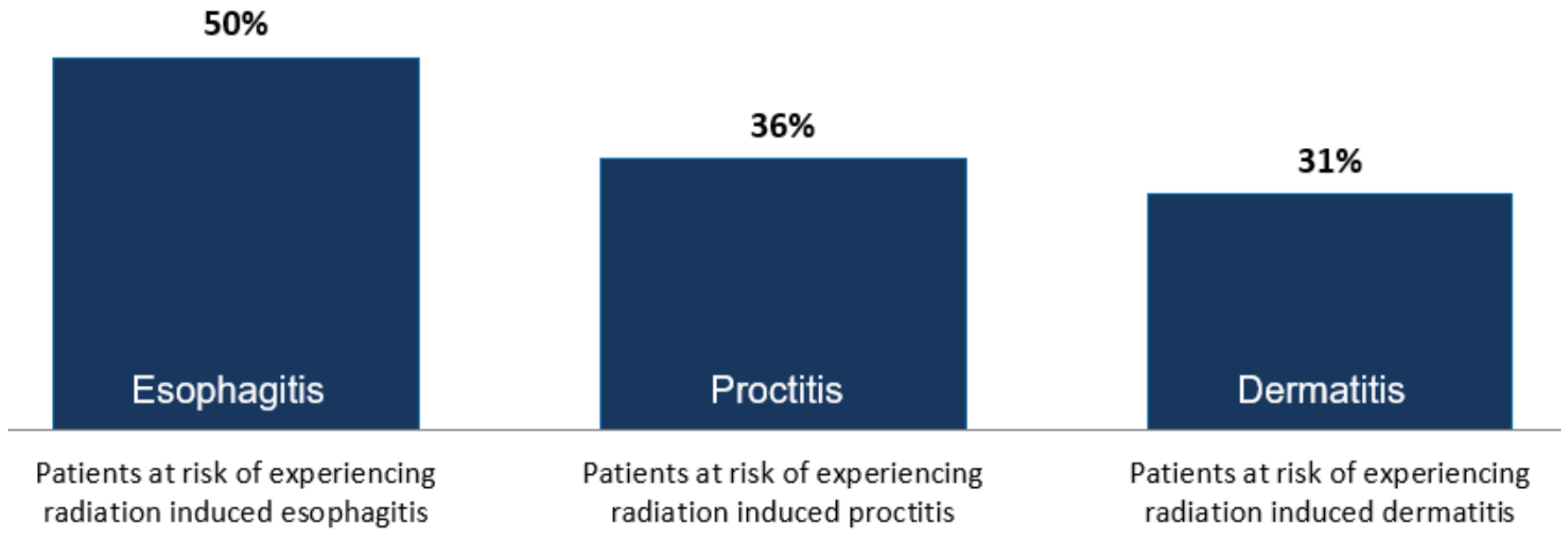
700
Top centers where >80% HNC patients are treated





Beyond Oral Mucositis: Other RT-Related Toxicities

Physicians view SOM 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

2,200,000
Global Lung Cancer Incidence

238,000
US Patients Diagnosed each year

50,000
US Patients at Risk for RT-related Esophagitis

Locally advanced NSCLC frequently treated with IMRT and chemotherapy

Source: Globocan 2020 and US SEER Data in CA Cancer J Clin 2023

Esophagitis: High Unmet Need in Lung Cancer

Common Side Effect of Chemoradiotherapy (IMRT x 6 weeks)

50-60% Get Grade 2+[1]
20-30% Get Grade 3+[2,3]

NCI Grading for esophagitis[4]

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 in Lung Cancer

Single-arm Phase 2 Trial

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

- Will compare esophagitis rate with historical data

[1]Palma, DA. (2013). Int J Radiation Oncol Biol Phys, Vol. 87 (4), 690-696.
[2]LAMP Study. Belani, CP et al. (2005). J Clin Oncol, 23:5883-5891 (carboplatin + paclitaxel chemo).
[3]RTOG 9410. Curran, WJ et al. (2011). J Natl Cancer Inst, 103:1452–1460 (cisplatin + vinblastine).
[4]NCI Common Toxicity Criteria 5.0.

Esophagitis Trial (AESOP)

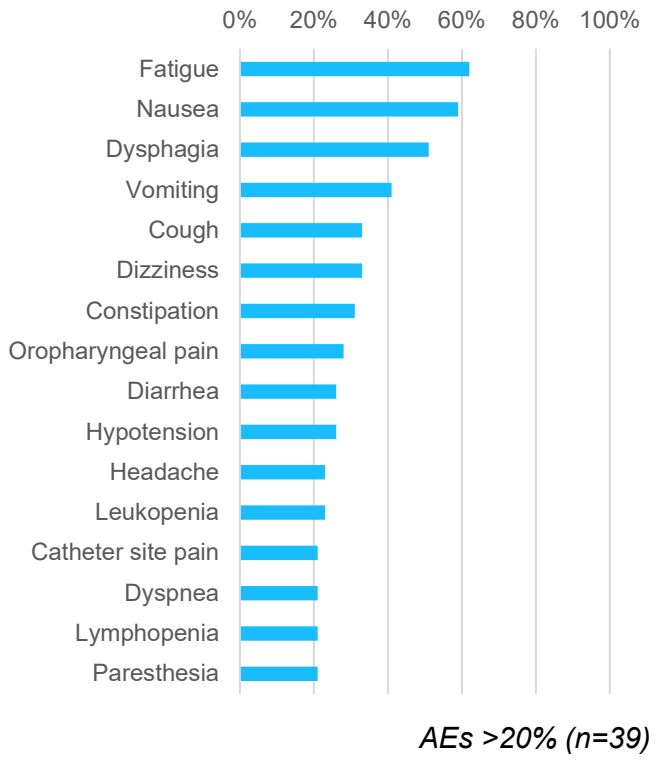
Low incidence of Grade 3+ esophagitis with avasopasem compared to literature

Trial Design
Patients and Treatment

- Single-arm Phase 2a open-label trial
- Patients with lung cancer (NSCLC or SCLC)
- Standard-of-care chemoradiotherapy over 6 weeks (60 Gy IMRT) + avasopasem 90mg
- Eligibility criteria required ≥5 cm (≥20%) of the esophagus in the radiotherapy field
  - ➢ Patients who get ≥60 Gy to ≥17% of their esophagus are considered at highest risk: 59% risk of grade ≥2 and 22% of grade ≥3 esophagitis[1]

Pt #	Disposition
39	Enrolled (Safety)
35	Full Chemoradiation (6 weeks)
29	Per Protocol AVA (≥5 weeks)

Safety
AE profile consistent with chemoradiotherapy



AESOP Results
(Per Protocol n=29)

Esophagitis Incidence by Grade[2]

	Weeks of IMRT					
	1	2	3	4	5	6
Gr. 2	-	10%	17%	38%	48%	45%
Gr. 3	-	-	**3%**	-	-	**3%**
Gr. 4-5	-	-	-	-	-	-

- Grade 3 esophagitis was much less than in comparable trial results
- Most patients free of Grade 3 for most weeks of treatment—no Grade 4 or 5

Trial	Pt #	CXRT Arms	Grade 3+4
AESOP	**29**	**CT+RT**	**7%**
LAMP Study[3]	74	CT → CT+RT	19%
	92	RT+CT → CT	28%
RTOG 9410[4]	193	CT+RT	22%

[1]Palma, DA. (2013). Int J Radiation Oncol Biol Phys, Vol. 87 (4), 690-696.
[2]NCI Common Toxicity Criteria 5.0.
[3]LAMP Study. Belani, CP et al. (2005). J Clin Oncol, 23:5883-5891 (carboplatin + paclitaxel chemo).
[4]RTOG 9410. Curran, WJ et al. (2011). J Natl Cancer Inst, 103:1452–1460 (cisplatin + vinblastine).

Thank you.

Galera® Therapeutics, Inc