Galera Therapeutics, Inc

Transforming Radiotherapy

with

Dismutase Mimetics

November 2020

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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.

Superoxide Dismutase Mimetics – Vision

Rapid elimination of Superoxide ($O_2^{\bullet-}$)

IMRT
Intensity Modulated RT

Potential to Reduce Toxicity

Severe Oral Mucositis Head & Neck Cancer (SOM in HNC)	Esophagitis NSC Lung Cancer (NSCLC)
	
Phase 3 ROMAN	Phase 2 Trial

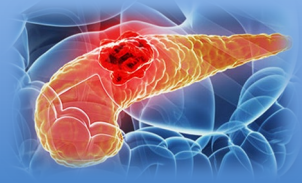
Normal tissue toxicity limits optimal radiotherapy treatment of tumor

Over half of cancer patients receive radiotherapy as part of their care[1, 2]

Increase H_2O_2 in tumors

SBRT
Stereotactic Body RT

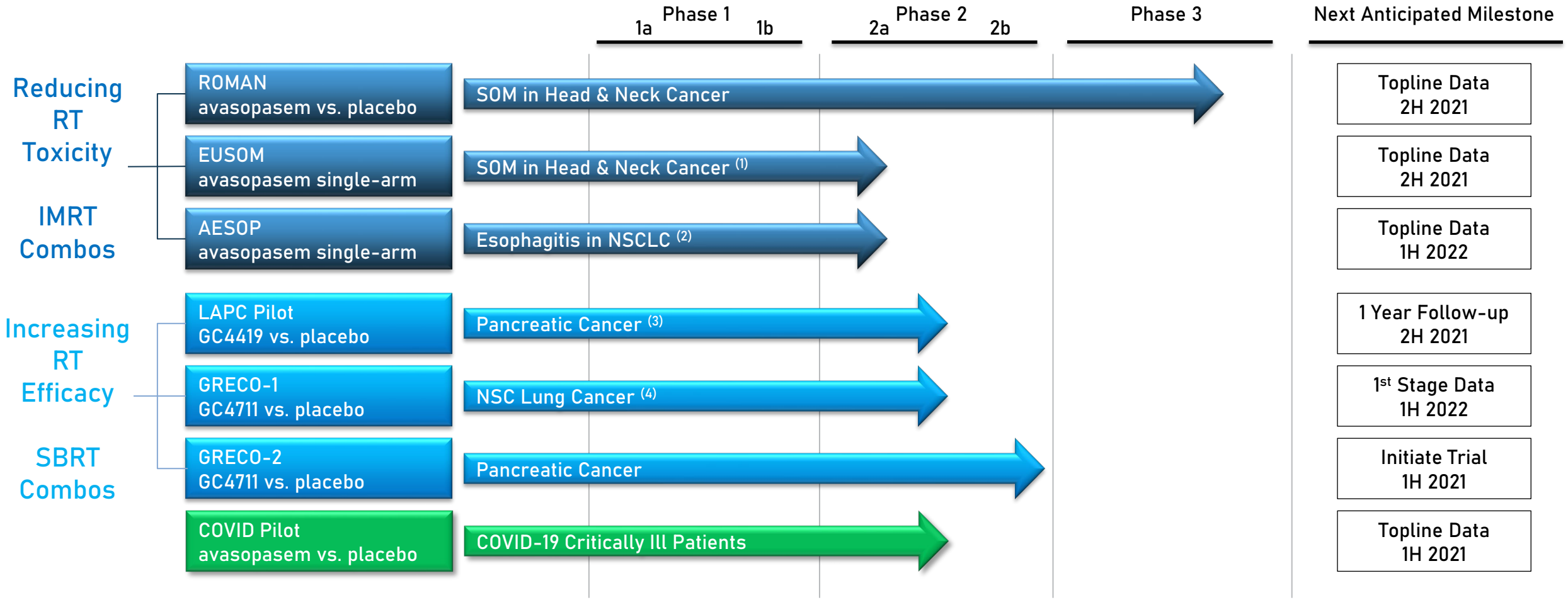
Potential to Increase Efficacy

Pancreatic Cancer Locally Advanced (LAPC)	Lung Cancer Locally Advanced (LANSCLC)
	
Phase 1b/2a SBRT Combo	Phase 1b/2a SBRT Combo

Radiotherapy is SoC for many local tumors but need remains for greater efficacy

[1] *Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment… Cancer. 2005;104:1129-1137*
[2] *Begg AC, Stewart FA, Vens C. Strategies to improve radiotherapy with targeted drugs. Nat Rev Cancer. 2011;11:239-253*

Clinical Stage Pipeline



(1) EUSOM is a single-arm multi-center trial evaluating the safety 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) This first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial have been used to guide development of GC4711 to assess anti-cancer efficacy in combination with SBRT.

(4) Two stage trial with first stage to assess anti-cancer efficacy of SBRT +/- GC4711 and the second stage to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711.

Investment Highlights

Avasopasem GC4419

Reducing IMRT toxicity in patients with head & neck cancer

- Robust efficacy in randomized Phase 2b trial (n=223)
- Breakthrough therapy designation granted by FDA
- Single Phase 3 sufficient for registration (n≈450)

2nd Product GC4711

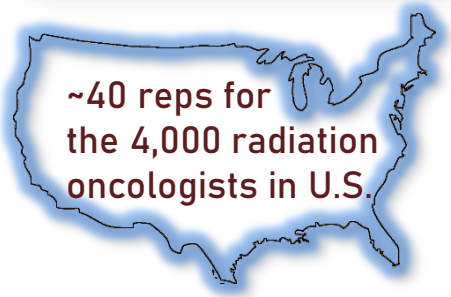
Increasing SBRT anti-cancer efficacy in patients

- Improved local control and overall survival in pilot LAPC trial (n=42)
- Preparing to initiate randomized Phase 2b trial in pancreatic cancer
- Randomized Phase 1/2 trial ongoing in NSCLC

Planning US Launch

Galera is building a commercial team for the US Launch

- 65,000 head & neck cancer patients diagnosed annually in the US
- 4,000 radiation oncologists in ~2,500 radiotherapy sites in US
- Galera's quantitative market research reached ~5% of US Rad Oncs



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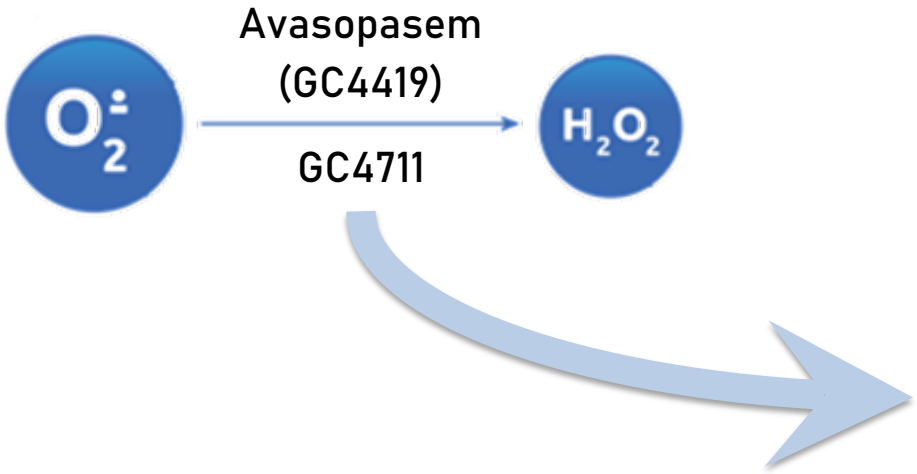
Dismutase Technology

Unique Technology

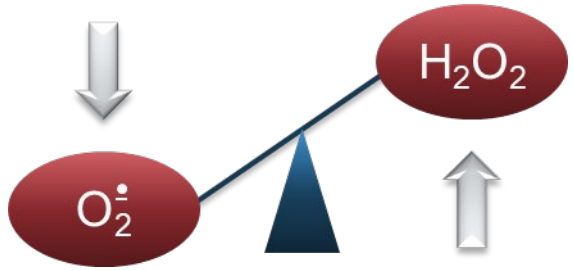
Dismutase Mimetics

Small Molecule Enzyme Mimetics

- Mimic human superoxide dismutase (SOD) enzymes
- Rapidly convert superoxide ($O_2^{\bullet-}$) to hydrogen peroxide (H_2O_2)



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



$O_2^{\bullet-}$ more damaging to normal cells than cancer cells

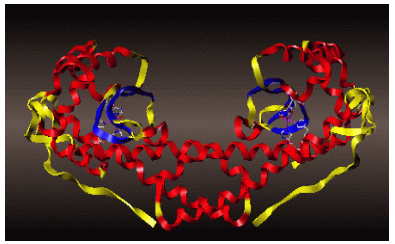
H_2O_2 more toxic to cancer cells than normal cells

Galera's Dismutase Mimetics

Native SOD Enzymes

Native SOD Enzymes

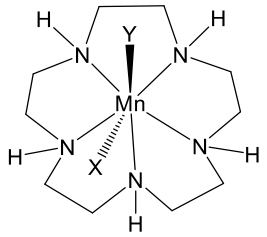
- Overexpression reduces RT toxicity
- Large size, immunogenicity & short half-lives limit bioavailability
- Inactivation/inhibition by reactive oxygen species



Small Molecule Mimetics

Challenge: suitable small molecule dismutase mimetics

- Fast catalytic rates & high selectivity for superoxide
- Firmly hold manganese in macrocyclic ring
- Stable, safe & suitable for manufacturing



Dismutase Mimetics Core Structure
Pentaaza Macrocycles

Small Molecule Dismutase Mimetics with Attractive Drug Characteristics

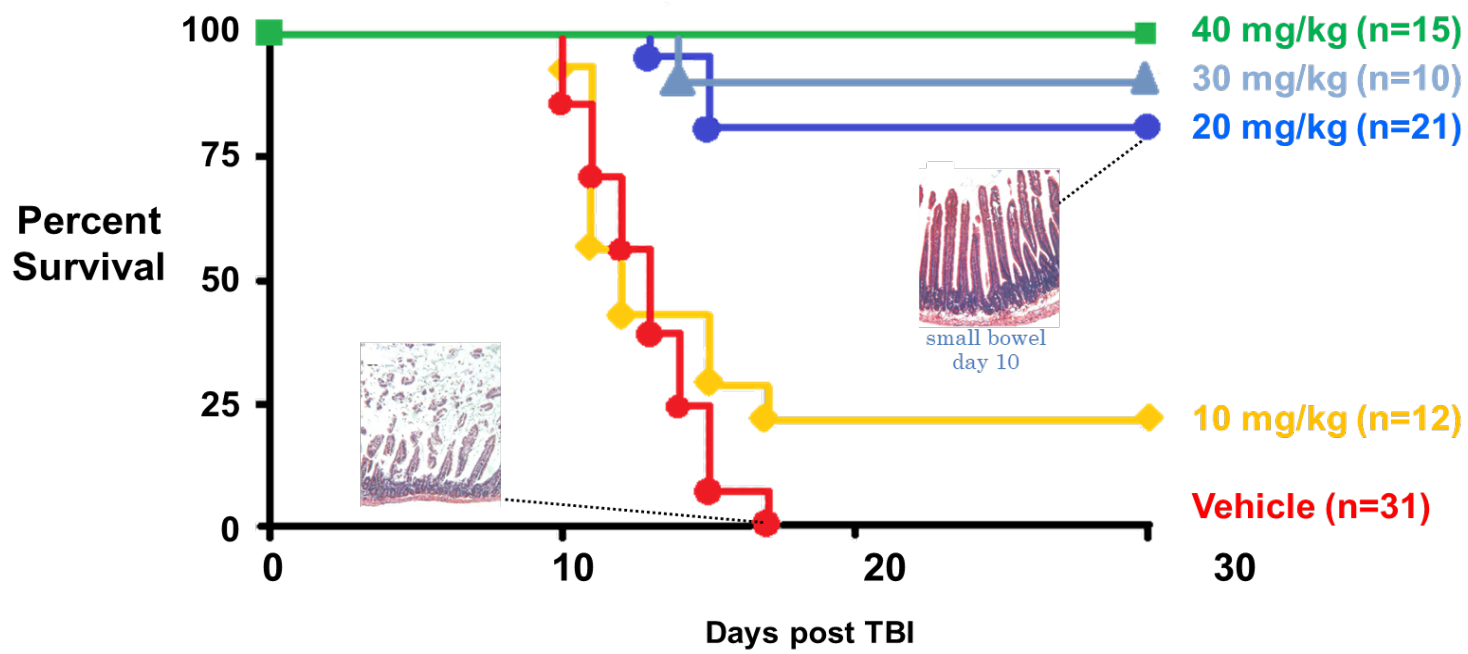
Speed	Selectivity	Stability	Safety	Synthesis
Comparable to native SODs ($2x10^7$ molecules per sec)	Interact with superoxide alone, not other reactive oxygen species	Firmly hold Mn atom in macrocyclic ring	Well-tolerated preclinically and clinically	Efficient & cost-effective manufacturing process

Dismutase Mimetics Reduce Radiation Toxicities

Reduce Radiation Mucositis

Lethal dose of Total Body Irradiation (8.5 Gy) to mice

- 100% death on control, 100% survival with 40mg/kg
- Main cause of death was intestinal mucositis



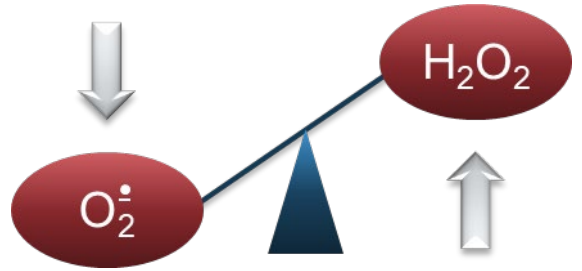
Thompson, et al., Free Radical Research, 44(5):529-540, 2010
Galera internal data

Dismutase Mimetics Increase Anti-Cancer Efficacy with High Fraction-Dose RT in Preclinical Models

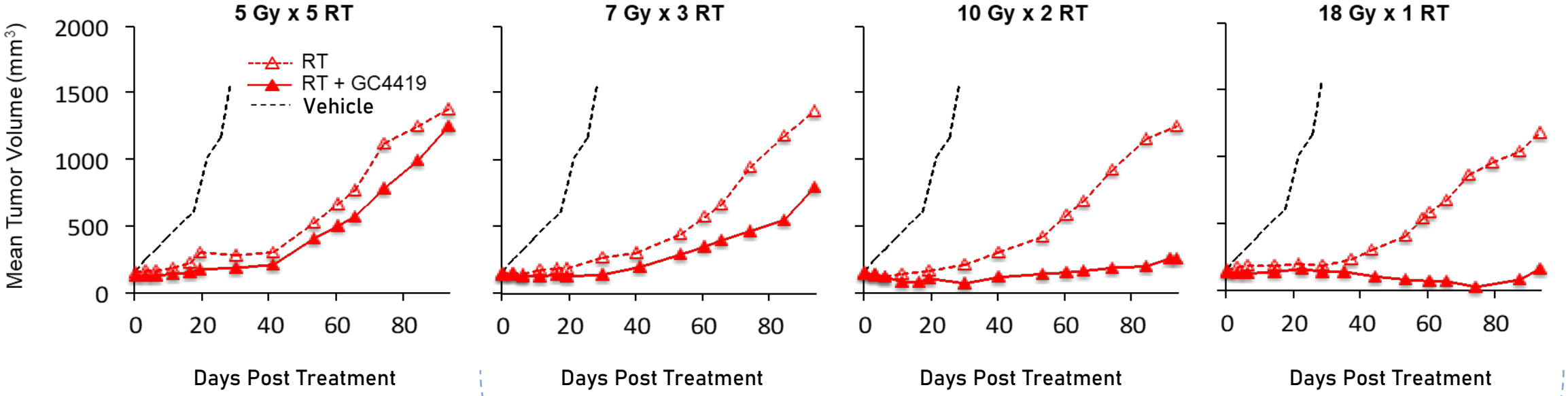
Increase Radiotherapy Efficacy

Focal irradiation of human tumor xenografts (H1299 NSCLC) in mice

- RT anti-cancer synergy of GC4419 increases with bigger RT fractions
- Bigger fraction → More $O_2^{\bullet}$ → More H_2O_2
- Also demonstrated with human pancreatic cancer xenografts



RT with Biological Equivalent Doses



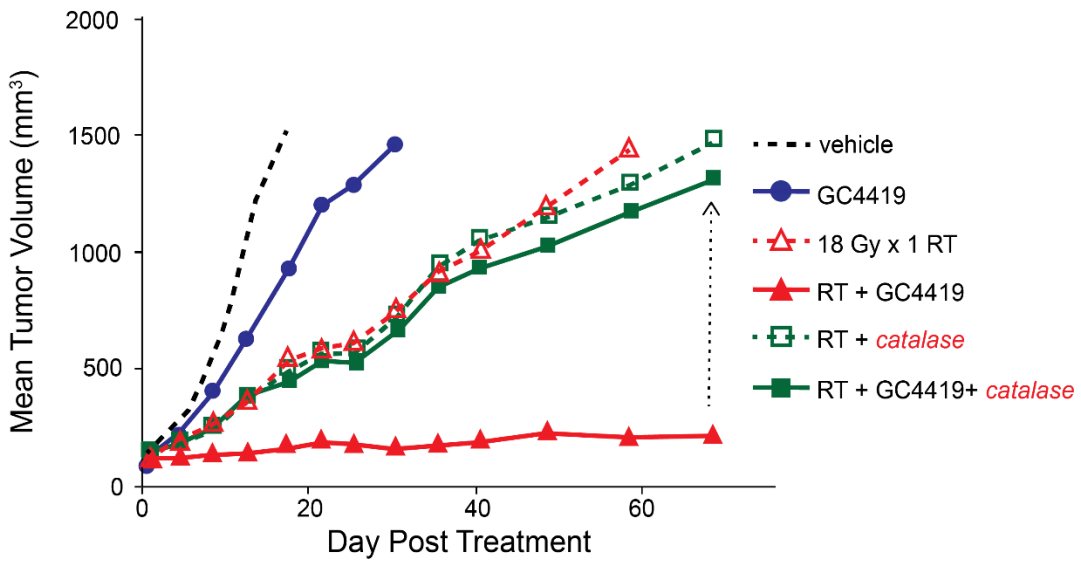
SBRT
Stereotactic Body Radiation Therapy

Courtesy of M Story (UTSW)

…Increasing Anti-Cancer Efficacy via H_2O_2

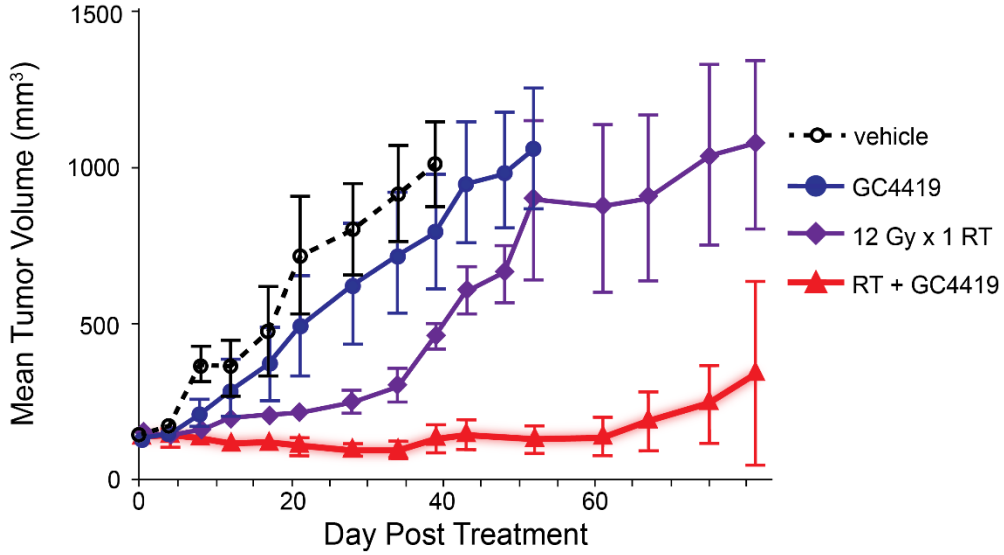
Tumor tissue H_2O_2 reduced when doxycycline added, losing the synergy

Genetically modified H1299^{CAT} – with doxycycline-inducible catalase



Larger RT fraction → more $O_2^{\bullet}$
Dismutase Mimetics → more H_2O_2

PANC-1 PDAC xenograft



Sishc et al, AACR, 2018
Sishc, et al, AACR Pancreatic Cancer, 2019

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Reducing Toxicity of IMRT – Clinical Data

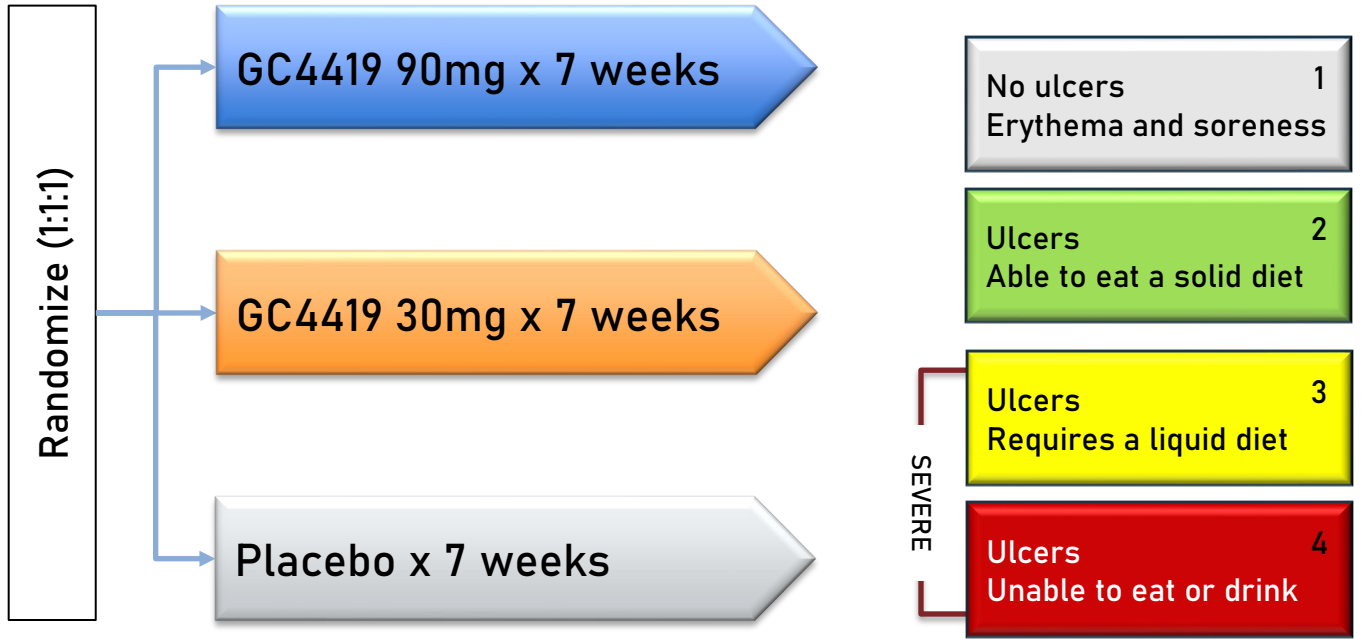
(Intensity Modulated Radiotherapy)

GT-201: 223-Patient Randomized Phase 2b OM Trial

Supportive trial to the ROMAN Phase 3 for the NDA

Trial Design

Treatment	• Avasopasem (GC4419) 90mg, 30mg, or placebo • 60 minute IV infusion, Mon-Fri. • Ending <60 mins pre-RT
Population	• Patients with HNC • Locally-advanced, squamous cell • Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	• Tumor HPV Status: positive or negative • Cisplatin Schedule: q3wks or weekly
Endpoints	• Primary – Reduction in median duration of SOM – WHO Grades 3 & 4
	• Secondary – Reduction in incidence and severity of SOM at pre-specified timepoints • Exploratory – Time to SOM onset
	• Tumor outcomes (2 year follow-up) • Locoregional control, distant mets, PFS, OS



Anderson et al, JCO, 2019

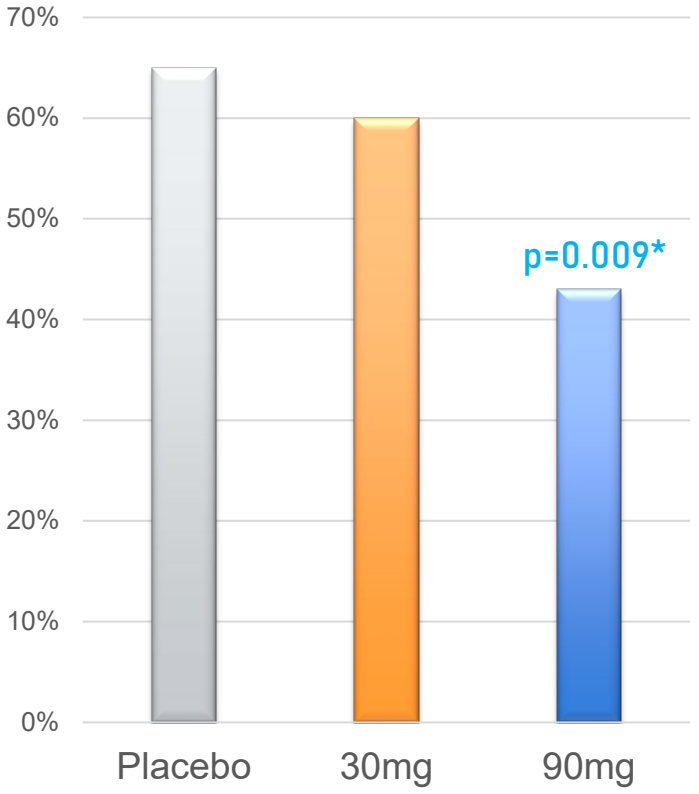
Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg

INCIDENCE

34% Reduction through all RT

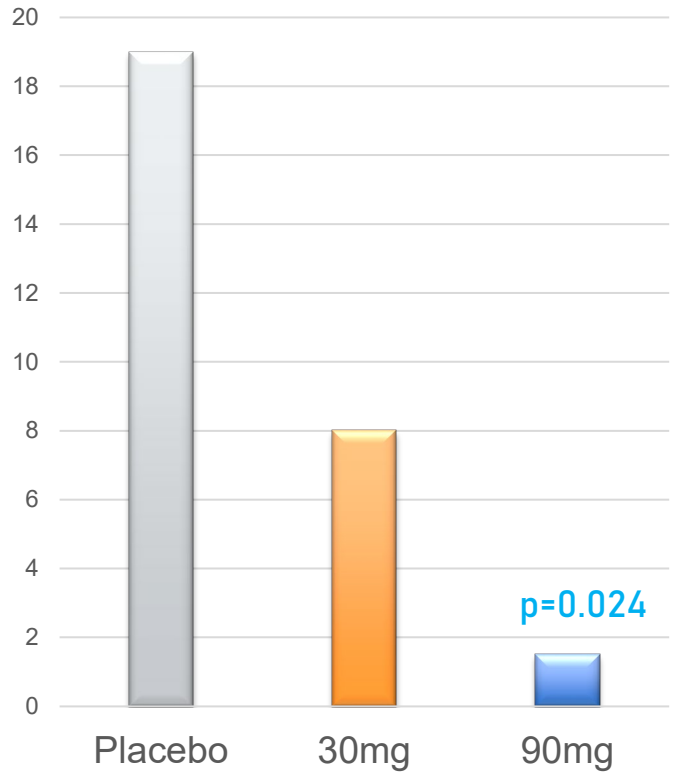
90 mg vs. Placebo



DURATION

92% Reduction in median days of SOM

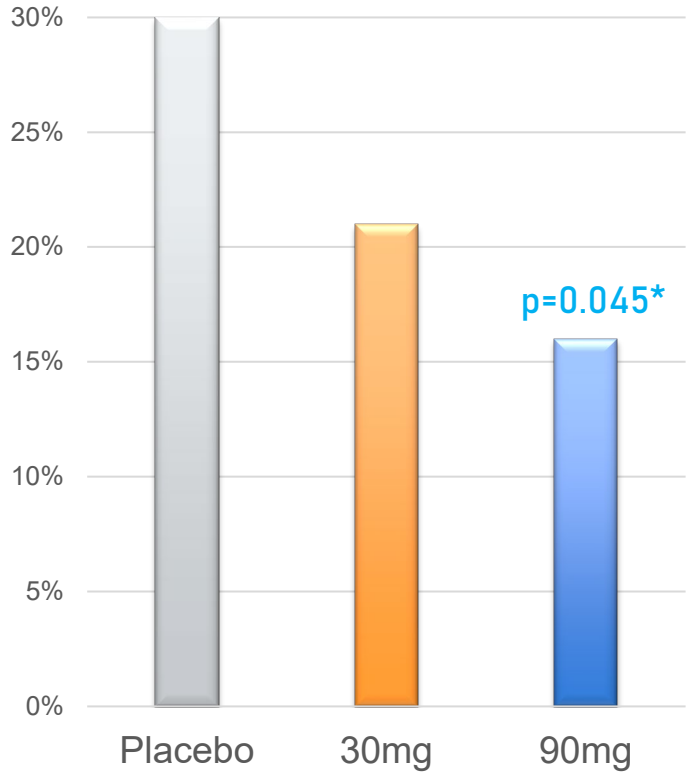
90 mg vs. Placebo



SEVERITY

47% Reduction in Incidence of Grade 4 OM

90 mg vs. Placebo



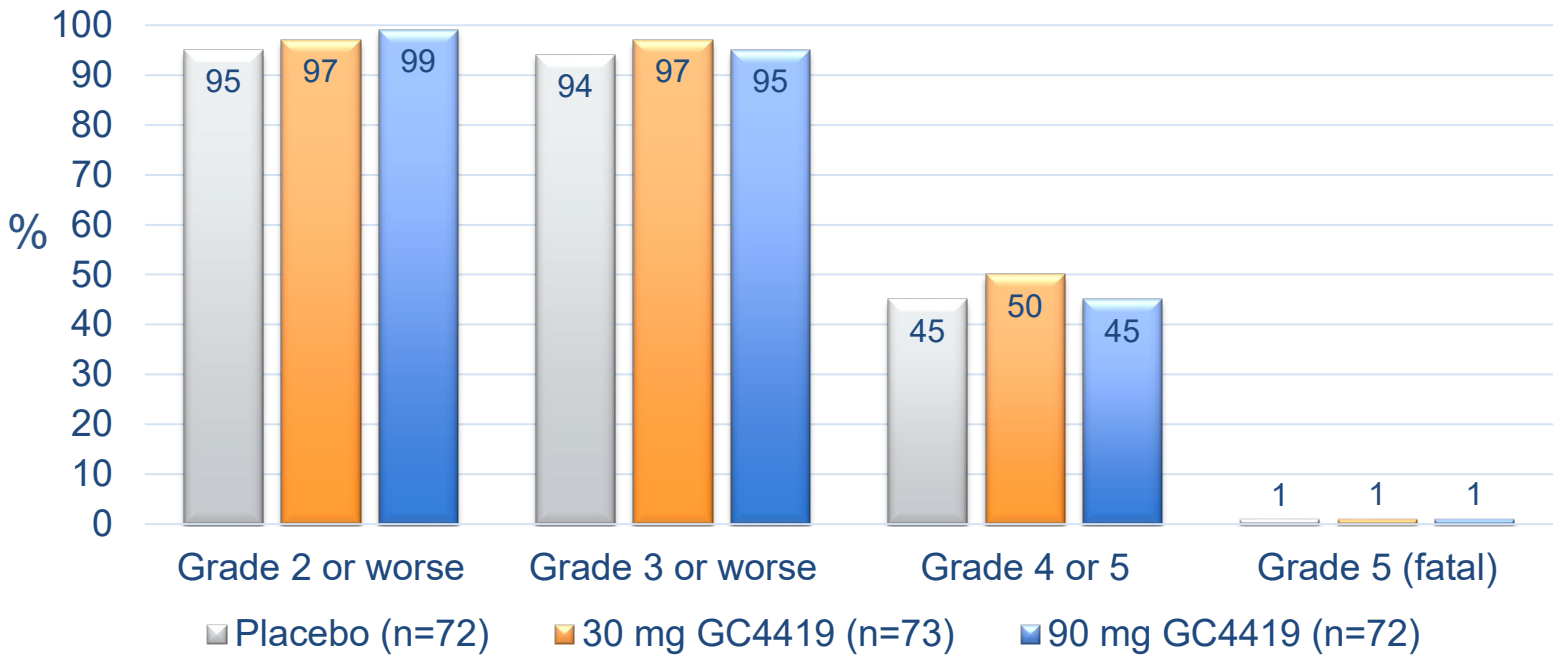
Primary endpoint was duration - defined as # days from 1st occurrence of grade 3 or 4 SOM until the 1st event of grade 2 or less (there being no subsequent grade 3 or 4 events.)

**Secondary endpoints (incidence and severity) have nominal p values compared to placebo*

ITT = Intent-To-Treat population (n=223)

Safety Summary – Rand. Phase 2b Trial

Safety Profile of Both Avasopasem (GC4419) Doses Comparable to Placebo



Avasopasem (GC4419) was well tolerated at both doses

Most frequent AE's are those expected with SoC cisplatin – RT regimen

Most Frequent AEs (any grade)	Placebo (n=72)	30 mg GC4419 (n=73)	90 mg GC4419 (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 et al, JCO, 2019

GT-301: The ROMAN Trial – Phase 3 Confirmatory Trial Enrolling

Reduction in Oral Mucositis with Avasopasem Manganese (GC4419)

Trial Design (n≈450 pts)

Treatment	• Avasopasem (GC4419) 90mg or placebo • 60 minute IV infusion, Mon-Fri • Ending <60 mins pre-RT
Population	• Patients with Head & Neck Cancer • Locally-advanced, squamous cell • Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	• Surgery Status: post-op or definitive • Cisplatin Schedule: q3wks or weekly
Endpoints	• Primary – Reduction in incidence of SOM – WHO Grades 3 & 4
	• Secondary – Reductions in severity of SOM and number of days of SOM experienced • Tumor outcomes[1] – LRC, DM-free, PFS, OS

Randomize (3:2)

- GC4419 90mg x 7 weeks
- Placebo x 7 weeks

WHO Grading Scale

1. No ulcers
   Erythema and soreness
2. Ulcers
   Able to eat a solid diet

SEVERE

3. Ulcers
   Requires a liquid diet
4. Ulcers
   Unable to eat or drink

[1] LRC = locoregional control, DM-free = free of distant mets, PFS = Progression-Free Survival, OS = Overall Survival

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Increasing SBRT Efficacy – Clinical Data

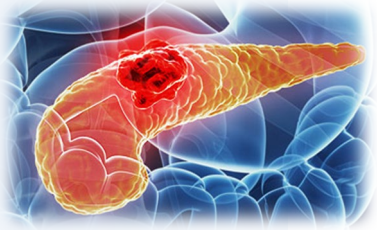
(Stereotactic Radiotherapy)

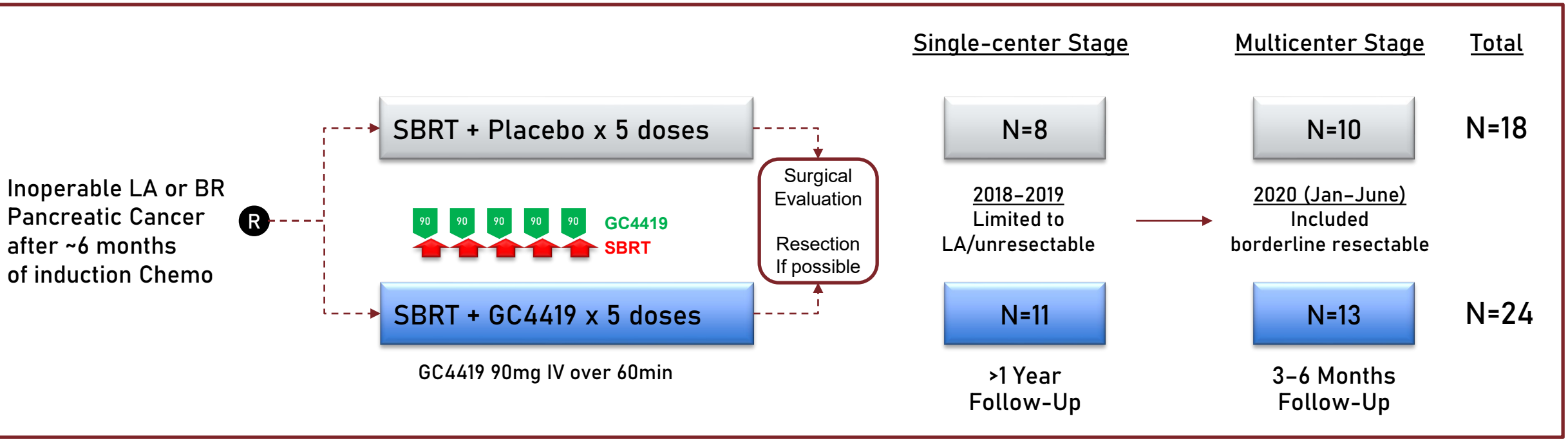
Pilot Phase 1/2 in Pancreatic Cancer: SBRT +/- GC4419

SBRT
GC4419
Pilot

Double-blind, Placebo-controlled, Randomized Trial

- Patients with Locally Advanced Pancreatic Cancer (LAPC) post ~6 mos chemo
- Optimal SBRT fraction selected based on 90-day safety/efficacy (LO-ET[1])
- Tumor outcome measures: ORR, LRC, DM, Resectability, PFS, OS





[1]*LO-ET = Late-Onset Efficacy-Toxicity (Jin IH, Liu S, Thall PF, Yuan Y. J Am Stat Assoc 2014;109:525-36) SBRT = stereotactic body radiation therapy, LA = Locally-Advanced, BR = Borderline Resectable*
ORR = Overall Response Rate, LRC = Locoregional Failure, DM = Distant Metastases, PFS = Progression-Free Survival, OS = Overall Survival

Baseline Characteristics (n=42)

	Placebo (n=18)	Avasopasem (n=24)
Median age (range), yrs	68 (48–82)	72 (41–83)
Male/Female	7/11	16/8
Borderline resectable/Locally advanced	2/16	7/17
ECOG Performance status 0/1/2	9/9/0	12/11/1
Prior chemo, duration median (range), wks	21.9 (12.0–36.3)	17.9 (9.1–67.1)
CA19-9 at randomization, median (range)	26.25 (0.5–2186)	28.5 (0.3–70)
Smokers/Nonsmokers	3/15	2/22

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

Safety – Grade 3+ Adverse Events (All Causes)

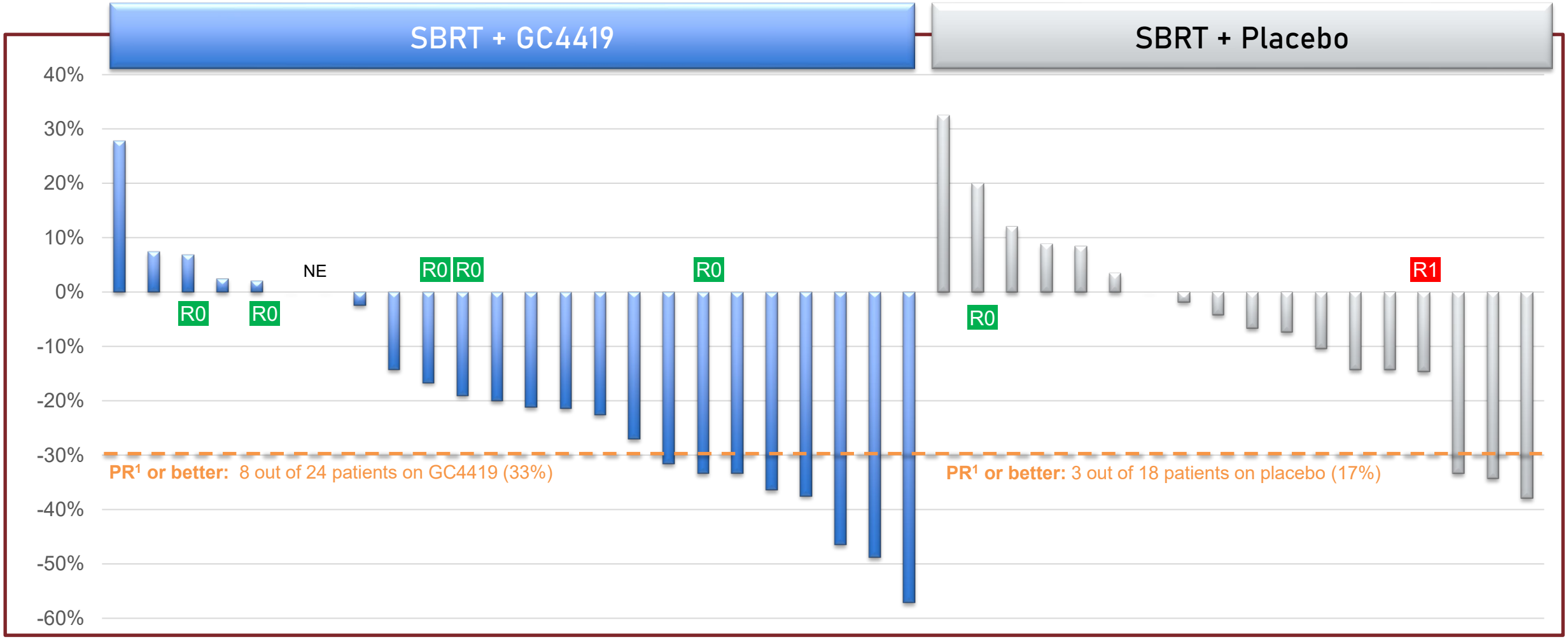
	Placebo (n=18)	Avasopasem (n=24)
Acute Adverse Events (up to 90 days post SBRT)		
Patients with acute Grade 3+ AEs*	4 (22%)	6 (25%)
Grade 3 acute GI toxicity**	2 (11%)	2 (8%)
Late Adverse Events (91 days–1 year post SBRT)		
Patients with late Grade 3+ AEs	5 (28%)	7 (29%)

**Only 1 patient > Gr. 3 (aspiration pneumonia, hypoxia & atrial fibrillation, resolved with supplemental O_2, antibiotics & beta blocker)*
***No bleeding ulcers by 12-week endoscopy, no GI toxicity > Grade 3*

AE = adverse event; GI = gastrointestinal

Best Response from Baseline Tumor in SBRT Field (n=42)

Waterfall plot through August 24, 2020; follow-up ongoing



RO = Surgical resection (R0 = clear margins). R1 = Surgical resection (R1 = tumor at margins). NE = not evaluable.

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

Patients Who Underwent Resection Post SBRT

Surgical Decision Based on Multiple Factors (n=7)

Treatment SBRT Arm	Initial Tumor Staging LA or BR		Margins Post Resection R0/R1		Histopath Analysis Post Resection		
Avasopasem (n=5)	LA		R0		pCR		
		BR	R0				pPR
		BR	R0				pPR
		BR	R0				pPR
	LA		R0				pPR
Placebo (n=2)		BR	R0				pPR
	LA			R1		pNR	

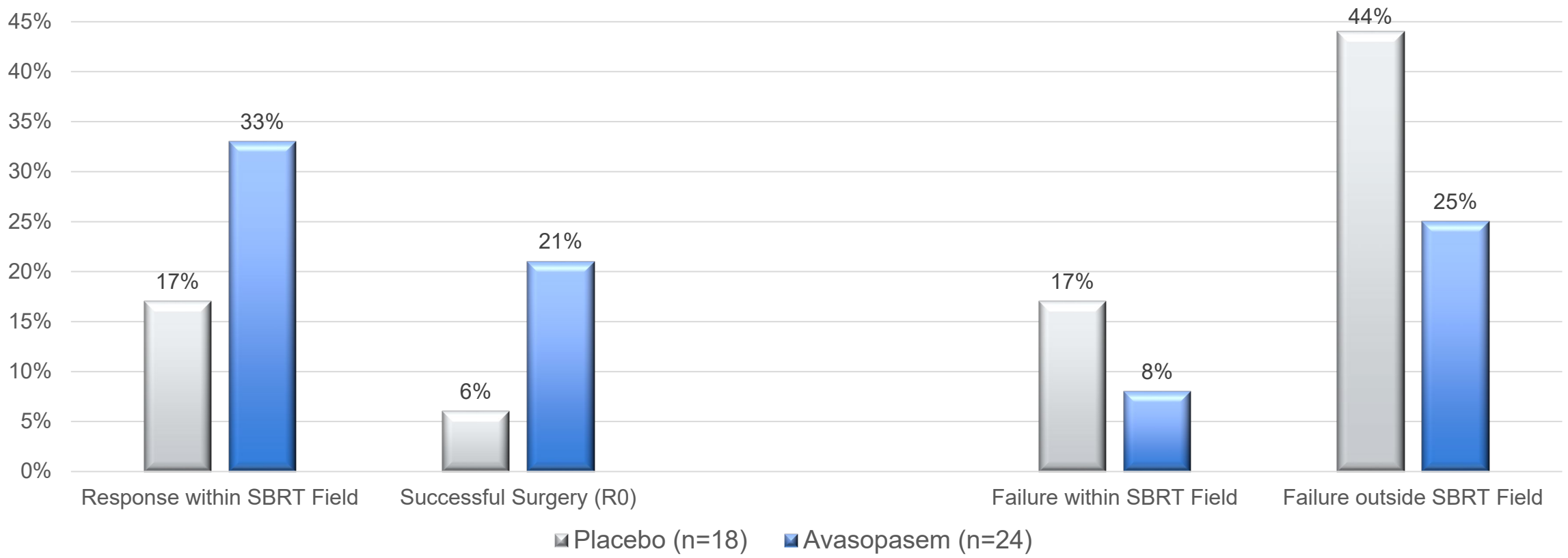
- No significant perioperative complications after SBRT for all 7 patients

LA/BR = locally advanced or borderline resectable; pCR/pNR/pPR = pathological complete, near, or partial response;
R0/R1 = resectable results: R0 = clear margins, R1 = positive microscopic margins; SBRT = stereotactic body radiation therapy

SBRT + GC4419 Demonstrated Better Preliminary Outcomes Than SBRT + PBO

Exhibited Better Local Control

Exhibited Less Failures Inside & Outside RT Field



Data through August 24, 2020; follow-up ongoing

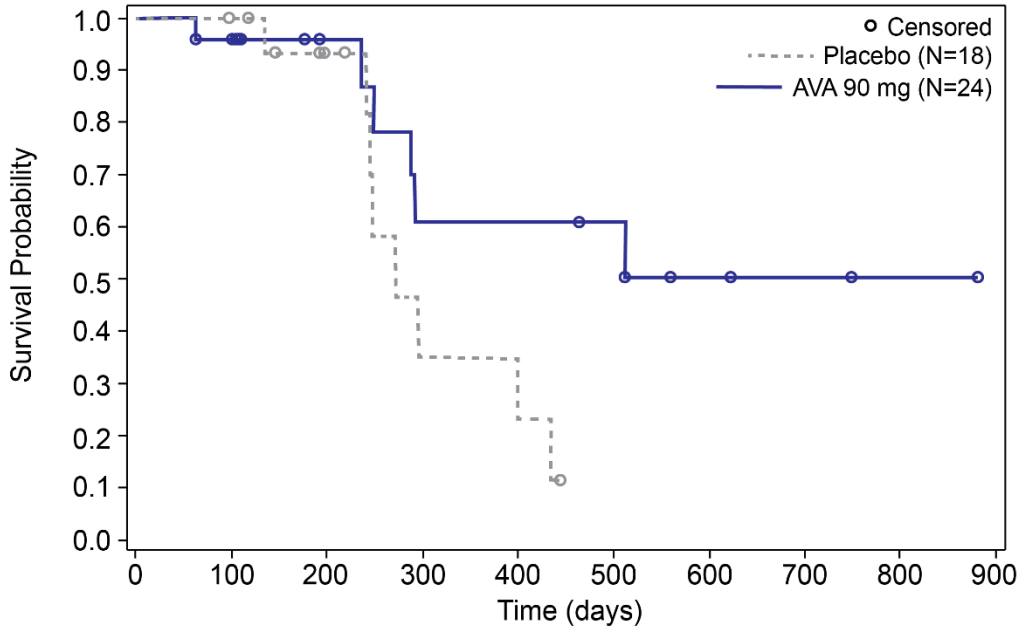
Response within SBRT Field = % of patients with partial response or better per Modified RECIST; Successful Surgery = % of patients with R0 margins post resection
Failure within SBRT Field = % of patients with locoregional failure; Failure outside SBRT Field = % of patients with distant metastases

Encouraging Survival in All Patients (data as of Aug 24, 2020)

Kaplan-Meier Analysis by Treatment (ITT, n=42)

N=42

Overall Survival (OS)

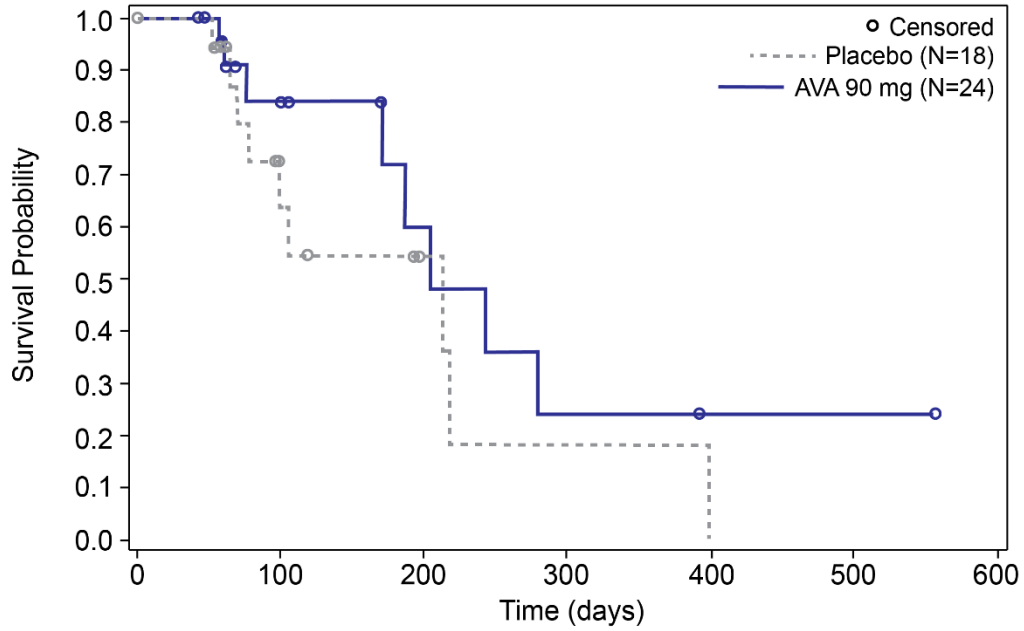


Number of Patients at Risk

Placebo	18	16	9	3	2	0				
AVA 90 mg	24	21	11	7	7	6	3	2	1	0

Log Rank *P* value = 0.0643, HR = 0.4

Progression-Free Survival (PFS)



Number of Patients at Risk

Placebo	18	8	3	1	0		
AVA 90 mg	24	12	5	2	1	1	0

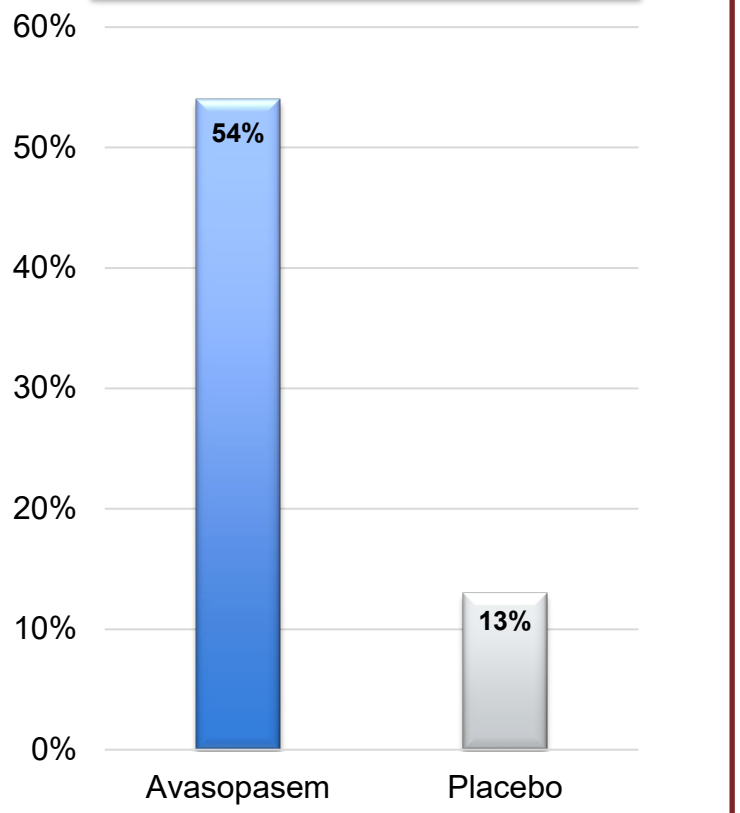
Log Rank *P* value = 0.29, HR = 0.6

Note: Resected patients (n=7) censored at time of surgery for PFS (5 on GC4419 arm)

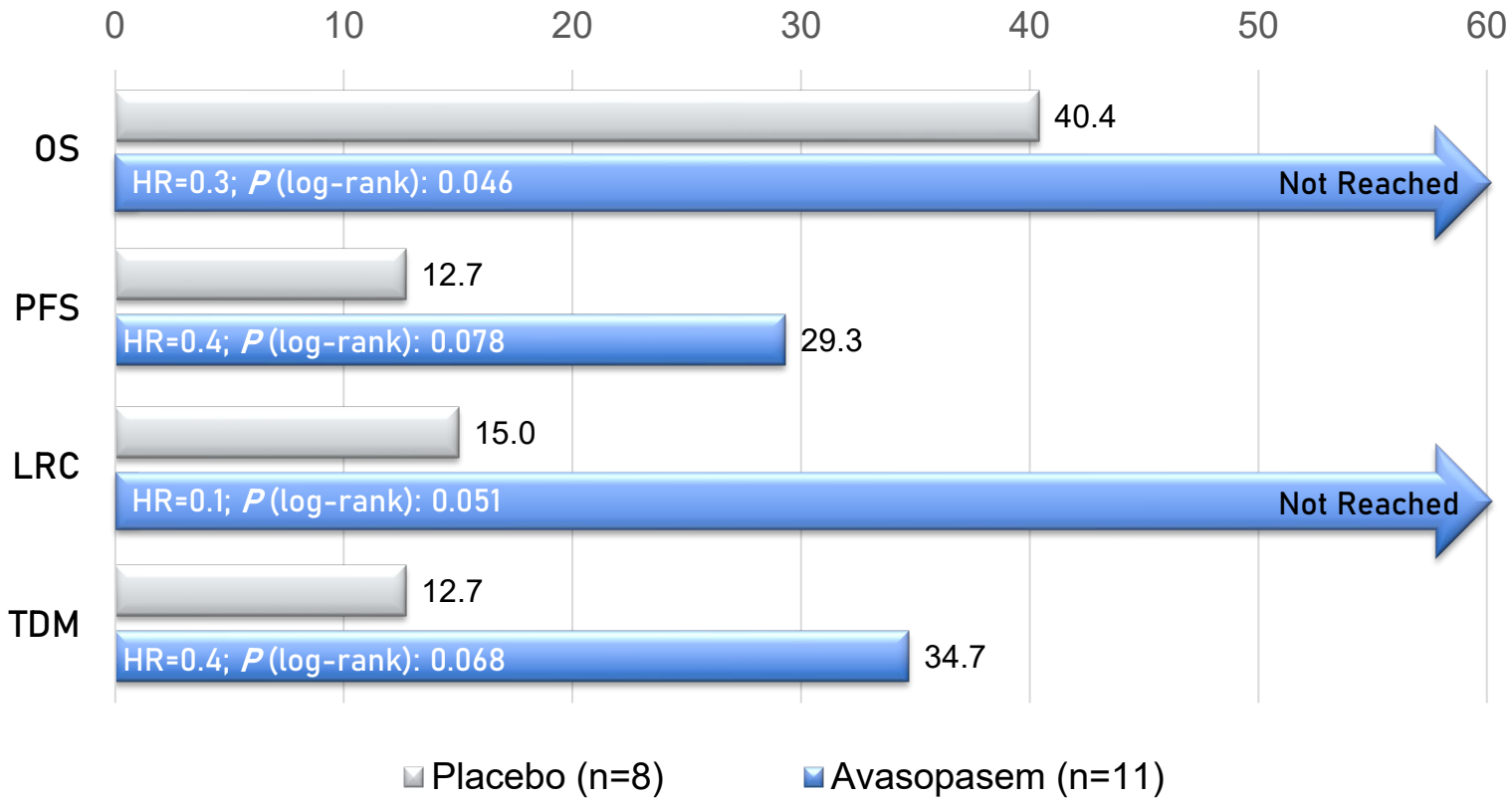
AVA = GC4419 or Avasopasem

Efficacy Endpoints in Patients Followed for >1 Year (n=19, ITT)

Best Response Rate



Medians (Weeks From SBRT)



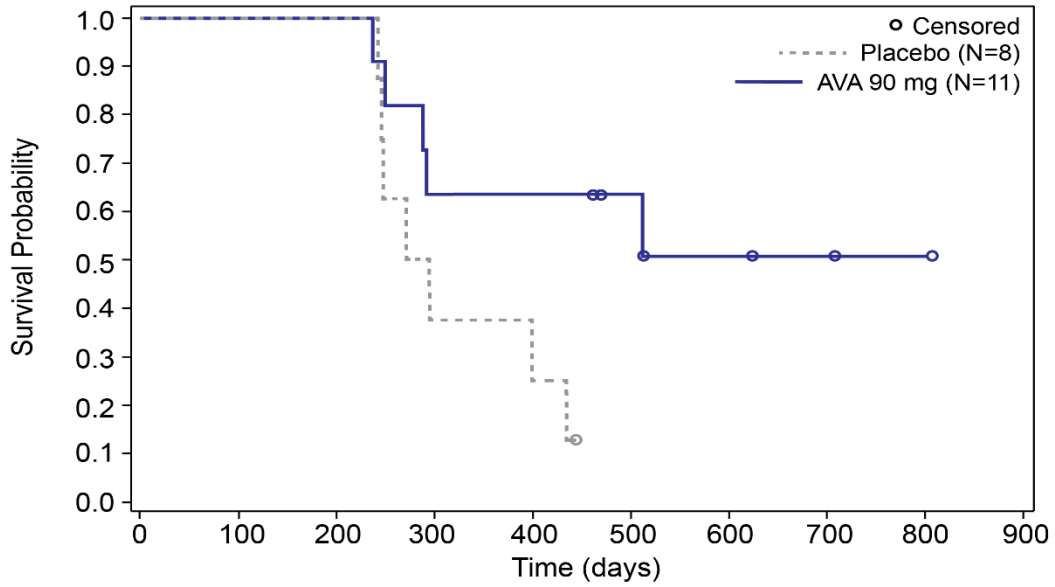
HR = Hazard ratio; LRC = locoregional control; OS = overall survival, PFS = progression-free survival, TDM = time to distant metastases.

Encouraging Survival in Patients Followed for >1 Year

Kaplan-Meier Analysis by Treatment (ITT, n=19)

N=19

Overall Survival (OS)

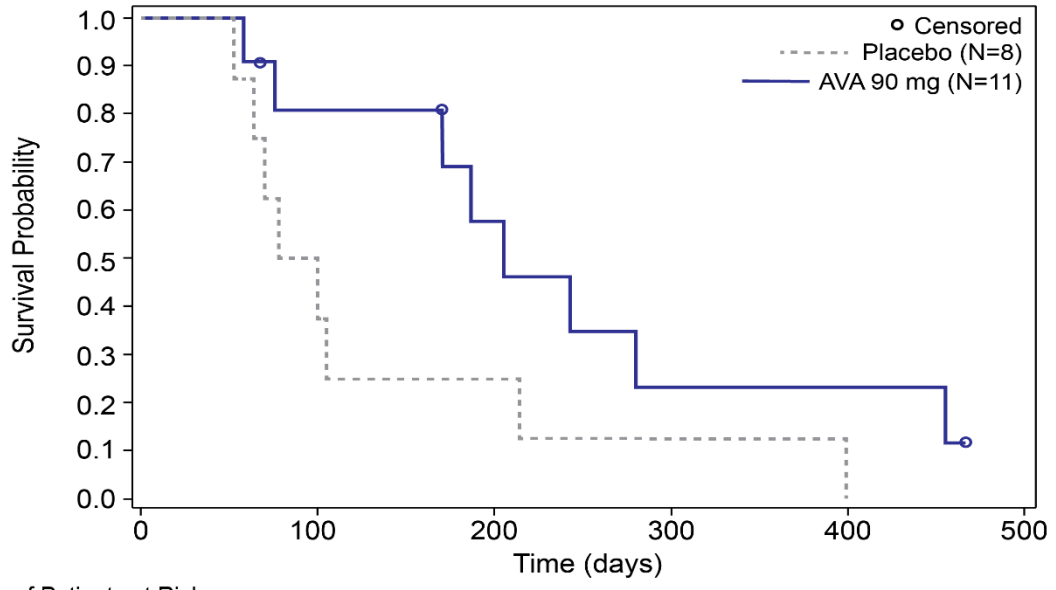


Number of Patients at Risk

Placebo	8	8	8	3	2	0				
AVA 90 mg	11	11	11	7	7	5	3	2	1	0

Log Rank *P* value = 0.0463, HR = 0.3

Progression-Free Survival (PFS)



Number of Patients at Risk

Placebo	8	4	2	1	0	
AVA 90 mg	11	8	5	2	2	0

Log Rank *P* value = 0.078, HR = 0.4

AVA = GC4419 or Avasopasem

Hazard Ratios on all Efficacy endpoints appear to favor GC4419 arm

Comparison of Mature (n=19) and All Patients (n=42) – as of August 24, 2020

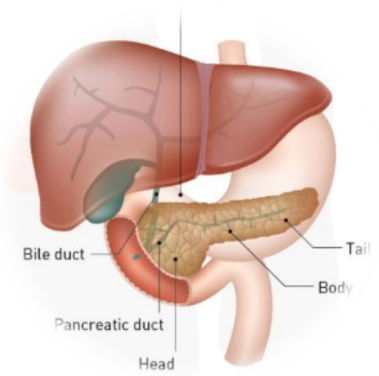
Comparison of Hazard Ratios (95% Confidence Intervals)	Initial Stage Pts (n=19)	All Patients (n=42)
Overall Survival (OS)	0.3 (0.09-1.05)	0.4 (0.12-1.11)
Progression-Free Survival (PFS)	0.4 (0.15-1.14)	0.6 (0.23-1.56)
Loco-Regional Control (LRC)	0.1 (0.01-1.37)	0.2 (0.02-2.22)
Time to Distant Mets (TDM)	0.4 (0.11-1.13)	0.4 (0.13-1.29)

Pancreatic Cancer Population in US

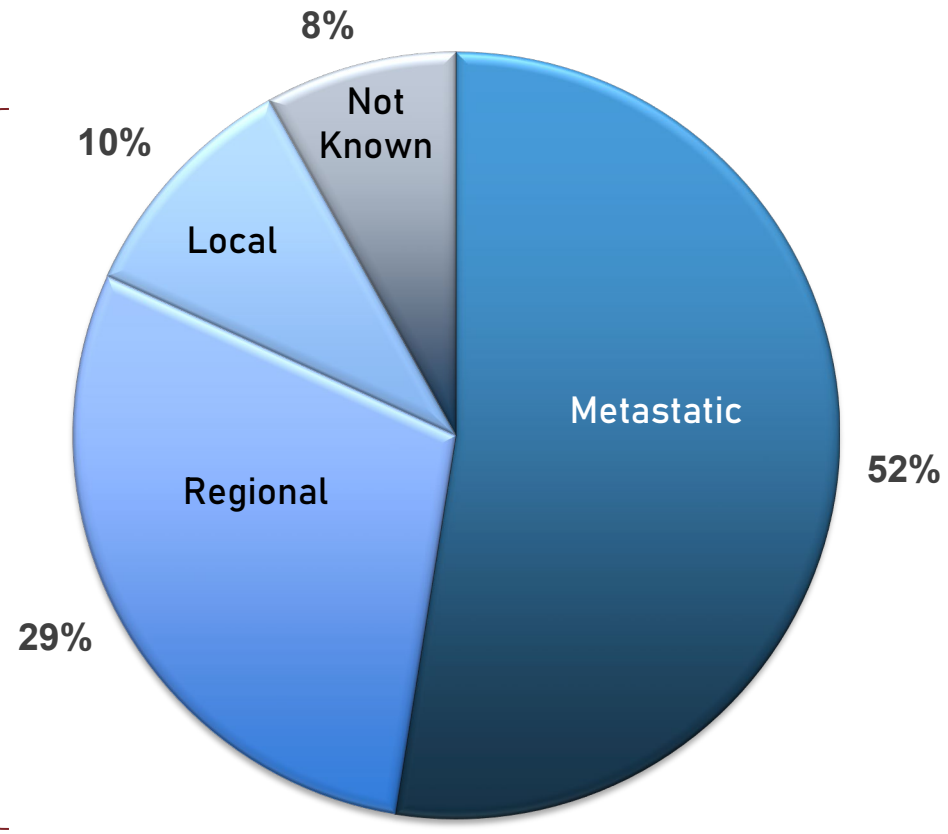
5-Year Survival is ~10%

Annual new cases
460,000 Globally[1]
57,000 in US[2]

9-13% 5-year Survival



GRECO-2
Double-Blind
Placebo-controlled
Randomized trial



1/6th get attempted surgical resection

1/3rd get chemotherapy upfront then some considered for SBRT

Half at diagnosis are beyond locoregional control and receive chemotherapy, with some getting RT as palliation to primary

[1] 2019 SEER Data [2] Epidemiology of Pancreatic Cancer: Global Trends, Etiology and Risk Factors, Rawla P et al. World J Oncol. 2019 Feb; 10(1): 10–27

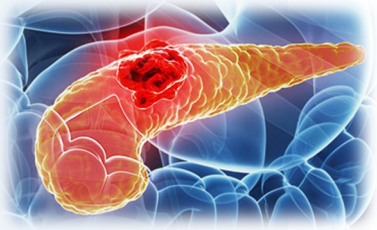
***GRECO** = **G**alera **R**adiotherapy **E**fficacy **C**ancer **O**ptimization*

GRECO-1 for Lung Cancer SBRT +/- GC4711

SBRT GC4711 Combo Trial

Double-blind, Placebo-controlled, Randomized Trial after Short Phase 1

- NSCLC Locally Advanced – Previously untreated (1st line)
- Objectives: Safety (reducing Pneumonitis), ORR, LRC, DM, PFS, OS
- Stage 1 to access SBRT +/- GC4711; Stage 2 SBRT + Checkpoint Inhibitor +/- GC4711



1st Stage:

1st–line NSCLC
Centrally located
or Large Tumors
ECOG PS 0-3

Phase 1 (n=5 pts)

100 100 100 100 100 GC4711
SBRT

SBRT + GC4711 x 5

30 Day Safety SRC Review

GC4711 100 mg IV in 15min
SBRT 10-12 Gy* x 5

Randomized Phase 2 (n≈ 66 pts)

R

SBRT + Placebo x 5

100 100 100 100 100 GC4711
SBRT

SBRT + GC4711 x 5

GC4711 100 mg IV in 15min
SBRT 10-12 Gy* x 5

SBRT dose is 10-12 Gy x 5, determined by SBRT Planning.

***GRECO** = **G**alera **R**adiotherapy **E**fficacy **C**ancer **O**ptimization, NSCLC = Non-Small Cell Lung Cancer; ECOG PS = Eastern Cooperative Group Performance Status*

Galera Therapeutics, Inc

Commercial Considerations

Large Commercial Opportunity Addressing Clear Unmet Need

Severe Oral Mucositis & Esophagitis

Galera Therapeutics, Inc

Severe Oral Mucositis Head & Neck Cancer

42k HNC Pts

~65k new cases/year in US
2/3rd get IMRT & cisplatin as standard-of-care
→ 70% get SOM
20-30% get Grade 4
No approved drug

Rad Oncs report severe oral mucositis is most burdensome side effect of HNC RT treatment

220 Rad Oncs in market research

5% of Rad Oncs

Galera's quantitative market research to date includes ~5% of US radiation oncologists

Supports significant, rapid uptake[2]

SOM common and costly

~$32,000

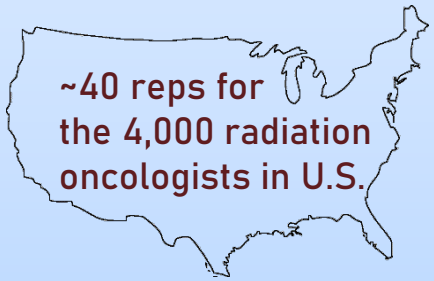
Patients with OM incur ~$32,000 more in medical expenses in first 6 months from start of RT

Current approaches inadequate – while frequently used, only 1 in 5 believe they are useful

Targeted salesforce In U.S.

~40 Reps

Focused commercial infrastructure



~2,500 RT sites in US
~60% of patients are treated in ~500 centers[1]

Esophagitis in Lung Cancer

50k NSCLC Pts

~50k NSCLC patients treated with IMRT, 50% get ≥ Grade 2 esophagitis[3]
→ inability to swallow, severe pain, ulceration, bleeding & hospitalization

SOM efficacy seen by radiation oncologists as supportive for esophagitis[4]

[1] Medicare Claims Analysis by Galera in 2019 [2] Hypothetical Product X for SOM with a similar profile to avasopasem Phase 2b results
[3] NCI or RTOG grading scales, [4] Galera Market Research (150 Radiation Oncologists), Rad Oncs = Radiation Oncologists, SOM = Severe Oral Mucositis

Unmet Medical Need with Limited Treatment Options

Pancreatic Cancer

Lethal Common Cancer

Increasing Number of Pancreatic Cancer Patients Diagnosed Each Year

- Annually, 57,000 newly diagnosed in US[1] and 460,000 globally[2]
- It is the most lethal common cancer: 5-year survival 9-13%[1,2]
- Over 30% present with locally advanced unresectable or borderline resectable (18,000 in US)[2]

Novel Therapies Needed

First Line Treatment is Induction Chemotherapy for Over 80% of Patients[2]

- FOLFIRINOX or Gemcitabine/Abraxane most commonly used[3]
- 60% of patients fail induction therapy within 12 months[4]
- 60% on FOLFIRINOX develop Grade 3-5 toxicity[4]

SBRT is Accepted Tx Option

SBRT Use is increasingly used for locoregional control (by NCCN and others)[5]

- 1st or 2nd line option after 4-5 months of chemotherapy for locally advanced cancer
- For loco-regional recurrence after surgical resection
- For some patients with metastatic disease for palliative control of local disease

[1] 2019 SEER Data [2] Epidemiology of Pancreatic Cancer: Global Trends, Etiology and Risk Factors, Rawla P et al. World J Oncol. 2019 Feb; 10(1): 10–27.
[3] Acta Oncologica, 2015; 54: 979–985 [4] Suker M., Beumer B.R., Sadot E., Marthey L., Faris J.E., Mellon E.A. The Lancet Oncology. 2016;17(6):801–810.
[5] NCCN = National Comprehensive Cancer Network-2019

GRECO-1 Trial: GC4711 + SBRT Combination in NSC Lung Cancer

NSCLC

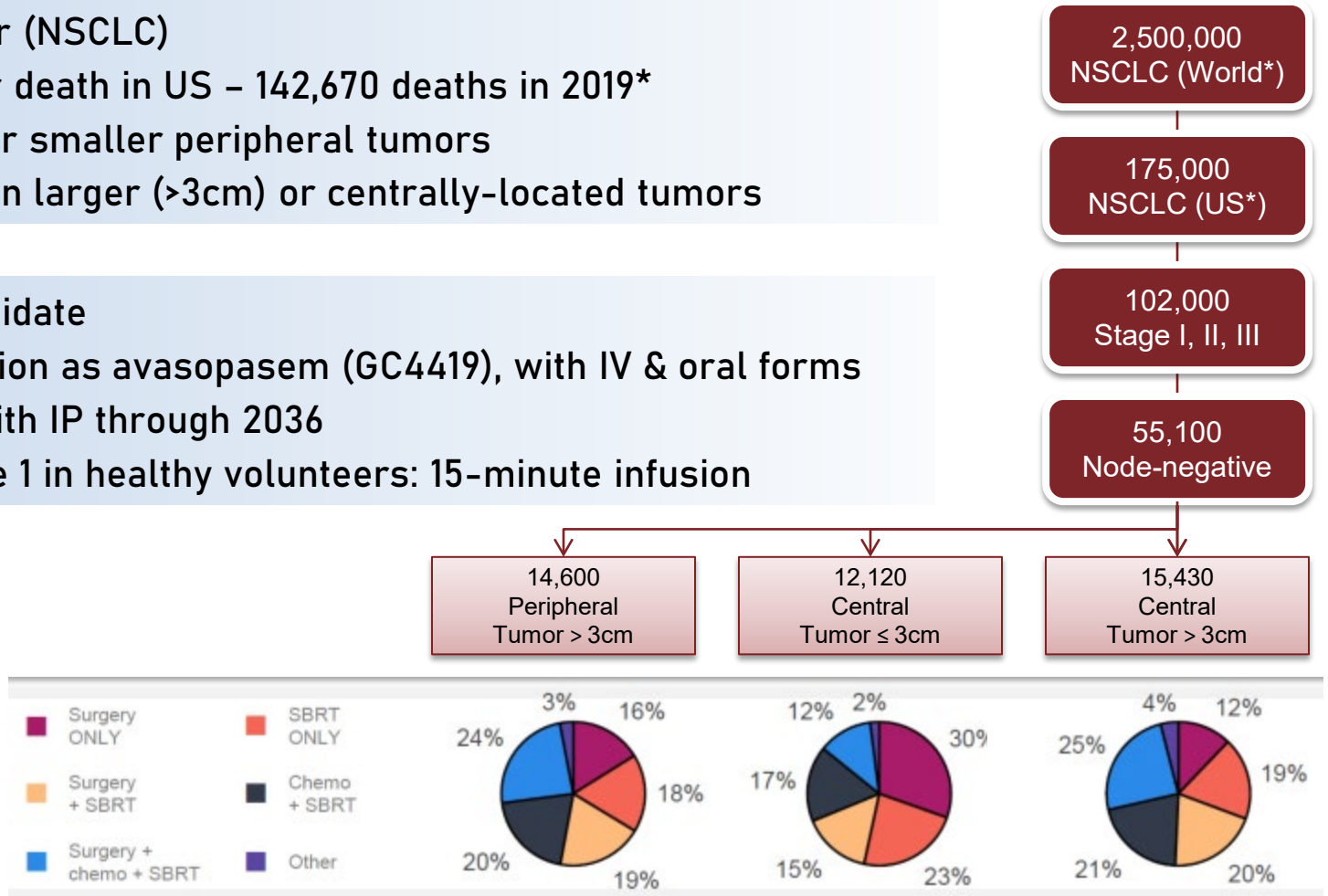
Non-Small Cell Lung Cancer (NSCLC)

- Leading cause of cancer death in US – 142,670 deaths in 2019*
- SBRT commonly used for smaller peripheral tumors
- Lung toxicity limits use in larger (>3cm) or centrally-located tumors

GC4711

GC4711 – SBRT Clinical Candidate

- Same mechanism of action as avasopasem (GC4419), with IV & oral forms
- Novel chemical entity with IP through 2036
- Completed 14-day Phase 1 in healthy volunteers: 15-minute infusion



*Globocan & US SEER Data**

Decision Resources Group (DRG) Primary Market Research, Oct 2020

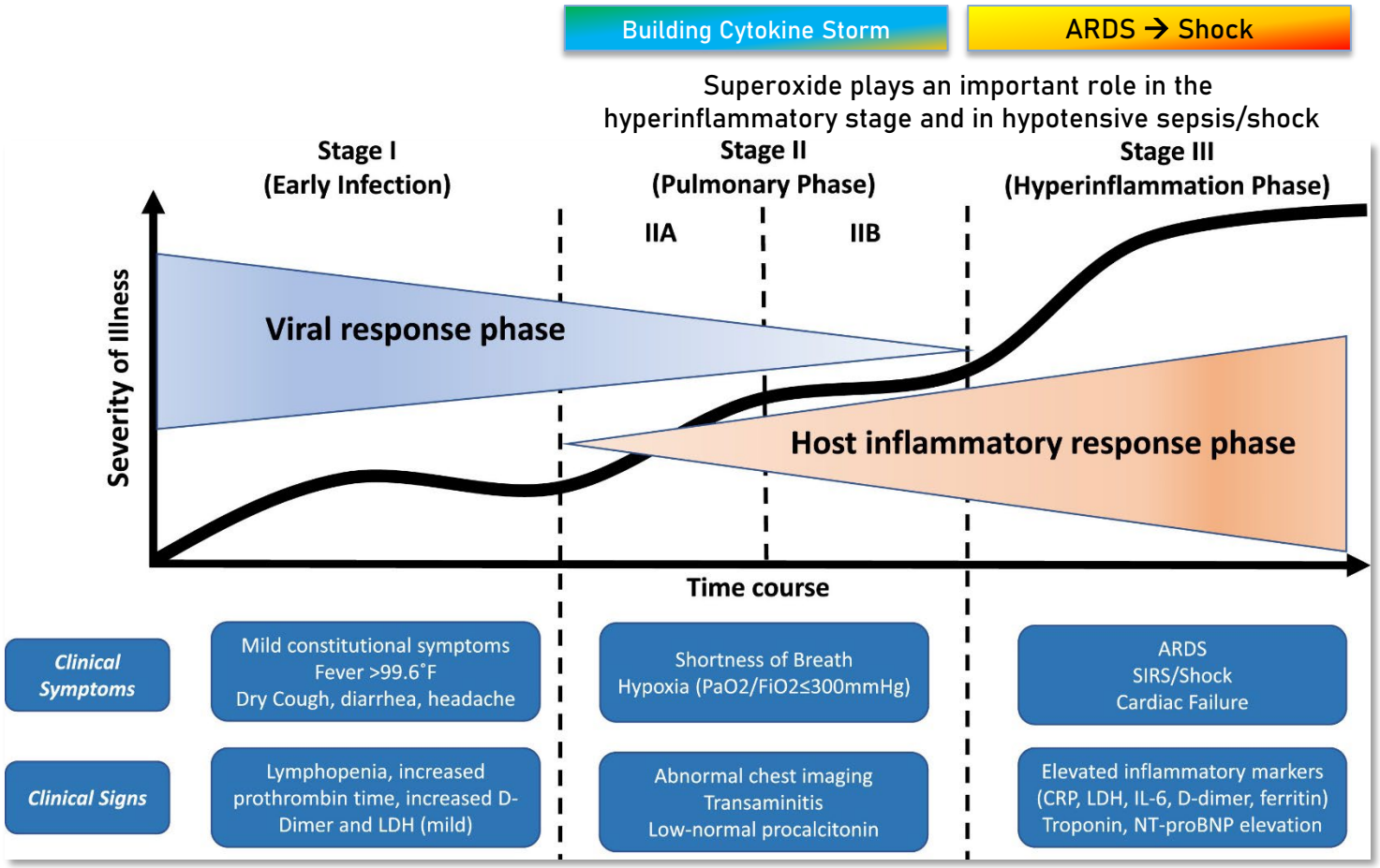
Galera Therapeutics, Inc

COVID-19 Trial

Superoxide plays important role in Late Stages of COVID-19 Infection

Classification of COVID-19 disease states and potential therapeutic targets. The figure illustrates 3 escalating phases of COVID-19 disease progression, with associated signs, symptoms, and potential phase-specific therapies.

ARDS, acute respiratory distress syndrome; CRP, C-reactive protein; JAK, janus kinase; LDH, lactate dehydrogenase; NT-proBNP, N-terminal pro B-type natriuretic peptide; SIRS, systemic inflammatory response syndrome; GM-CSF, Granulocyte Macrophage Colony Stimulating Factor.



COVID-19 illness in native and immunosuppressed states: A clinical–therapeutic staging proposal
Hasan K. Siddiqi, MD, MSCR, Mandeep R. Mehra, MD, MSc Published:March 20, 2020 DOI:https://doi.org/10.1016/j.healun.2020.03.012

Phase 2 Pilot Trial of Avasopasem in Patients with COVID-19

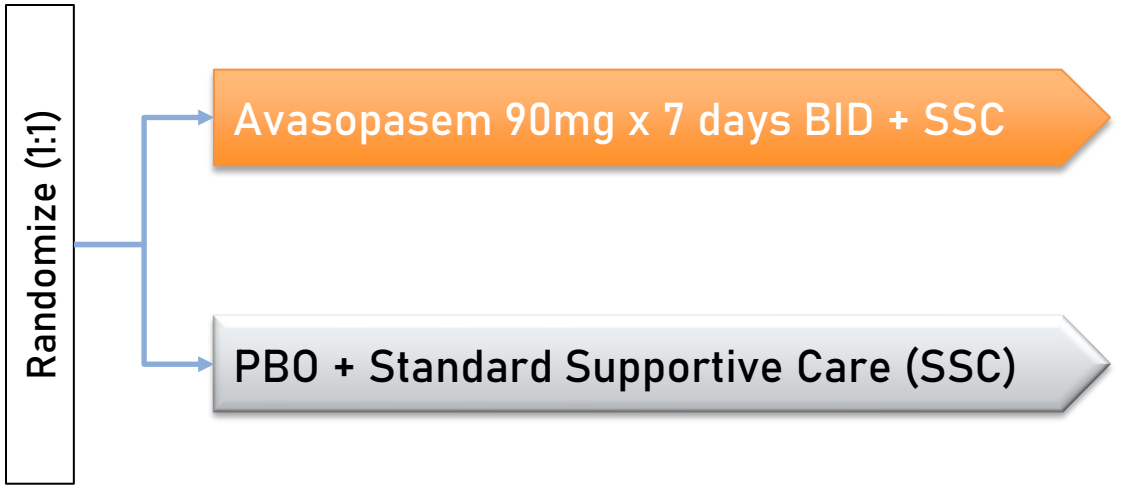
Randomized Placebo-Controlled Trial in Patients with Critical Illness (n=50)

GC4419 For COVID-19

Double-blind, Placebo-controlled, Randomized Trial

- Superoxide plays a central role in pathophysiology of acute respiratory distress syndrome (ARDS)
  - Causes endothelial cell damage, increased microvascular permeability, peroxynitrite ($ONOO^-$)
- Galera's dismutase mimetics inhibited these effects in animal ARDS models

Active Regimen	Avasopasem 90mg 3 hr IV infusion BID x 7d
Patients	COVID-19 test + critical phase respiratory failure
Stratification	Age < 60 or ≥ 60 years
Sites	Multi-center



Primary
- 28-day mortality (overall survival)

Secondary
- Safety of avasopasem in COVID patients
- Ventilator weaning
- Vent-free days in hospital
- ICU-free days
- Catecholamine support, BP <65mmHg
- SOFA scores

SSC = Standard Supportive Care, SOFA = Sequential Organ Failure Assessment

Salvemini, et al, Br J Pharmacology, 2001; Macarthur, et al, Crit Care Med, 2003; Cuzzocrea, et al, Crit Care Med, 2004; Ndengele, et al, Shock, 2005

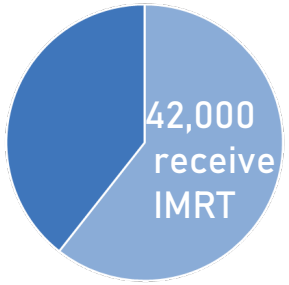
Galera Therapeutics, Inc

Appendix

Oral Mucositis in HNC – Large Unmet Medical Need

SOM and Head & Neck Cancer

- ~65,000 new HNC patients in US/Year
- ~65% get IMRT & cisplatin as standard-of-care
- ~70% of patients get SOM (can't eat)
- ~20-30% get Grade 4 (can't eat or drink)
- No approved drug available



Can Have Devastating Complications

- **Dehydration & Malnutrition**
  Often requiring PEG tube feeding
- **Pain**
  Often severe pain requiring opioids
- **Treatment interruption**
  Each week of treatment delay decreases tumor control by >10%
- **Increased economic burden**
  OM Dx → ~$32,000 in additional medical expenses in first 6 months from RT start

WHO Grading Scale

1	No ulcers Erythema and soreness
2	Ulcers Able to eat a solid diet
3	Ulcers Requires a liquid diet
4	Ulcers Unable to eat or drink

SEVERE

Current Treatments

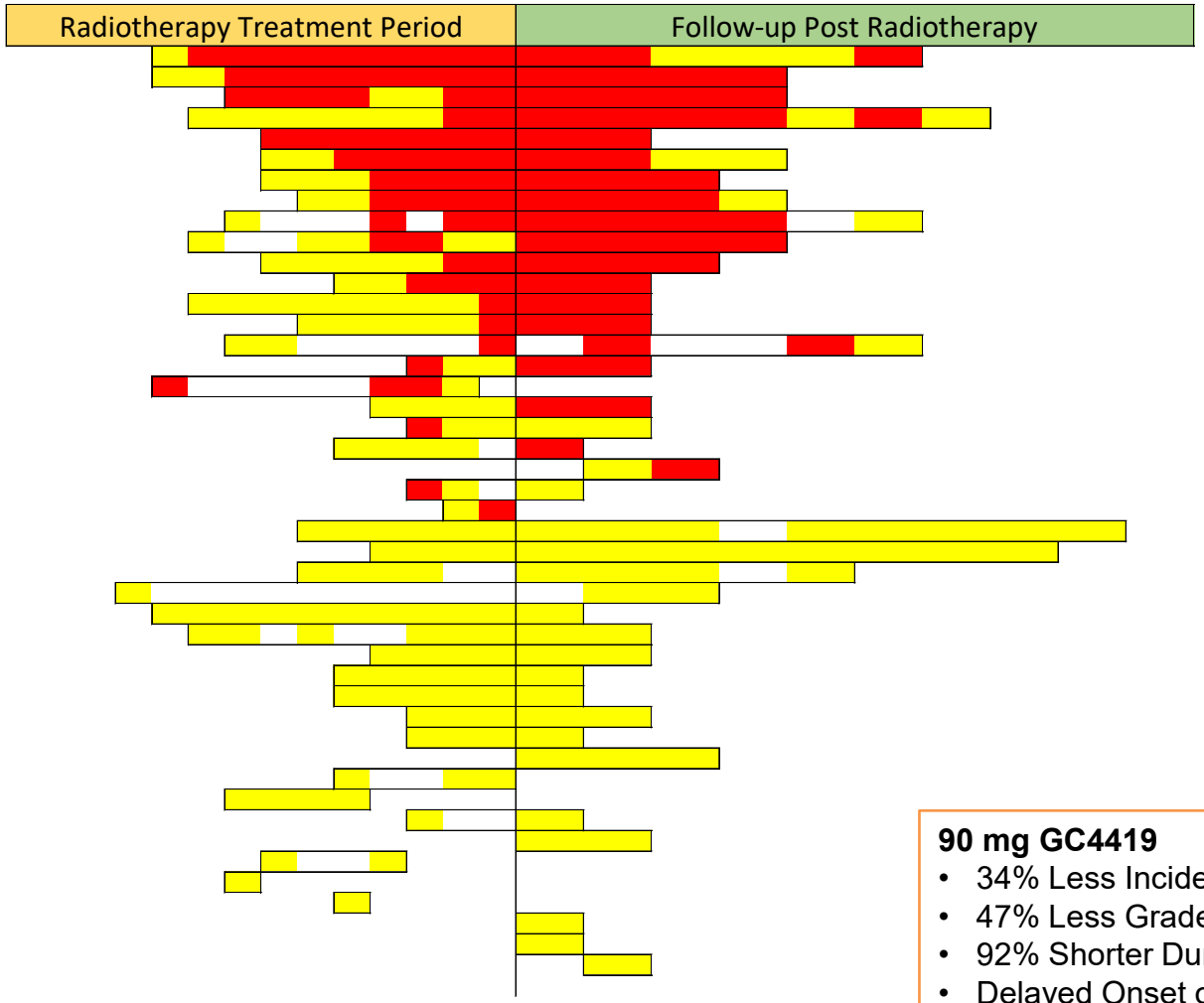
MASCC / ISOO Guidelines for HNC OM

Treatment Approach	Recommended for HNC OM due to RT?
Basic oral care	✓
Anti-microbials, coating agents, anesthetics, & analgesics (0.2% morphine mouthwash)	✓
Anti-inflammatories, benzydamine	?
Low level laser & other light therapy	?
Cryotherapy for 5-FU chemotherapy	✗
Natural & other agents	✗

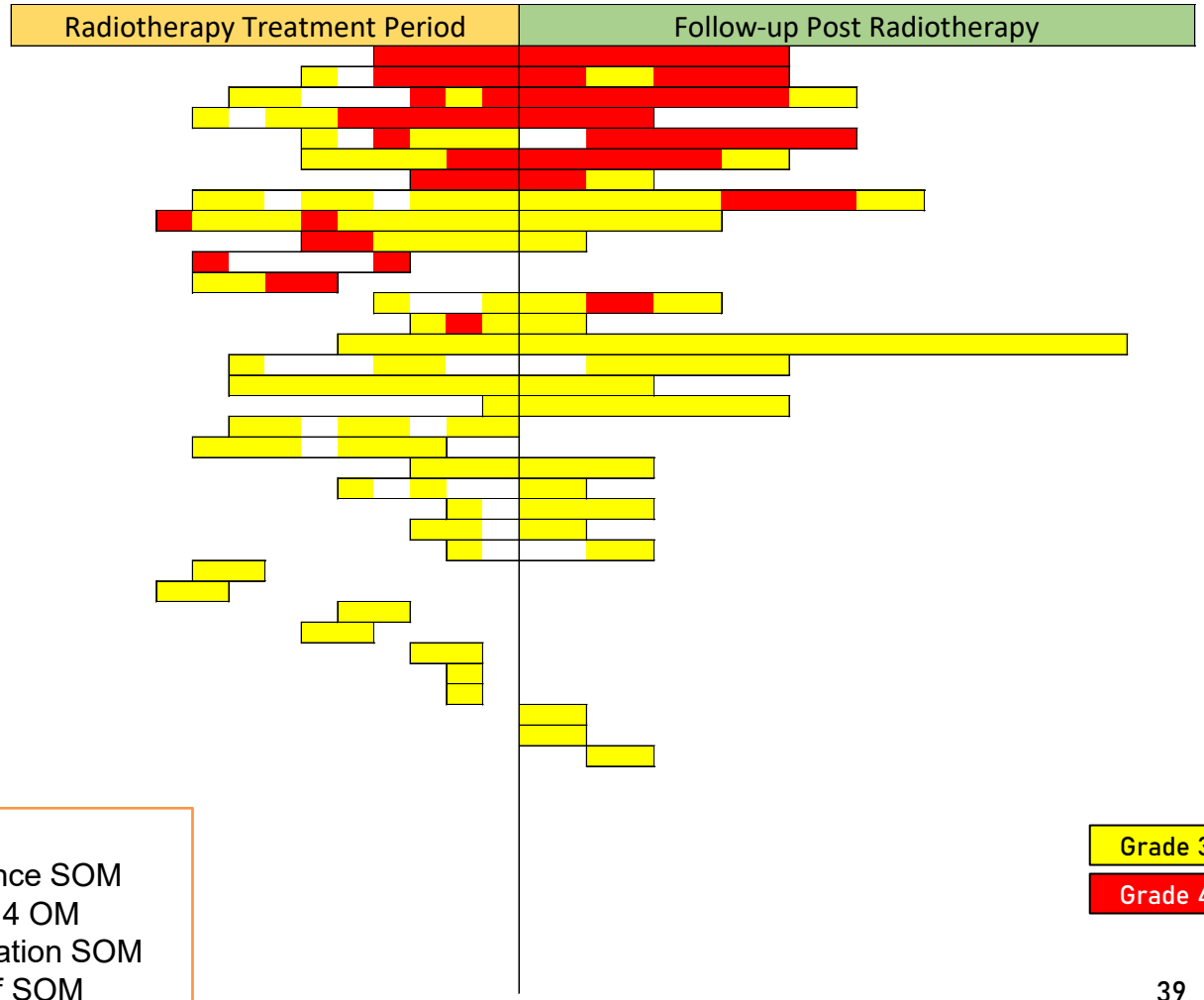
Efficacy Parameters Better on 90mg arm Compared to Placebo

Swimmers plot: each patient who developed at least one SOM episode is represented by a row

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



90MG Avasopasem (GC4419) Arm (35 of 76 Pts had ≥1 visit with SOM)



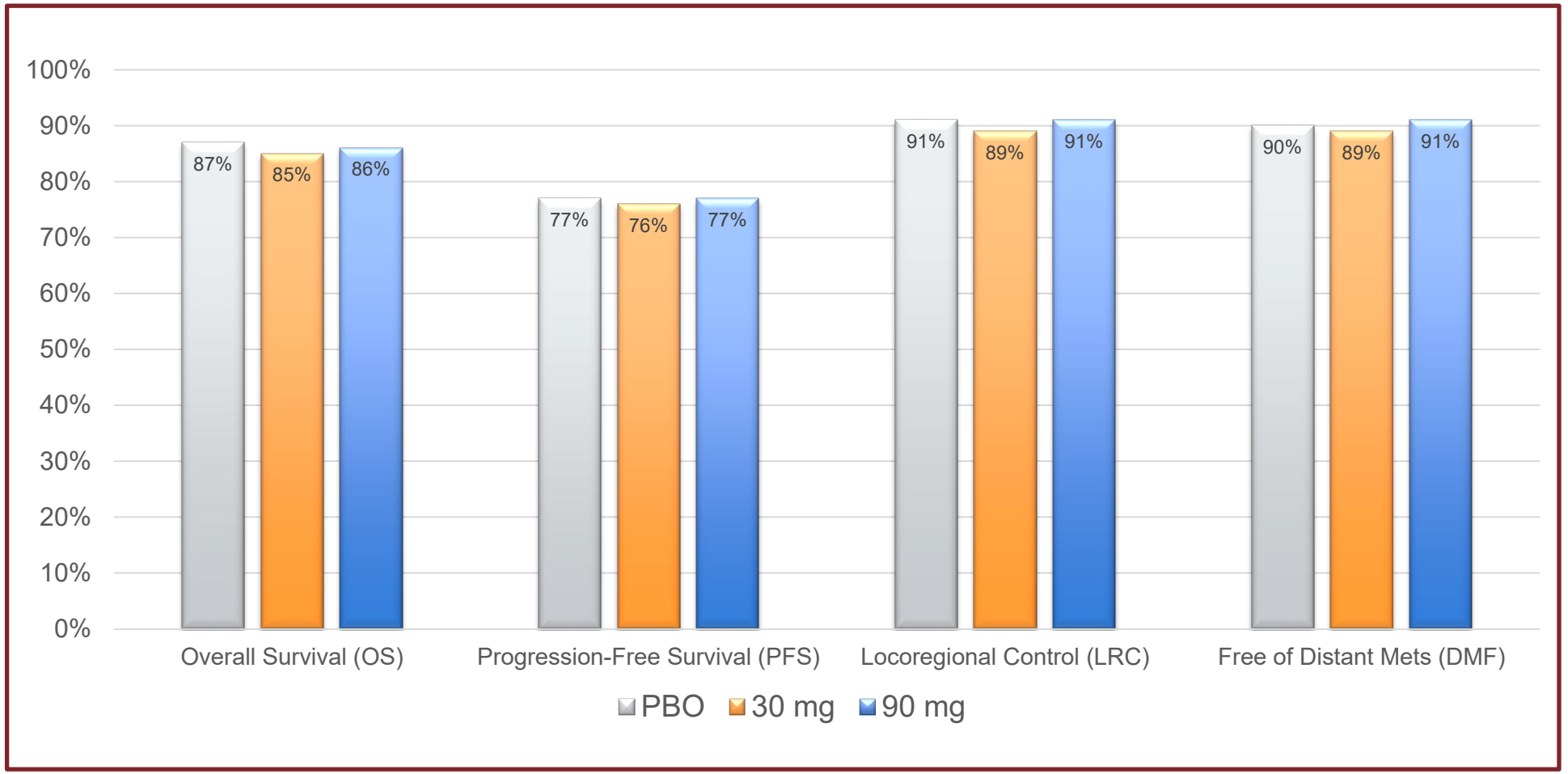
90 mg GC4419

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

Grade 3

Grade 4

Tumor Outcomes Maintained - 2 year follow-up



Final ITT Analysis

OS = Overall Survival, PFS = Progression-Free Survival, LRC = LocoRegional Control, DMF = Free of Distant Metastases

RT-related Mucositis Beyond Head and Neck Cancer

Mucositis of Esophagus

Radiotherapy-related Esophagitis in Lung Cancer

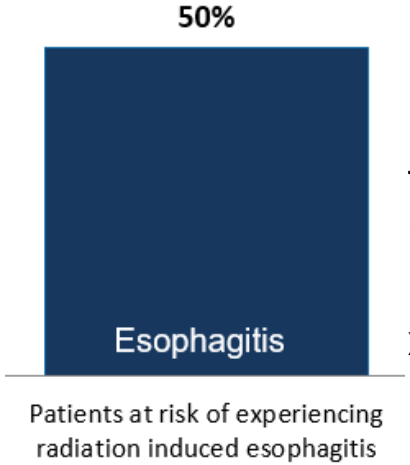
- SOM efficacy seen by radiation oncologists as supportive for esophagitis[1]
- ~50,000 lung cancer patients are treated with RT, 50% get ≥ Grade 2 esophagitis[2]
- Effects: inability to swallow, severe pain, ulceration, bleeding & hospitalization

Compendial Listing

Phase 2 to support Compendial Listing post-Approval for SOM

- Single-arm Phase 2a trial in 60 patients w/ locally-advanced lung cancers
- Standard IMRT to ≥ 5 cm of esophagus (30 fractions, 2Gy/day x5 for 6 weeks)
- Post approval for SOM in HNC, plan to seek compendial listing in U.S.

NCCN National Comprehensive Cancer Network®



Market Research Question
Patients with Other Conditions[1]

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?

[1]Galera Market Research (150 Radiation Oncologists)
[2] NCI or RTOG grading scales