



Transforming Radiotherapy

with

Dismutase Mimetics

October 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 ($O_2^{\cdot -}$)

Over half of cancer patients
receive radiotherapy
as part of their care^{1, 2}

Increase H_2O_2 in tumors

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

Transforming Radiotherapy with Dismutase Mimetics

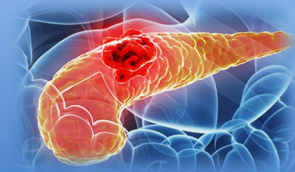
SBRT

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

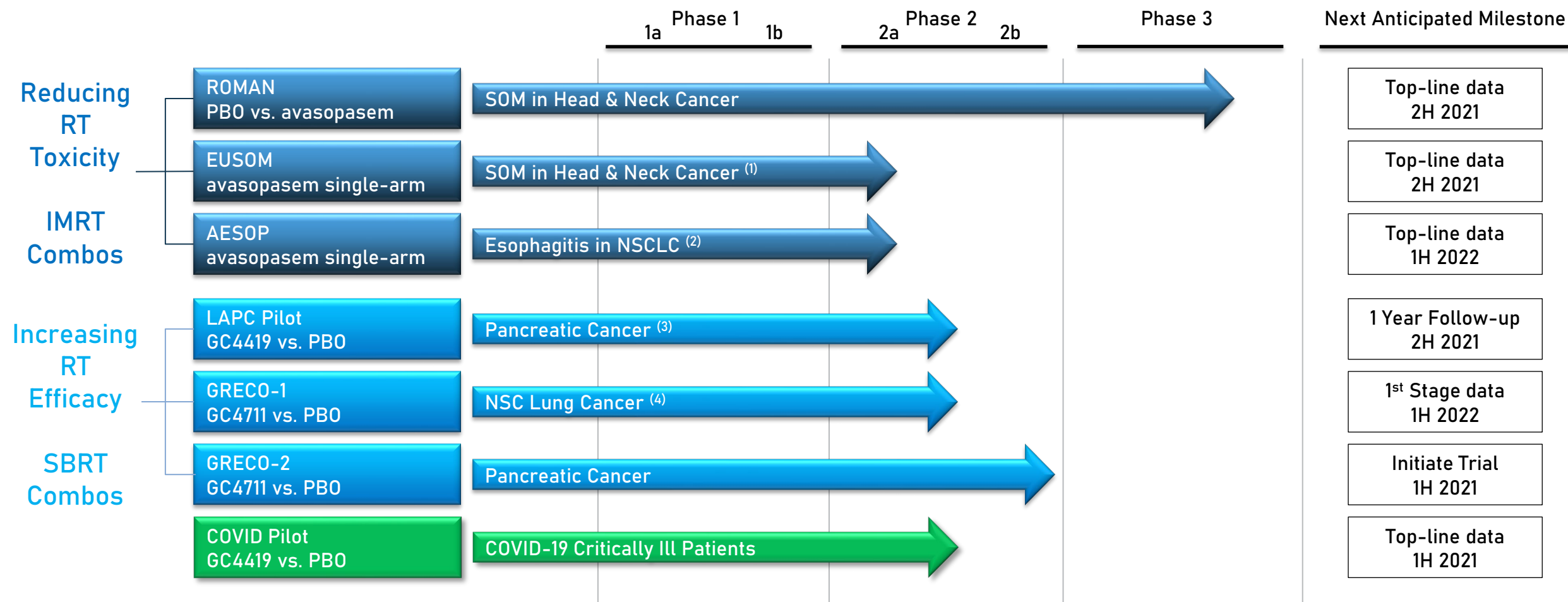
Normal tissue toxicity limits
optimal radiotherapy treatment of tumor

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. 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

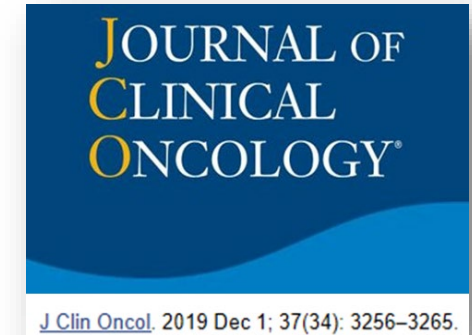
Increasing SBRT anti-cancer efficacy in patients

- 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





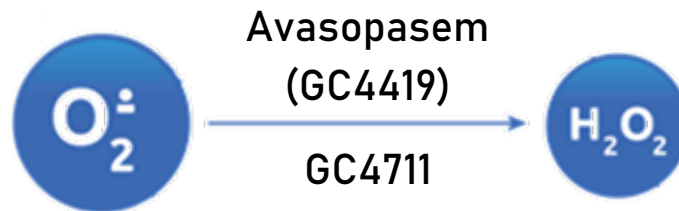
Dismutase Technology



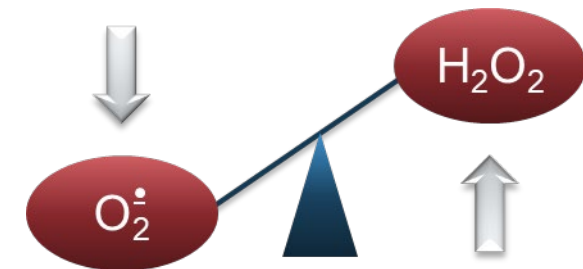
Dismutase Mimetics

Small Molecule Enzyme Mimetics

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



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

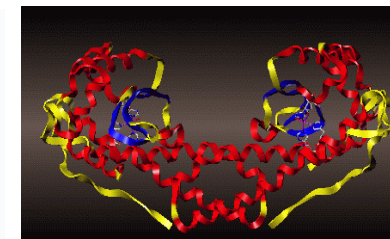


Galera's Dismutase Mimetics

Native SOD Enzymes

Native SOD Enzymes

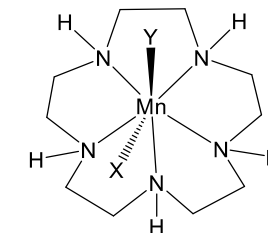
- Overexpression reduces RT toxicity
- Large size, immunogenicity & short half-lives limit bioavailability
- Inactivation/inhibition by reactive oxygen species



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

Comparable to native SODs
(2×10^7 molecules per sec)

Selectivity

Interact with superoxide alone,
not other reactive oxygen species

Stability

Firmly hold Mn atom
in macrocyclic ring

Safety

Well-tolerated
preclinically and clinically

Synthesis

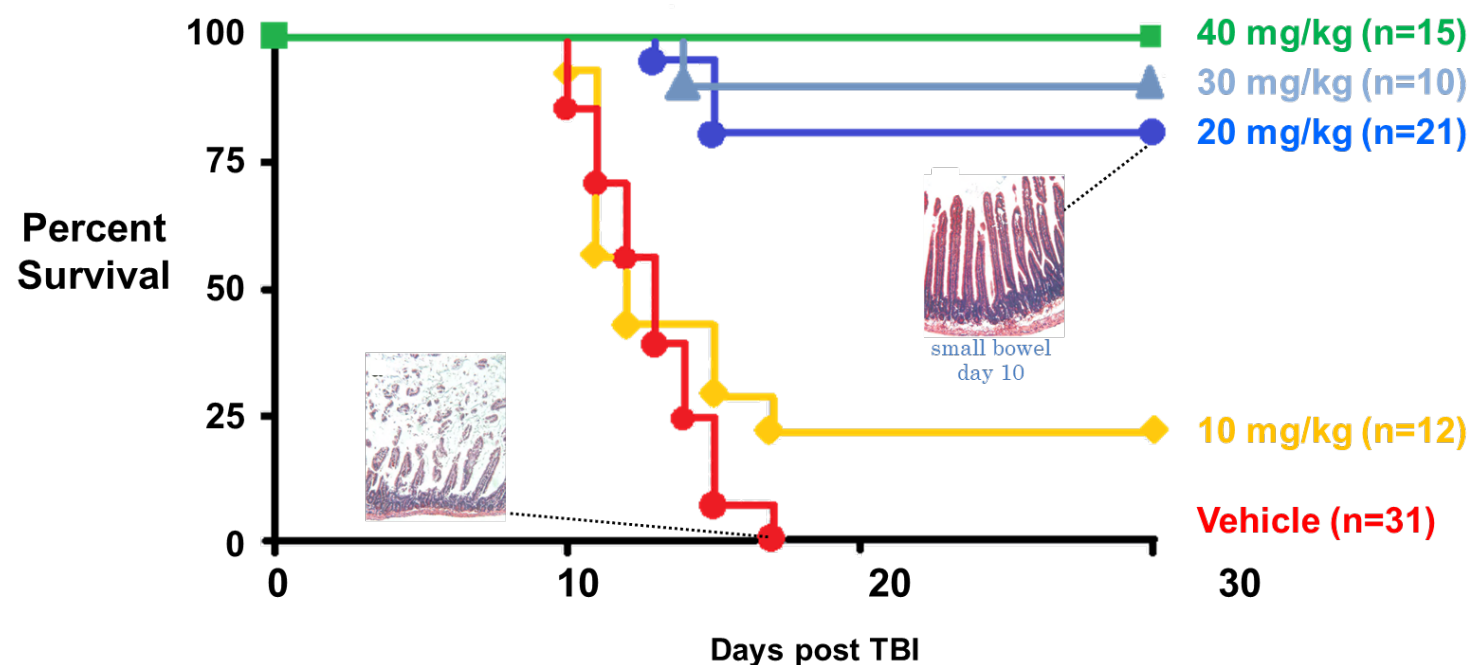
Efficient & cost-effective
manufacturing process

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

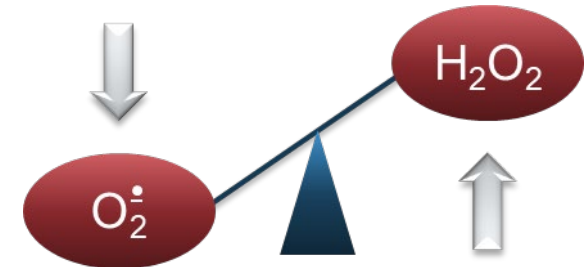


Dismutase Mimetics Increase Anti-Cancer Efficacy with High Fraction-Dose RT in Preclinical Models

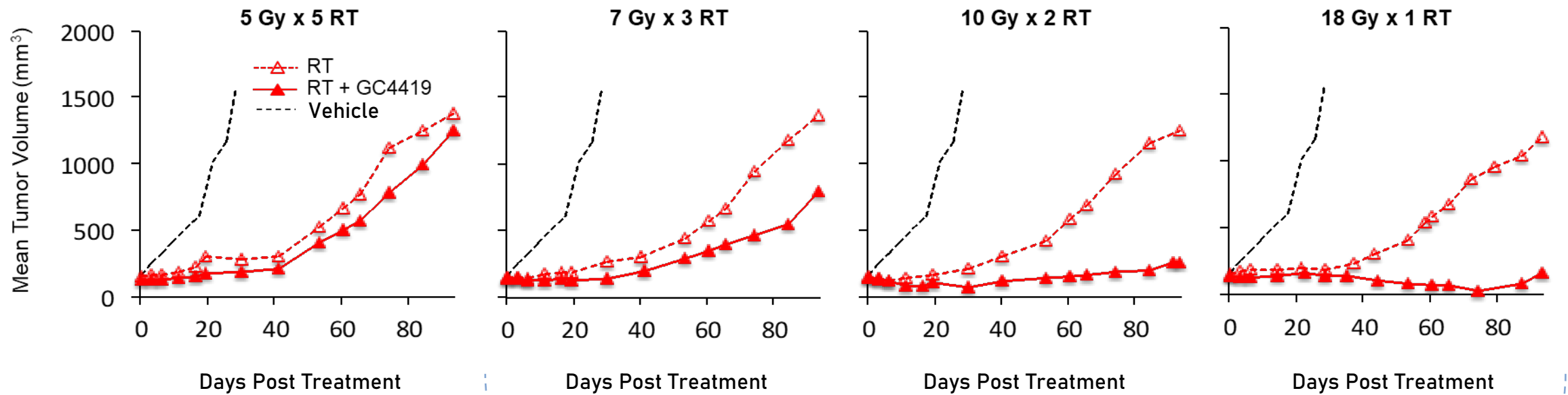
Increase
Radiotherapy
Efficacy

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

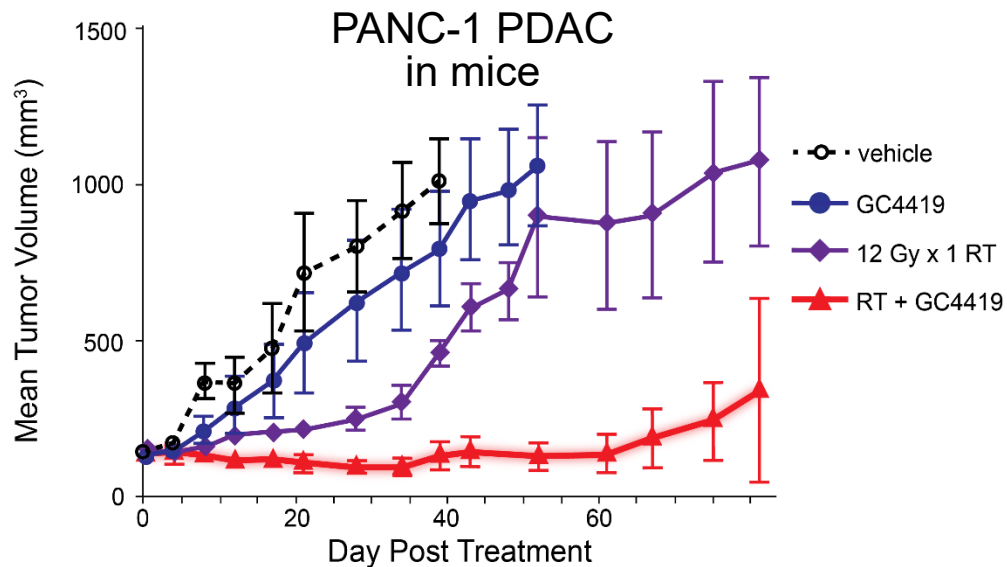
- RT anti-cancer synergy of GC4419 increases with bigger RT fractions
- Bigger fraction \rightarrow More $O_2^{\cdot-} \rightarrow$ More H_2O_2
- Also demonstrated with human pancreatic cancer xenografts



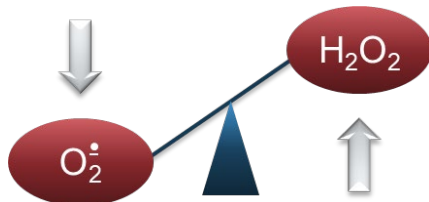
RT with Biological Equivalent Doses



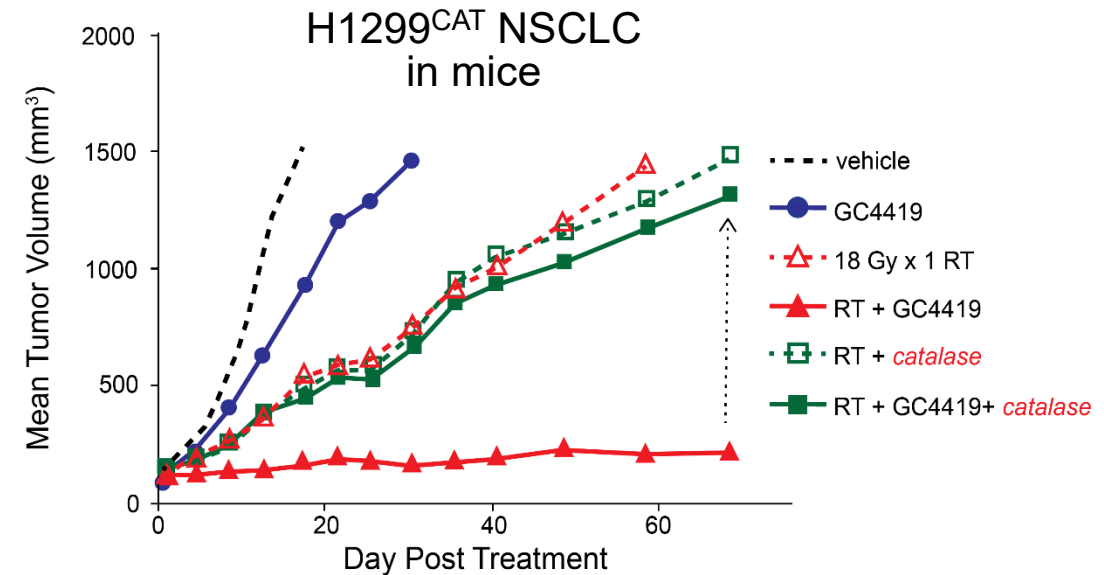
...Increasing Anti-Cancer Efficacy via H₂O₂



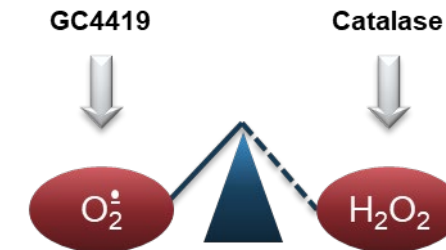
Larger RT fraction → more O₂[•]
Dismutase Mimetics → more H₂O₂



Genetically modified H1299 tumor with doxycycline-inducible catalase



Tumor tissue H₂O₂ reduced when doxycycline added, losing the synergy





Reducing Toxicity of IMRT – Clinical Data

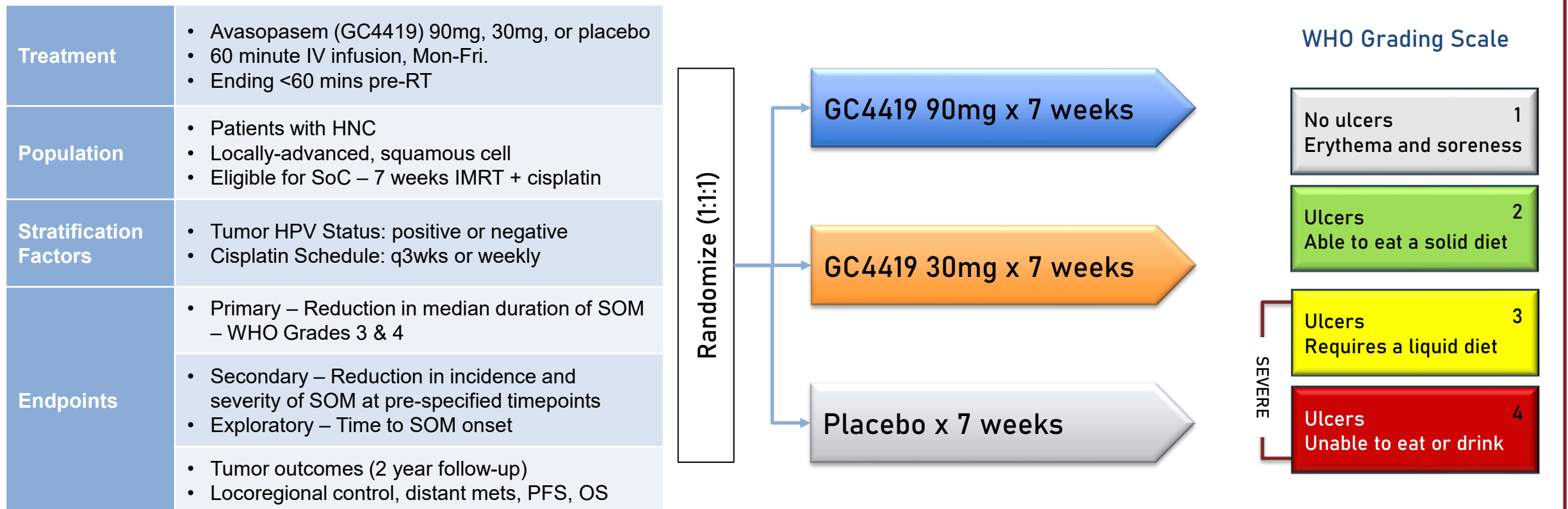
(Intensity Modulated Radiotherapy)



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

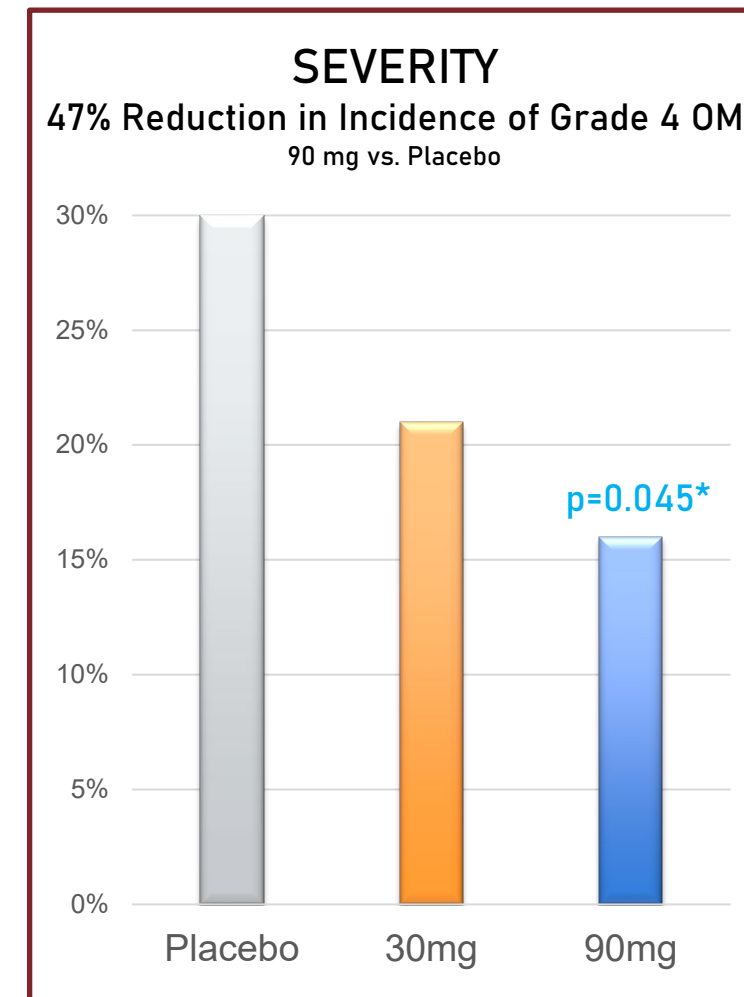
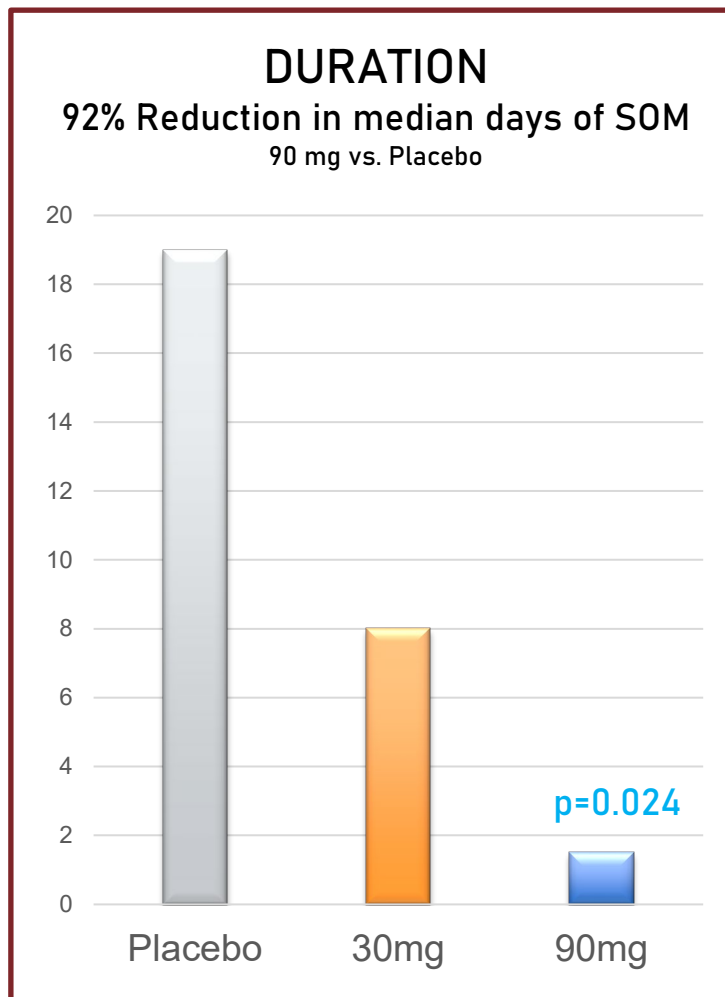
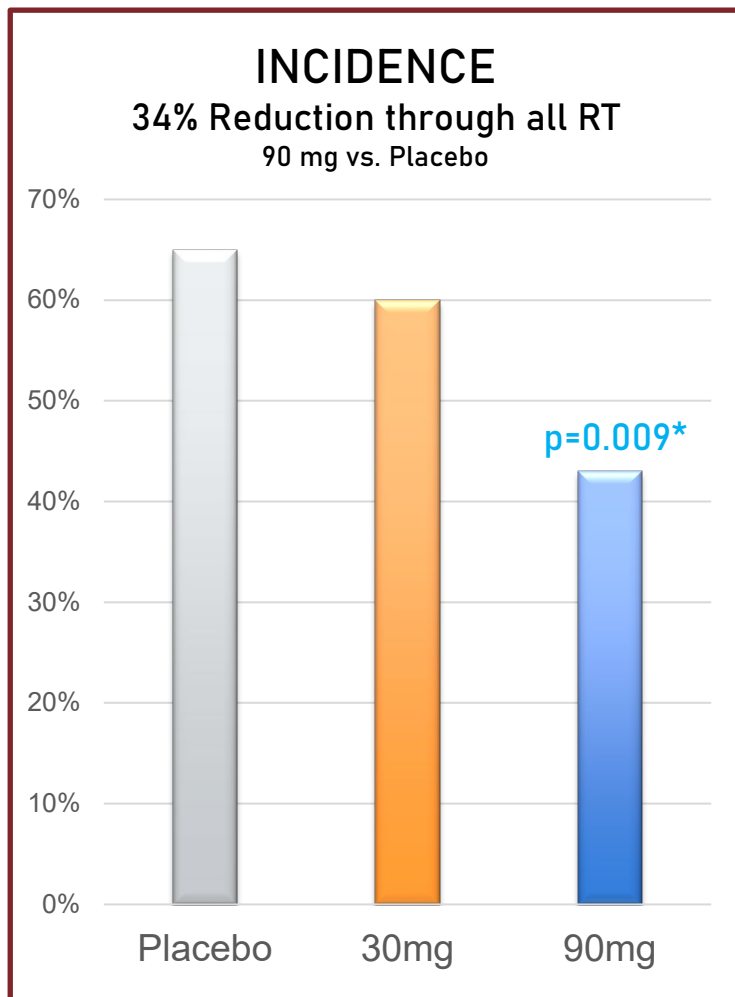
Supportive trial to the ROMAN Phase 3 for the NDA

Trial Design



Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg



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.)

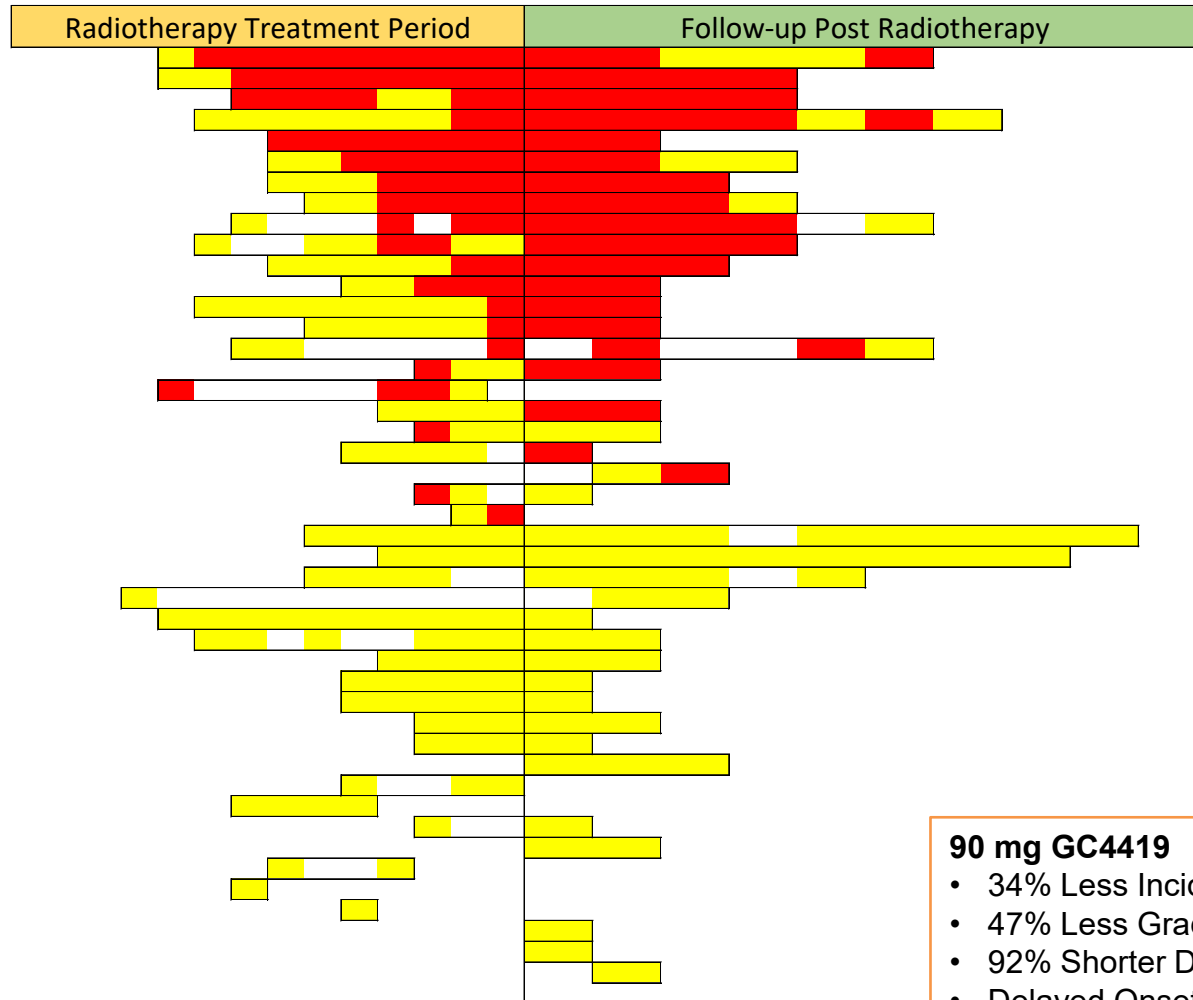
*Secondary endpoints (incidence and severity) have nominal p values compared to placebo

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

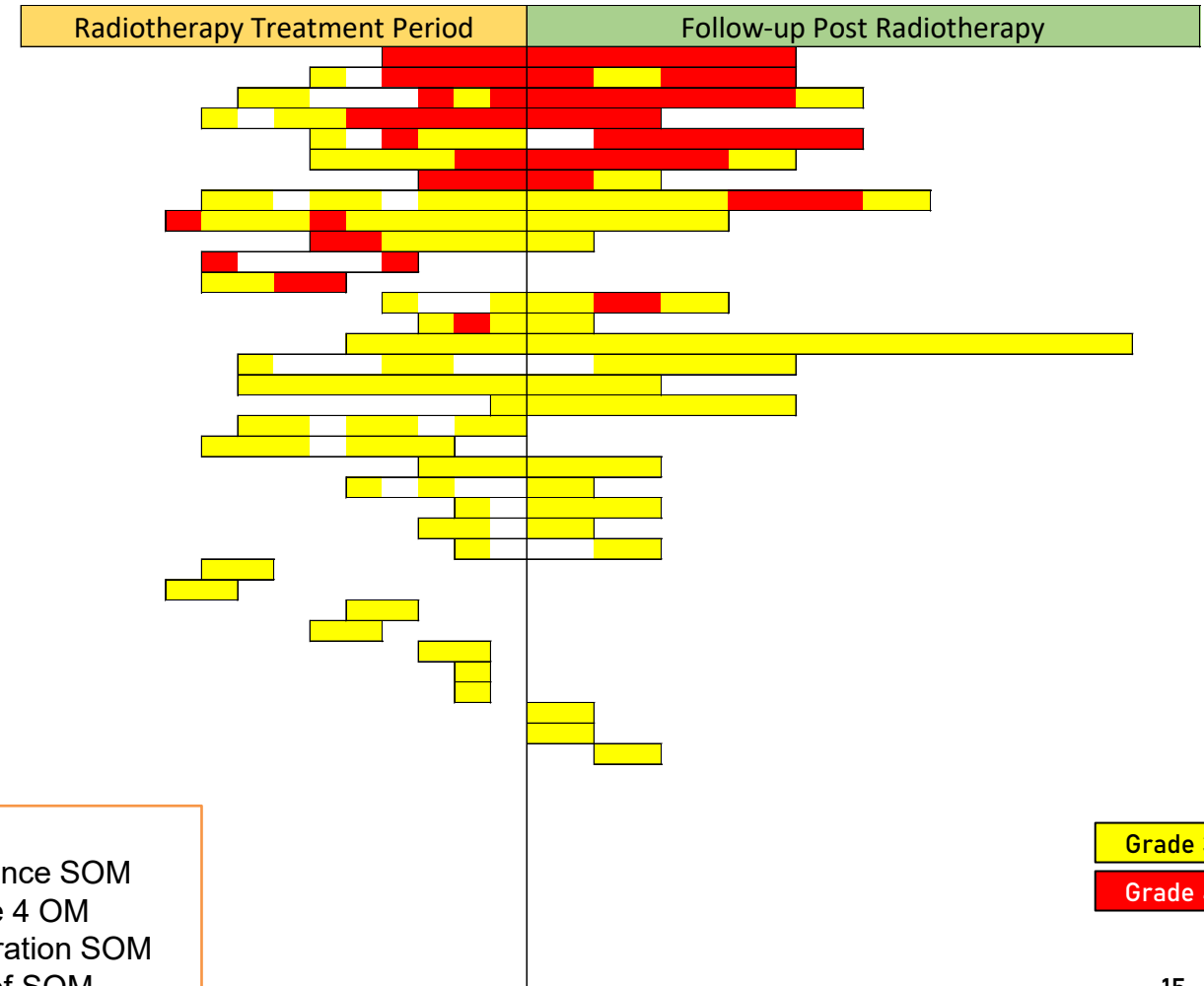
Efficacy Parameters Better on 90mg arm Compared to Placebo

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)



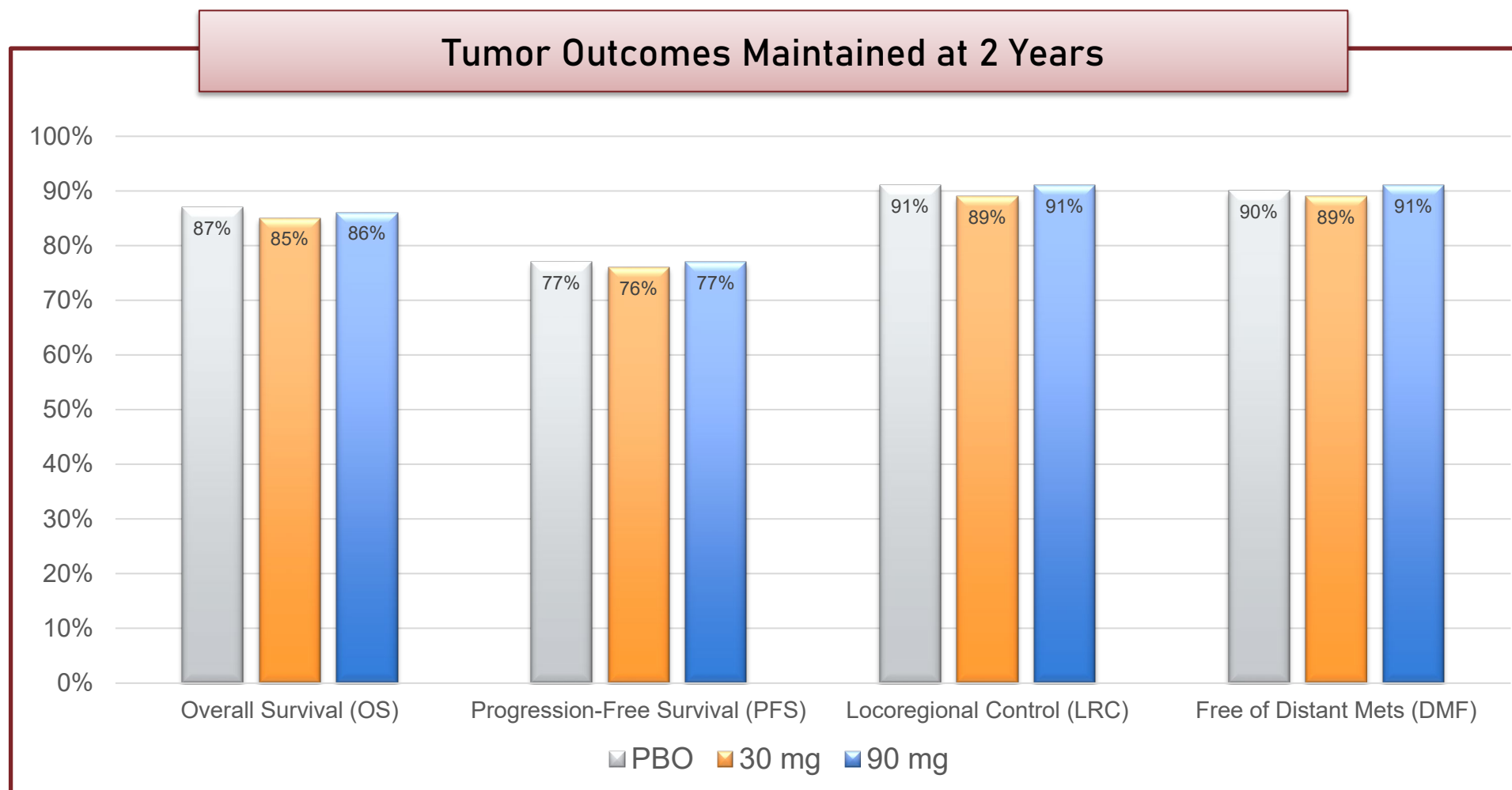
90 mg GC4419

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

Grade 3

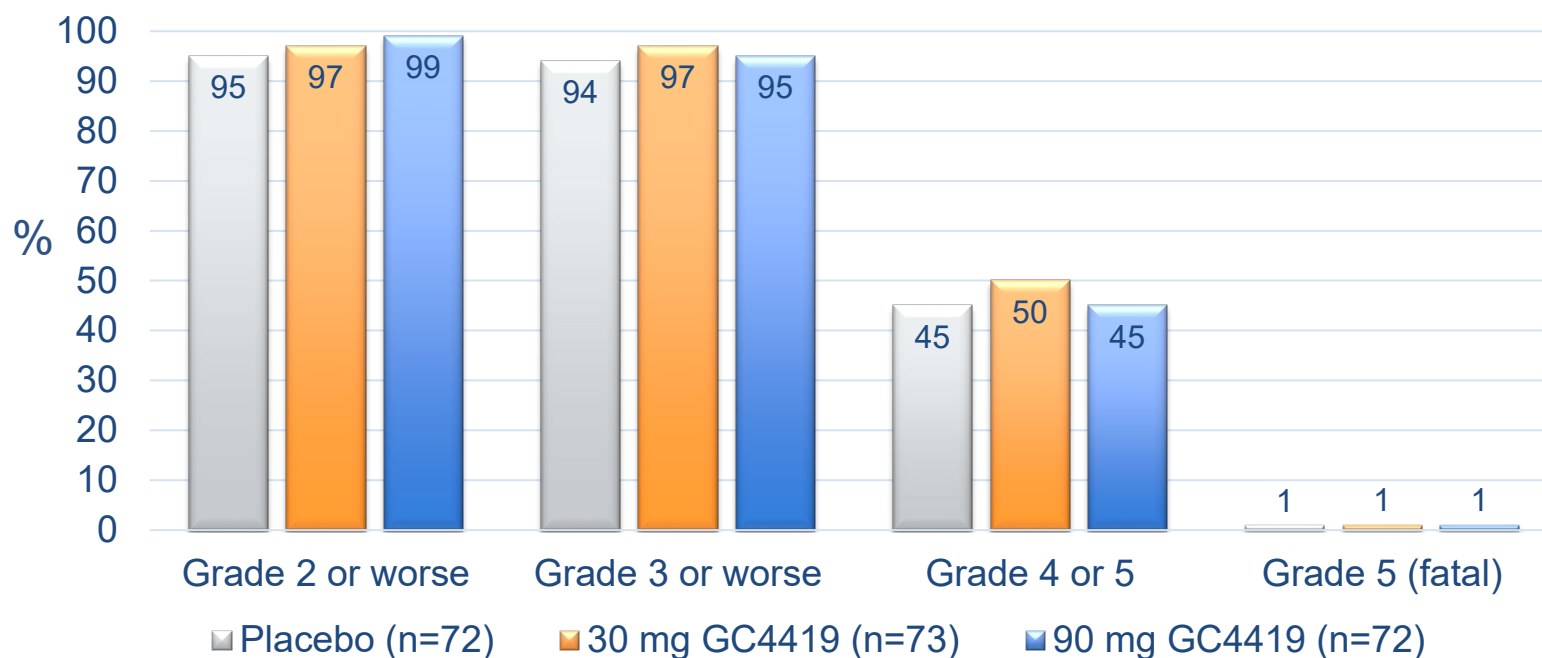
Grade 4

Tumor Outcomes Maintained - 2 year follow-up



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%

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

Reduction in Oral Mucositis with Avasopasem Manganese (GC4419)

Trial Design (n≈450 pts)

Treatment	<ul style="list-style-type: none"> Avasopasem (GC4419) 90mg or placebo 60 minute IV infusion, Mon-Fri Ending <60 mins pre-RT
Population	<ul style="list-style-type: none"> Patients with Head & Neck Cancer Locally-advanced, squamous cell Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	<ul style="list-style-type: none"> Surgery Status: post-op or definitive Cisplatin Schedule: q3wks or weekly
Endpoints	<ul style="list-style-type: none"> Primary – Reduction in incidence of SOM – WHO Grades 3 & 4 Secondary – Reductions in severity of SOM and number of days of SOM experienced Tumor outcomes¹ – LRC, DM-free, PFS, OS

Randomize (3:2)

GC4419 90mg x 7 weeks

Placebo x 7 weeks

WHO Grading Scale

No ulcers
Erythema and soreness 1

Ulcers
Able to eat a solid diet 2

Ulcers
Requires a liquid diet 3

Ulcers
Unable to eat or drink 4

SEVERE

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



Increasing SBRT Efficacy – Clinical Data

(Stereotactic Radiotherapy)



GC4419 + SBRT Pilot Phase 1/2 in Pancreatic Cancer

**SBRT
Combo
Pilot Trial**

Double-blind, Placebo-controlled, Randomized Adaptive Trial

- Enrollment of maximum of 24 patients on each arm (LO-ET¹ design)
- Primary objective is recommended dose of SBRT with GC4419 or placebo
- Secondary objectives include OS, PFS, local control, DM rate, ORR and surgical resectability

Patients Screened
After 6 months
of induction Chemo

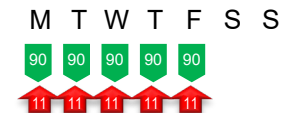
R

SBRT* + GC4419** x 5 doses

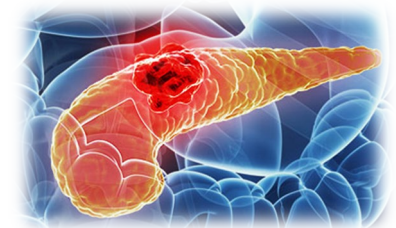
SBRT* + Placebo x 5 doses

Evaluated at 2,
3, 6 & 12 months

***SBRT** Dose Selected by
LO-ET Method on both arms



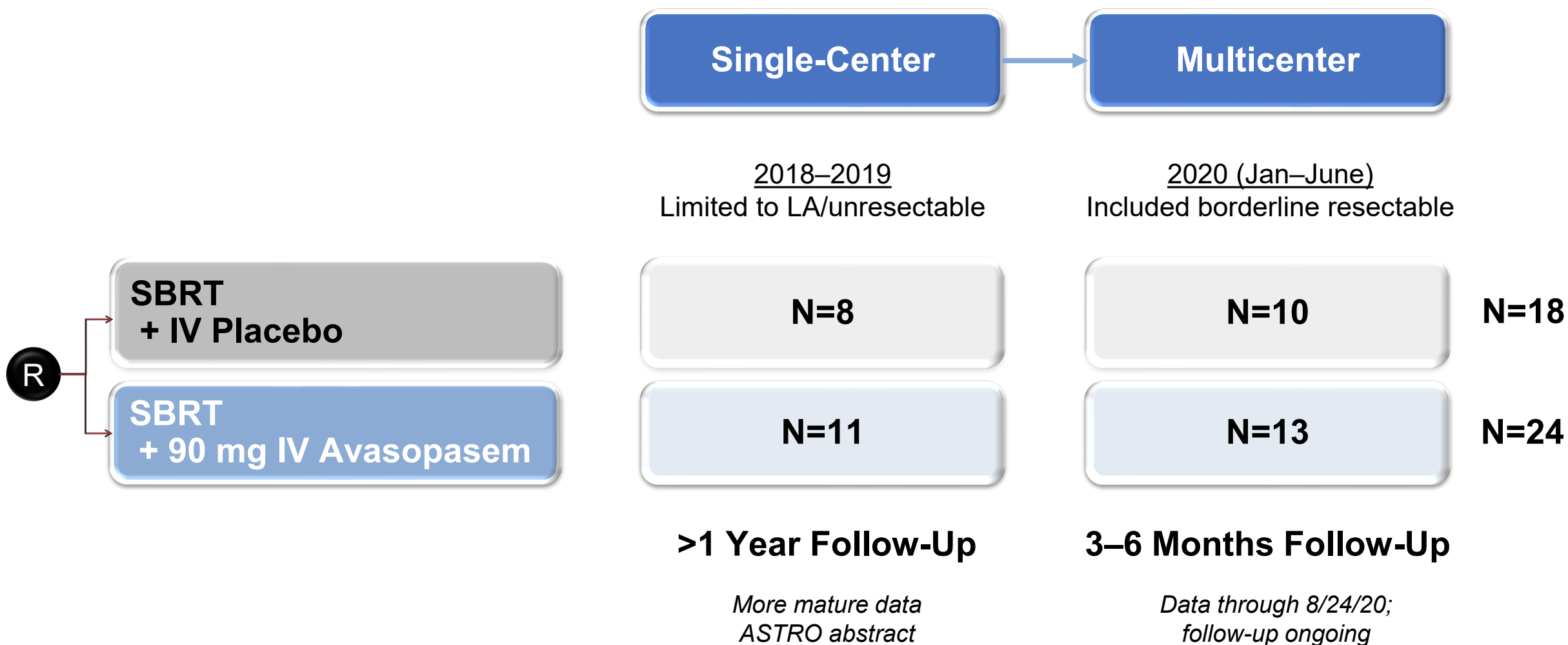
****GC4419** 60min IV
90mg x 5 doses



Baseline Characteristics

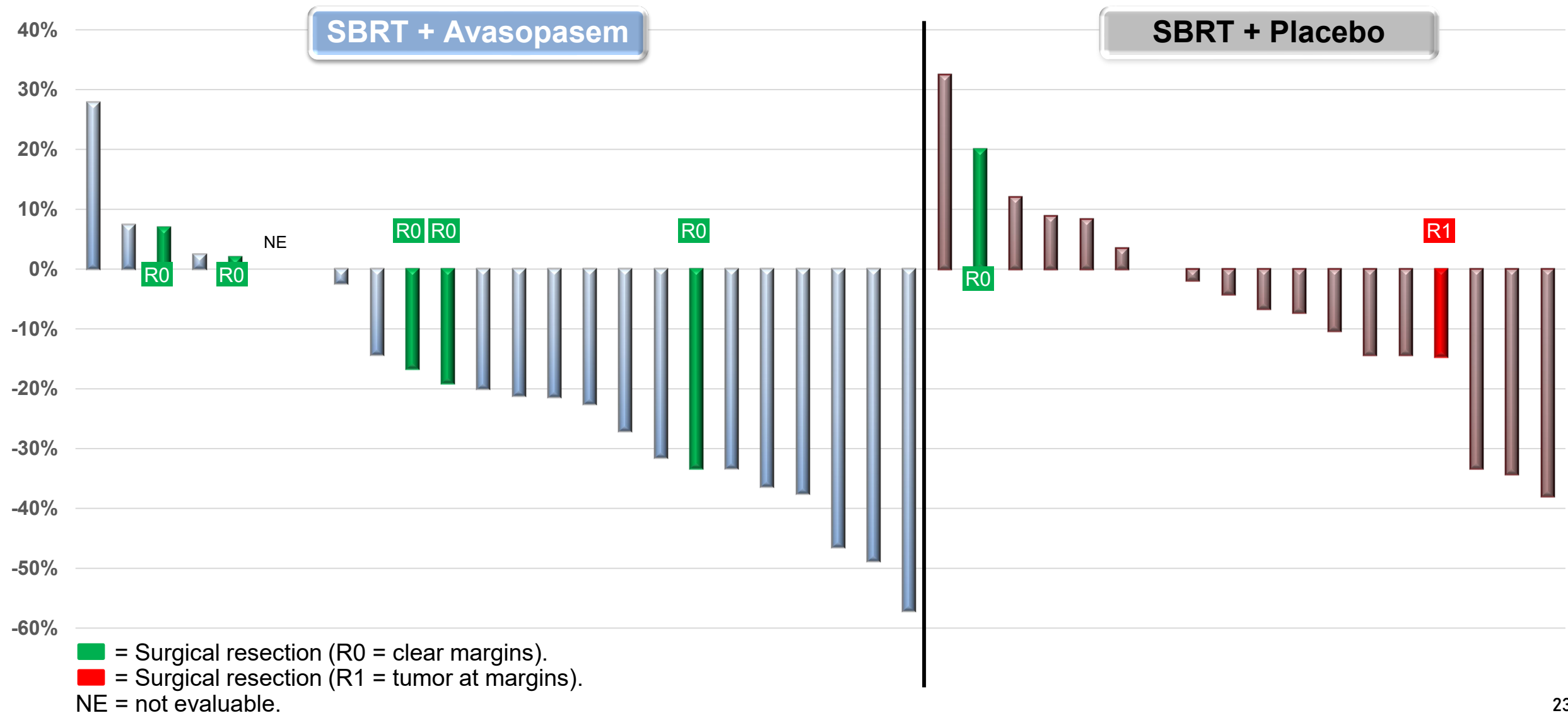
	Placebo (n=18)	Avasopasem (n=24)
Median age (range), yrs	68 (48–82)	72 (41–83)
Male/Female	7/11	16/8
Borderline resectable/Locally advanced	2/16	7/17
Performance status 0/1/2	9/9/0	12/11/1
Prior chemotherapy duration median (range), wks	21.9 (12.0–36.3)	17.9 (9.1–67.1)
CA19-9 at randomization, median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

Timeline - Pilot Trial in Pancreatic Cancer



Best Response from Baseline Tumor in SBRT Field

Data through August 24, 2020; follow-up ongoing



Patients Who Underwent Resection Post SBRT

Surgical Decision Based on Multiple Factors (n=7)

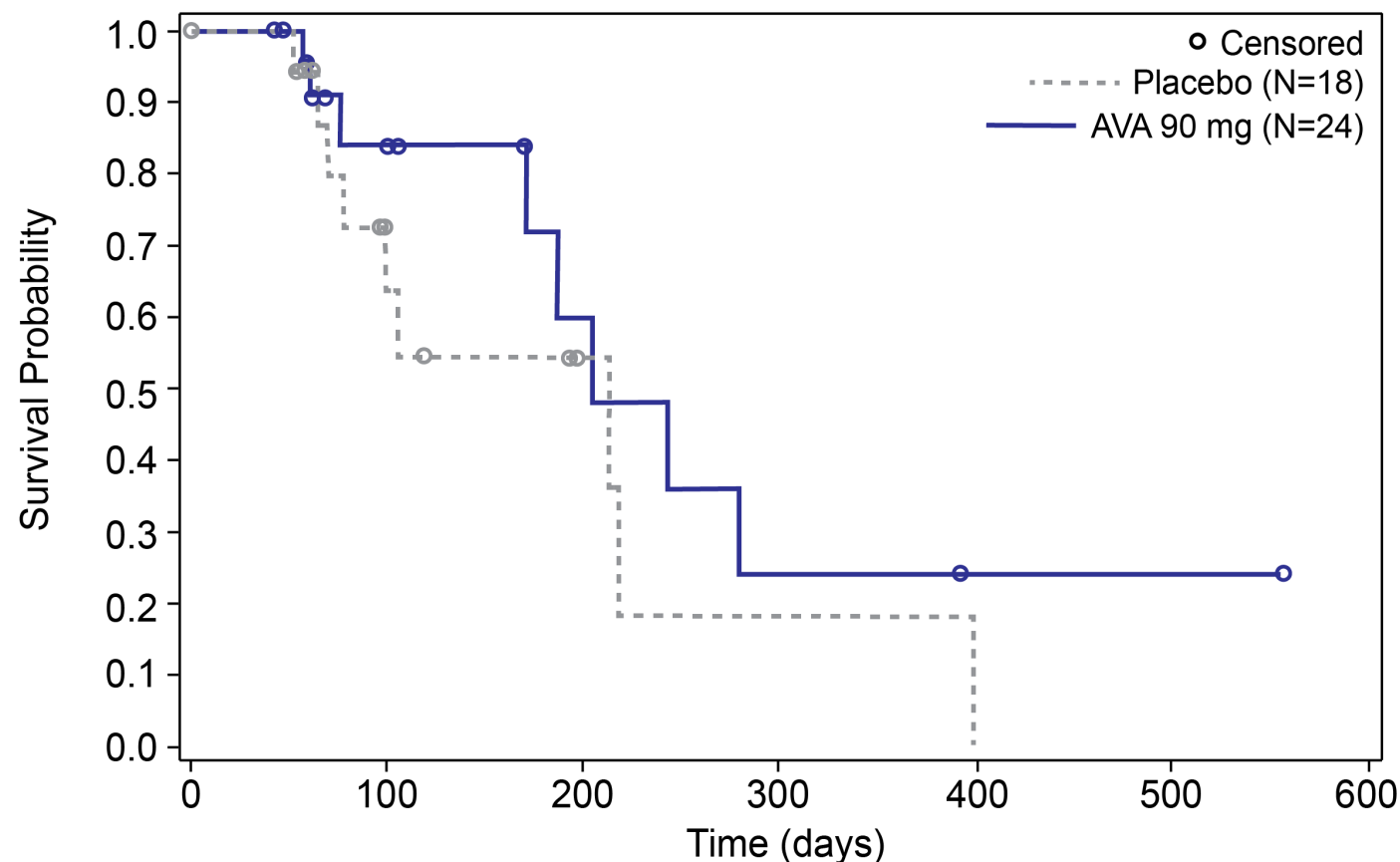
Treatment SBRT Arm	Initial Tumor Staging LA or BR		Margins Post Resection R0/R1		Histopath Analysis Post Resection		
Avasopasem (n=5)	LA		R0		pCR		
		BR	R0				pPR
		BR	R0				pPR
		BR	R0				pPR
	LA		R0				pPR
Placebo (n=2)		BR	R0				pPR
	LA			R1		pNR	

- No significant perioperative complications after SBRT for all 7 patients

AVA/PBO = avasopasem or placebo arm; LA/BR = locally advanced or borderline resectable; pCR/pNR/pPR = pathological complete, near, or partial response; R0/R1 = resectable results: R0 = clear margins; SBRT = stereotactic body radiation therapy.

Progression-Free Survival From Randomization (N=42)

Kaplan-Meier Analysis of PFS by Treatment (ITT)—Resected Patients Censored at Time of Surgery



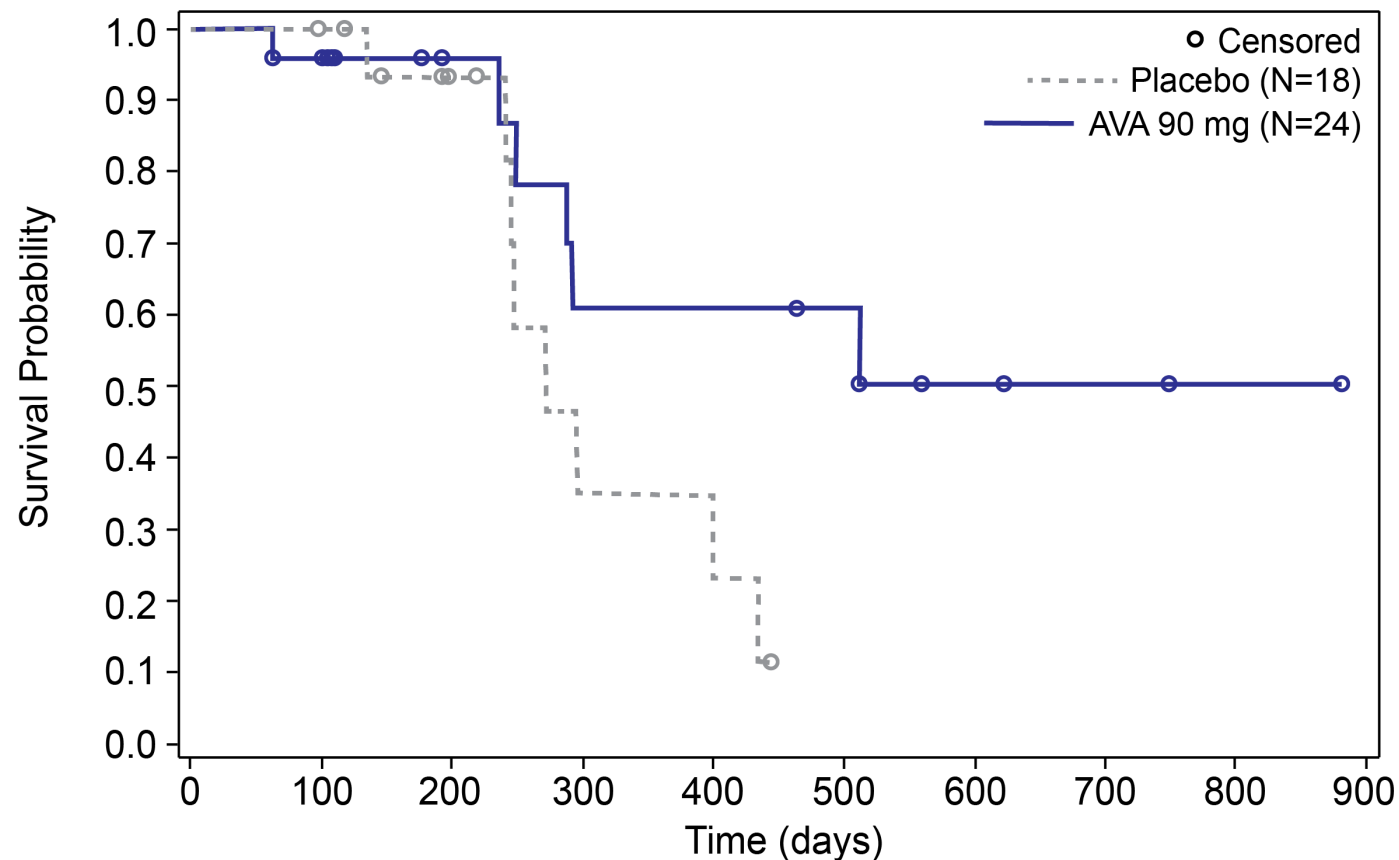
	Placebo (n=18)	Avasopasem (n=24)
Median PFS (wks)	30.6	29.3
<i>P</i> value (log-rank)	0.2852	
Hazard Ratio (95% CI)	0.6 (0.23–1.56)	

Number of Patients at Risk

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

Overall Survival From Randomization (N=42)

Kaplan-Meier Analysis of OS by Treatment (ITT)



	Placebo (n=18)	Avasopasem (n=24)
Median OS (wks)	38.7	NR
<i>P</i> value (log-rank)	0.0643	
Hazard Ratio (95% CI)	0.4 (0.12–1.11)	

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

Grade 3+ Adverse Events

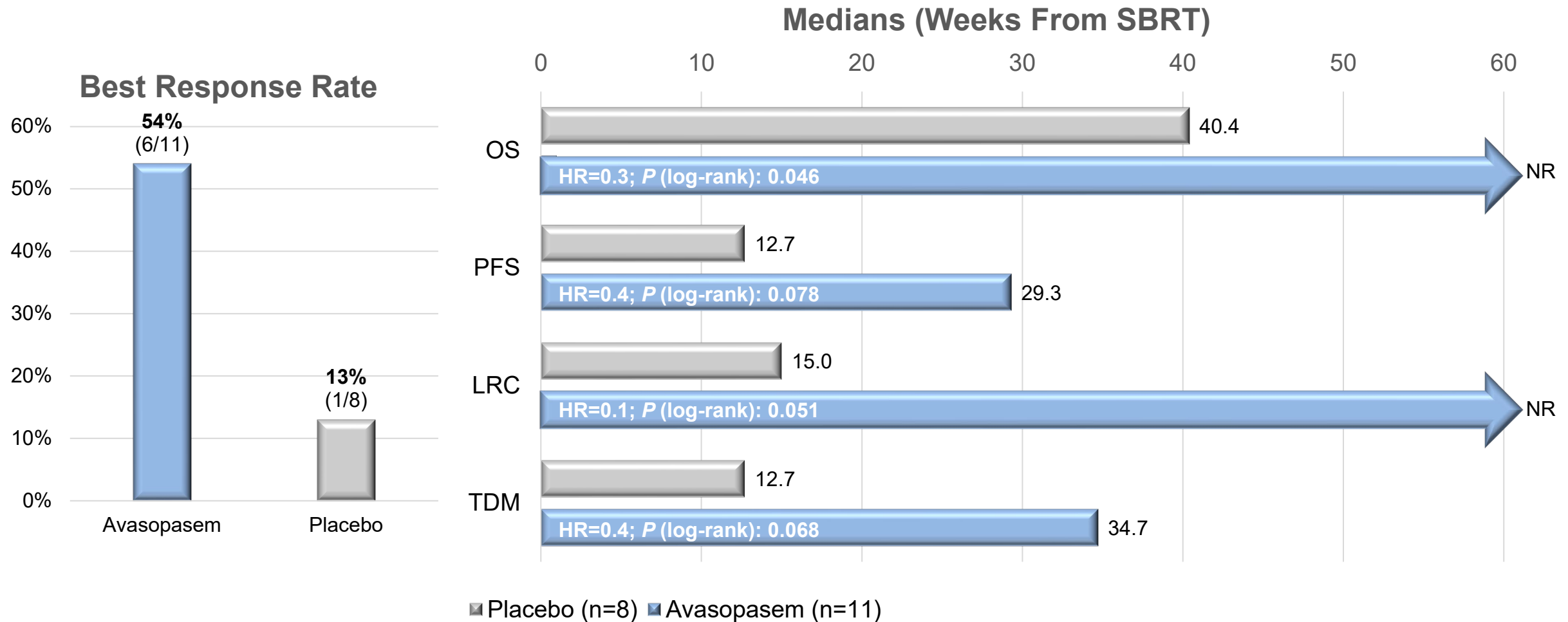
All Causalities

	Placebo (n=18)	Avasopasem (n=24)
Acute Adverse Events (up to 90 days post SBRT)		
• Any acute Grade 3+ AEs, n (%)	4 (22)	6 (25)
• Grade 3 or greater acute GI toxicity ^a	2 (11)	2 (8)
• Total number of Grade 3+ acute AEs	5	8
Late Adverse Events (91 days–1 year post SBRT)		
• Any Grade 3+ AEs, n (%)	5 (28)	7 (29)
• Total number of Grade 3+ late AEs	12	10

^aNo bleeding ulcers by 12-week endoscopy.

AE = adverse event; GI = gastrointestinal.

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

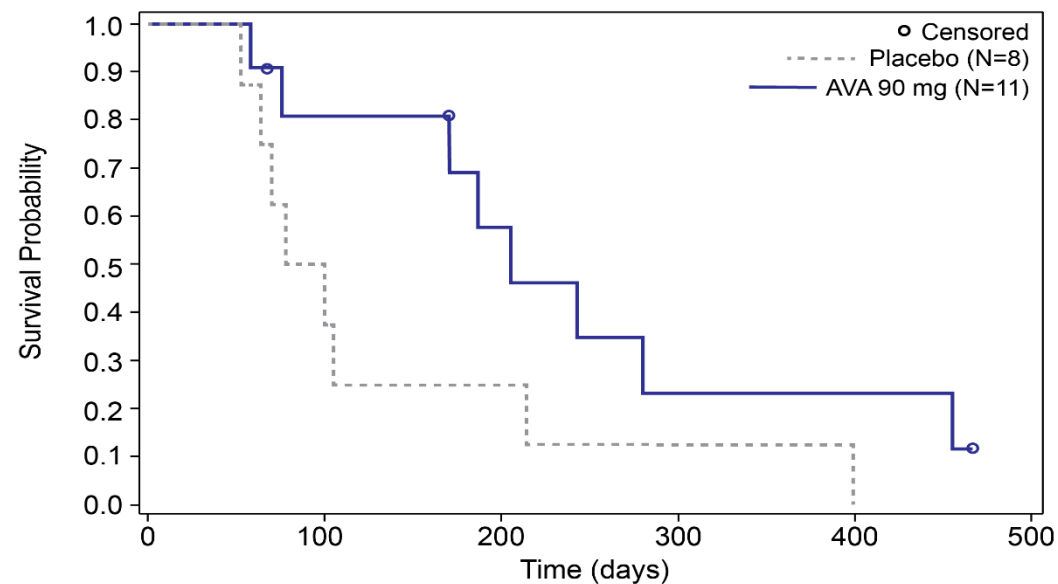


HR = Hazard ratio; LRC = locoregional control; OS = overall survival, PFS = progression-free survival, TDM = time to distant metastases.

Kaplan-Meier Analysis for Patients Followed for >1 Year

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

Progression-Free Survival (PFS)

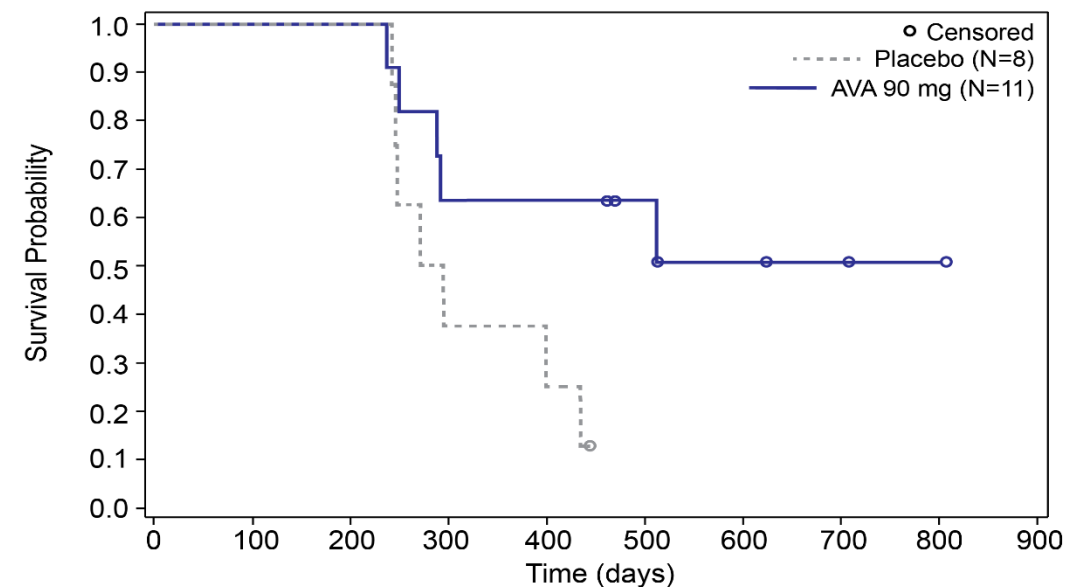


Number of Patients at Risk

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

Log Rank *P* value = 0.078

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

Log Rank *P* value = 0.0463

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

GC4711

GC4711 – SBRT Clinical Candidate

- Same mechanism of action as avasopasem (GC4419), with IV & oral forms
- NCE with new IP & lyophilized drug product
- Completed 14-day Phase 1 in healthy volunteers: 15-minute infusion

NSCLC

Non-Small Cell Lung Cancer (NSCLC)

- Leading cause of cancer death in US – 142,670 deaths in 2019¹
- SBRT commonly used for smaller peripheral tumors
- Lung toxicity limits use in larger or centrally-located tumors



Pilot Study

Phase 1/2 in NSCLC with GC4711 + SBRT

- 1st Stage: 5 fractions of SBRT +/- GC4711
- 2nd Stage: 5 fractions of SBRT + checkpoint inhibitor +/- GC4711
- Endpoints include safety, acute pneumonitis (DLCO²) & PFS

¹ 2019 SEER Data

² DLCO = diffusing capacity of the lung for carbon monoxide



Commercial Considerations



Large Commercial Opportunity Addressing Clear Unmet Need

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 uptake²

SOM clear
unmet need

70% get SOM

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

70% of patients get SOM (Grades 3 & 4) with standard-of-care RT & 20-30% get Grade 4

SOM common
& costly

~\$32,000

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

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

OM data
representative
for all
mucositis

4,000 Rad Oncs

~2,500 radiotherapy sites in US
~60% of patients are treated in ~500 centers¹

Market research suggests rad oncs view OM data as representative of efficacy in esophagitis

Targeted
salesforce
In U.S.

~40 Reps

Focused commercial infrastructure

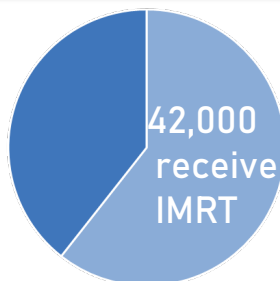
~40 reps for the 4,000 radiation oncologists in U.S.

Evaluating options for commercialization outside U.S.

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

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

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	✗

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 esophagitis¹
- ~50,000 lung cancer patients are treated with RT, 50% get \geq Grade 2 esophagitis²
- 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 \geq 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.



50%

Esophagitis

Patients at risk of experiencing
radiation induced esophagitis

Market Research Question Patients with Other Conditions¹

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?

¹Galera Market Research (150 Radiation Oncologists)

² NCI or RTOG grading scales

LAPC – Unmet Medical Need with Limited Treatment Options

Target Treatment Population

Increasing Number of Pancreatic Cancer Patients Diagnosed Each Year

- 57,000 newly diagnosed/year¹
 - 65% of Stage 2: unresectable (UR) or borderline resectable (BR) at Diagnosis
 - 85% of Stage 3: UR or BR at Diagnosis
- } 18,000 Pts²

Novel Therapies Needed

First Line Treatment is Induction Chemotherapy for Over 80% of Patients²

- FOLFIRINOX or Gemcitabine/Abraxane most commonly used³
- 60% of patients fail induction therapy within 12 months⁴
- 60% on FOLFIRINOX develop Grade 3-5 toxicity⁴

SBRT is Accepted Tx Option

NCCN Recommends SBRT for some Patients with Locally Advanced Pancreatic Cancer (LAPC)⁵

- For loco-regional recurrence after surgical resection
- 1st line option for locally advanced cancer
- 1st or 2nd line option after 4-5 months of chemotherapy

¹ 2019 SEER Data ² Derived from Kantar CancerMPact Treatment Architecture Report, October 2017.

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



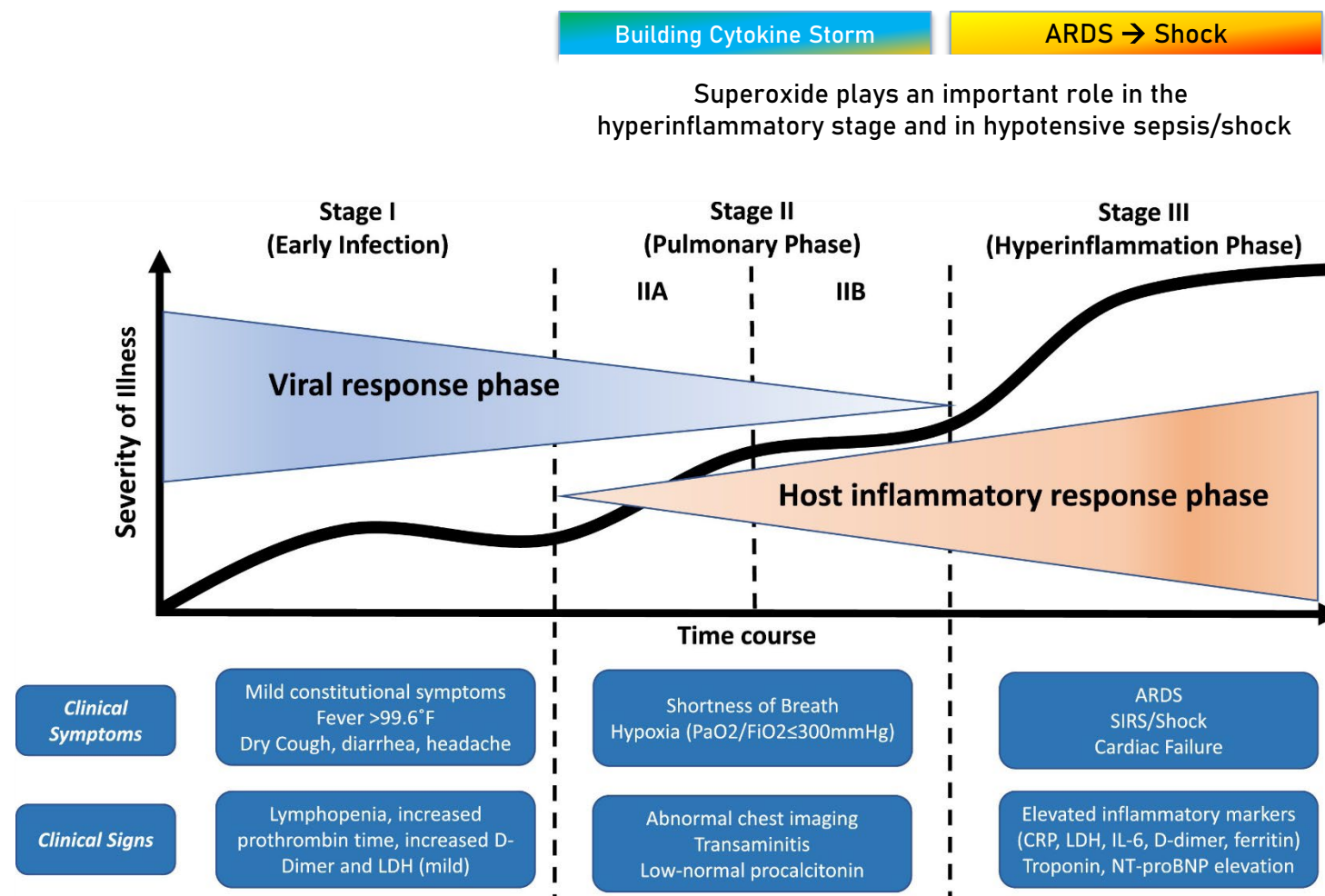
COVID-19 Trial



Role of Superoxide in Late Stages of COVID-19 Infection

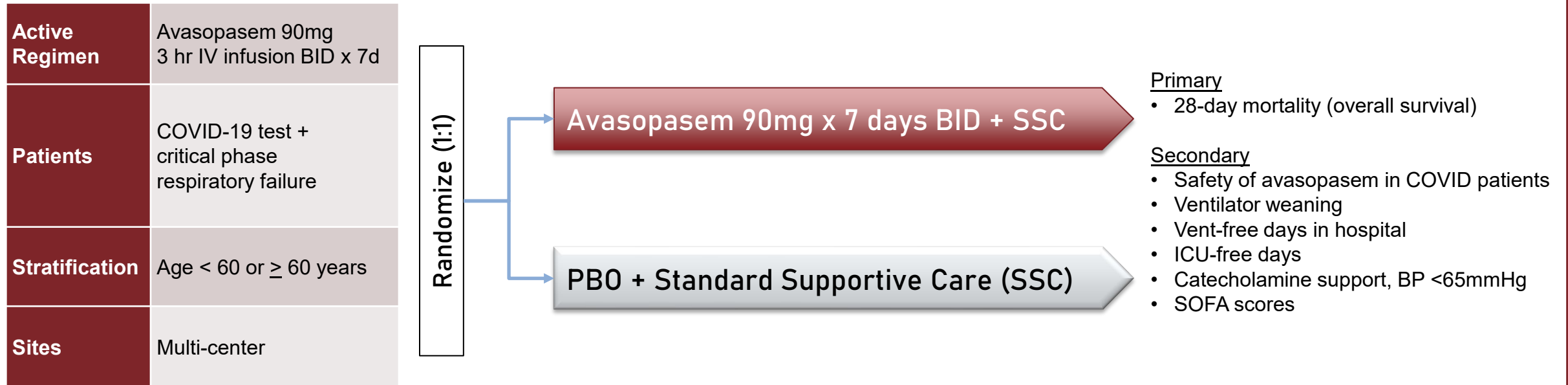
Superoxide plays a central role in pathophysiology of acute respiratory distress syndrome (ARDS)

- Causes endothelial cell damage & increased microvascular permeability
- Promotes formation of chemotactic factors such as leukotriene B4
- Causes lipid peroxidation and DNA single-strand damage
- Forms peroxynitrite (ONOO-) a potent cytotoxic proinflammatory molecule
- Galera's dismutase mimetics inhibited these effects and inflammatory cytokine production in animal ARDS models & in E. coli LPS-stimulated alveolar macrophages



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

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

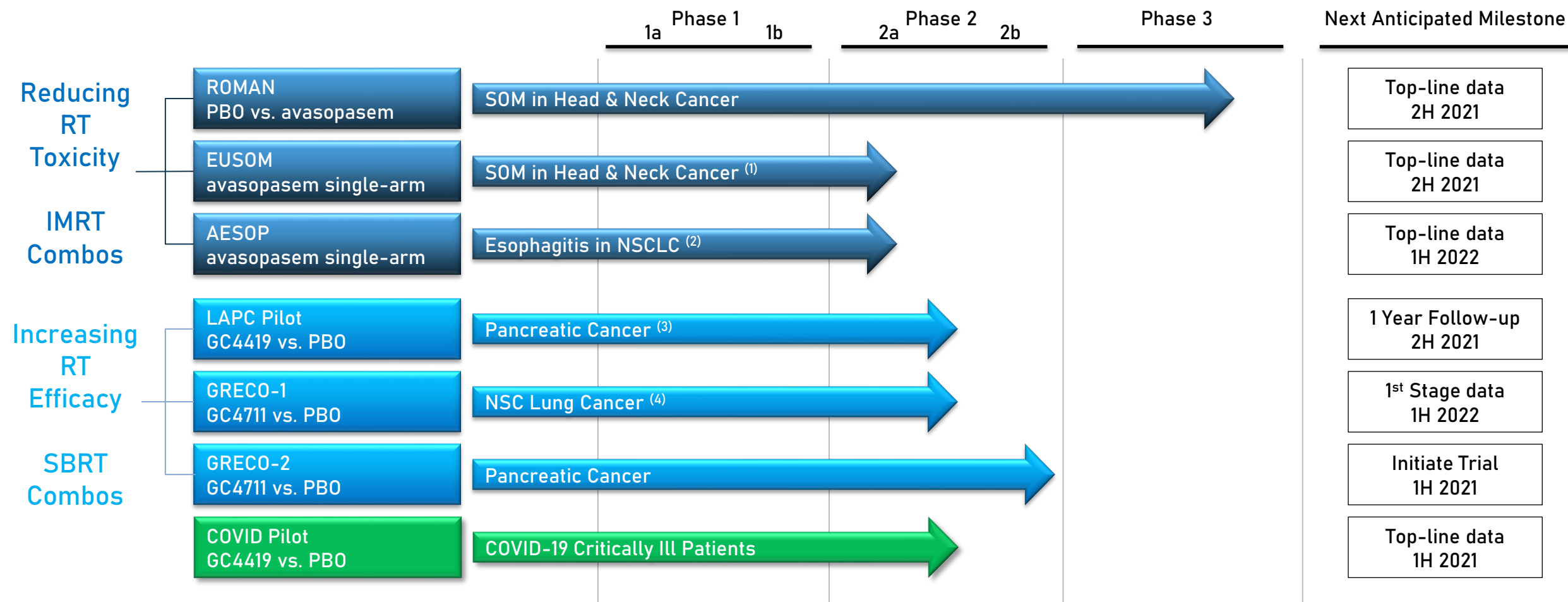




Summary



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. 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.

Superoxide Dismutase Mimetics – Vision

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

Over half of cancer patients
receive radiotherapy
as part of their care^{1, 2}

Increase H_2O_2 in tumors

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

Transforming Radiotherapy with Dismutase Mimetics

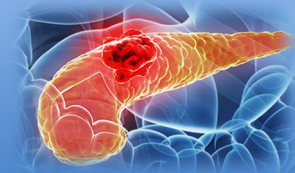
SBRT

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

Normal tissue toxicity limits
optimal radiotherapy treatment of tumor

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