UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 6, 2021

GALERA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39114	46-1454898
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

2 W Liberty Blvd #100
Malvern, PA 19355
(Address of principal executive offices) (Zip Code)

(610) 725-1500
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**GRTX**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

Galera Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On January 6, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at *www.galeratx.com*. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information contained in Item 7.01 of this Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Corporate Slide Presentation of Galera Therapeutics, Inc. dated January 6, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GALERA THERAPEUTICS, INC.

Date: January 6, 2021

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
President and Chief Executive Officer

Exhibit 99.1

Galera Therapeutics, Inc

Transforming Radiotherapy

with

Dismutase Mimetics

January 2021

Disclaimers and Forward-Looking Statements

Certain information contained in this presentation and statements made orally during this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and Galera's own internal estimates and research. While Galera believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. While Galera believes its internal research is reliable, such research has not been verified by any independent source.

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, the safety, efficacy, regulatory and clinical progress, and therapeutic potential of current and prospective product candidates, plans and timing for the commencement of and the release of data from clinical trials, our plans to prepare for commercialization and a US launch, the anticipated direct and indirect impact of COVID-19 on Galera's business and operations, planned clinical trials and preclinical activities, potential product approvals and related commercial opportunity, current and prospective collaborations, and timing and likelihood of success, plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The information in this presentation, including without limitation the forward-looking statements contained herein, represent our views as of the date of this presentation. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. The forward-looking statements in this presentation involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the drug development process and the regulatory approval process, our reliance on third parties over which we may not always have full control, and other important risks and uncertainties that are described in Galera's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC), Annual Report on Form 10-K for the year ended December 31, 2019 and Galera's other filings with the SEC. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

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 AESOP

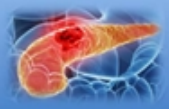
Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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 2b GRECO-2	Phase 1b/2 GRECO-1

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*

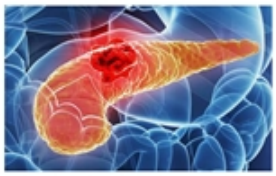
Corporate Highlights

Reducing IMRT Toxicity

Phase 3 ROMAN Results with Avasopasem
- Severe Oral Mucositis in Head & Neck Cancer
- Robust Phase 2b data → Breakthrough Therapy Designation

Increasing SBRT Efficacy

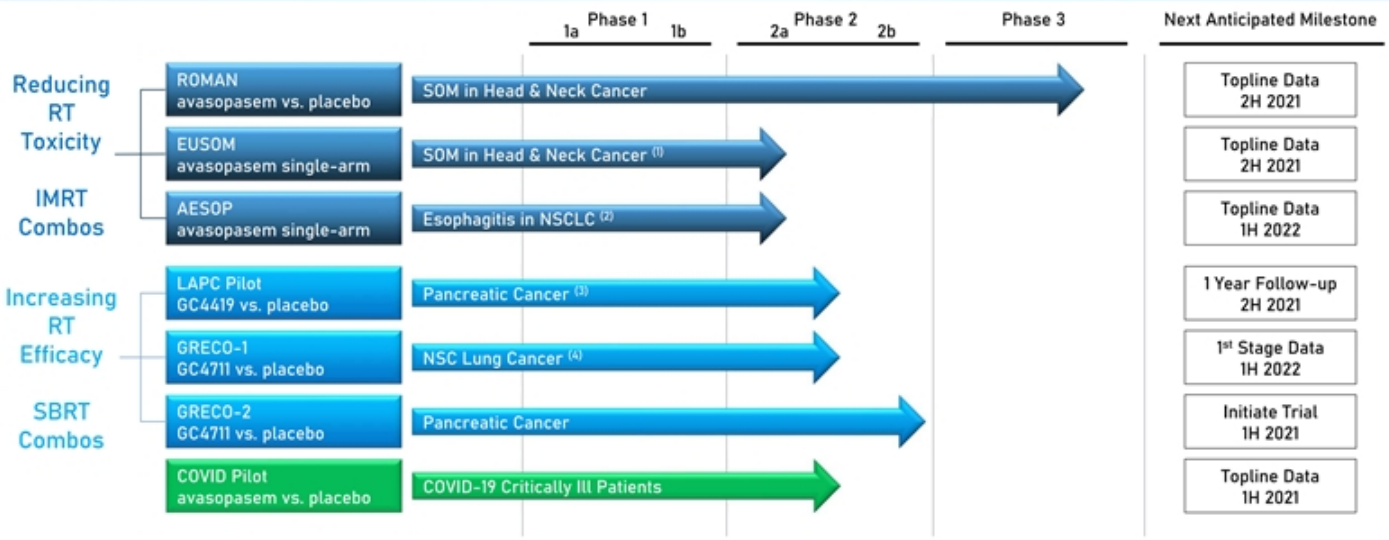
Complete Survival Results from Pancreatic Cancer Pilot
- 1-Year data on all patients from randomized LAPC trial
- Promising data from this trial was presented in 2020



Planning US Launch

Large Market Opportunities with High Unmet Medical Need
- Building commercial team for US launch of avasopasem
- US Target Patient Population of Lead Indication is 42,000

Clinical Stage Pipeline



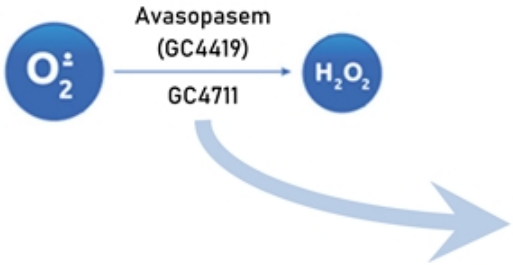
(1) EUSOM is a single-arm multi-center trial evaluating the safety of avasopasem in patients with HNC in Europe.
(2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC.
(3) This first SBRT combination trial used GC4419 (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.

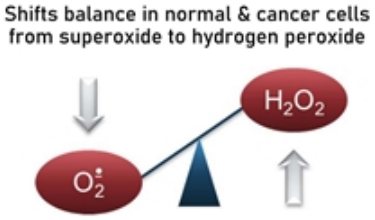
Unique Technology

Dismutase Mimetics

Small Molecule Enzyme Mimetics

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





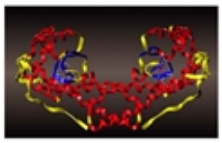
$O_2^{\bullet}$ more damaging to normal cells than cancer cells

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

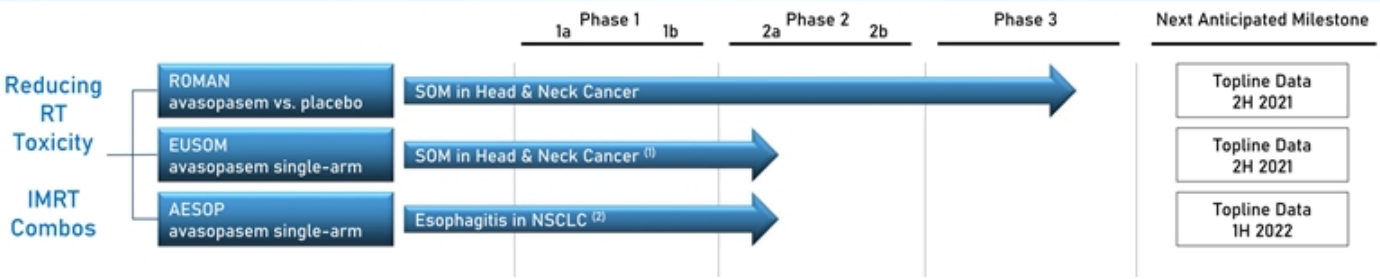
Speed	Selectivity	Stability	Safety	Synthesis
Comparable to native SODs ($2x10^7$ molecules per sec)	Interact with superoxide alone, not other reactive oxygen species	Firmly hold Mn atom in macrocyclic ring	Well-tolerated preclinically and clinically	Efficient & cost-effective manufacturing process

Galera Therapeutics, Inc

Reducing IMRT Toxicity

(Intensity Modulated Radiotherapy)

Reducing IMRT Toxicity – Large Unmet Medical Need



US Market Potential

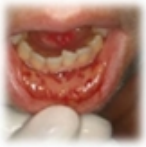
Cancer	US Target Patient Population			
	Annual Incidence	Target Indication	Subset	Patients
Head & Neck Cancer	65,000	Severe Oral Mucositis	Locally Advanced	42,000
NSC Lung Cancer	175,000	Esophagitis	Central Tumors	50,000

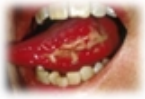
(1) EUSOM is a single-arm multi-center trial evaluating the safety of avasopasem in patients with HNC in Europe.
(2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC.

Severe Oral Mucositis in HNC – Large Unmet Medical Need

Large Target Patient Population (42K)

- ~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 Gr. 4 (can't eat or drink)
- No approved drug available





SOM 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
Ulcers Unable to eat or drink	4

SEVERE

Lack of Efficacy with Current Treatments

MASCC / ISOO Guidelines for HNC OM

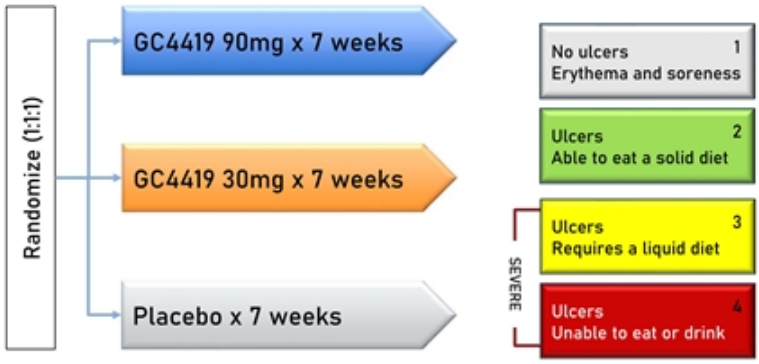
Treatment Approach	Recommended for HNC OM due to RT?
Basic oral care	✓
Anti-microbials, coating agents, anesthetics, & analgesics (0.2% morphine mouthwash)	✓
Anti-inflammatories, benzydamine	?
Low level laser & other light therapy	?
Cryotherapy for 5-FU chemotherapy	✗
Natural & other agents	✗

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

Supportive trial to the ROMAN Phase 3 for the NDA

Trial Design

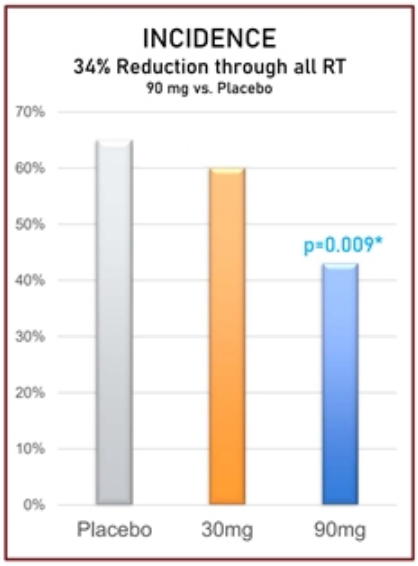
Treatment	• Avasopasem (GC4419) 90mg, 30mg, or placebo • 60 minute IV infusion, Mon-Fri. • Ending <60 mins pre-RT
Population	• Patients with HNC • Locally advanced, squamous cell • Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	• Tumor HPV Status: positive or negative • Cisplatin 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

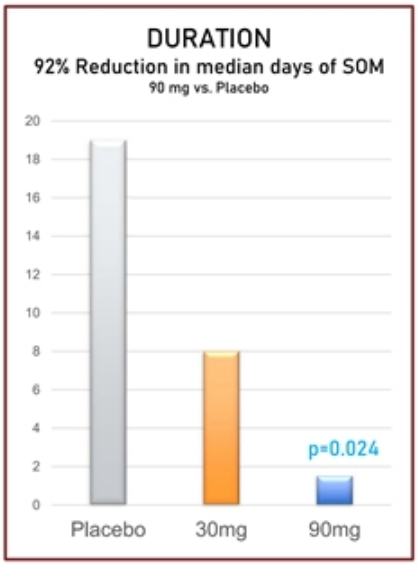


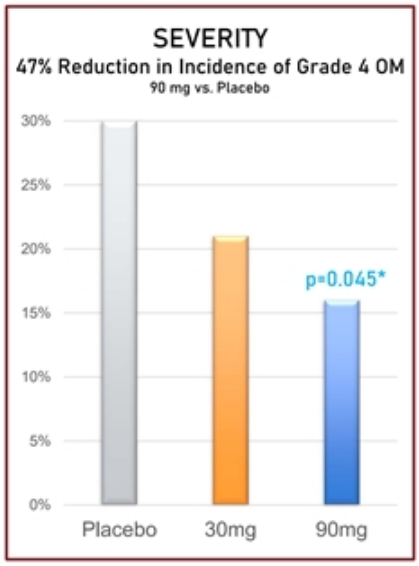
Anderson et al, JCO, 2019

Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg







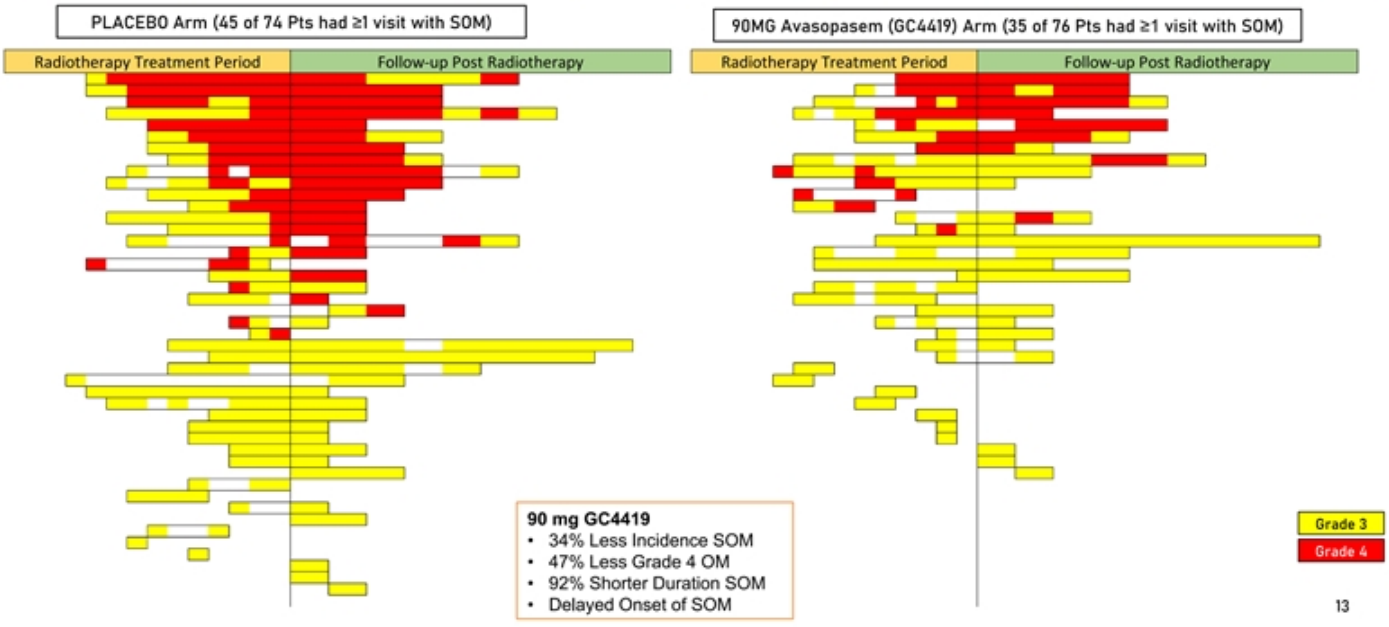
Primary endpoint was duration - defined as # days from 1st occurrence of grade 3 or 4 SOM until the 1st event of grade 2 or less (there being no subsequent grade 3 or 4 events.)

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

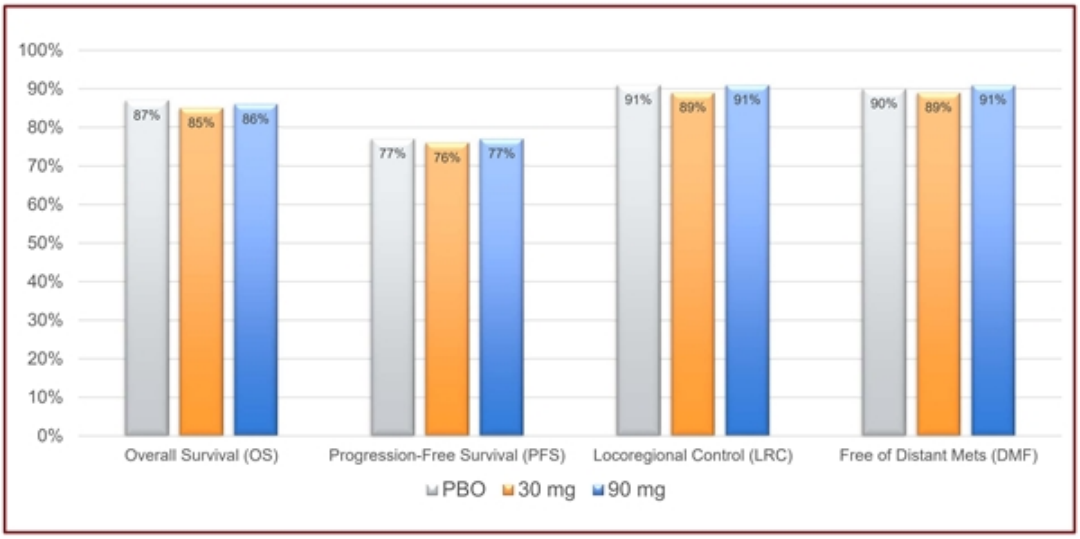
ITT = Intent-To-Treat population (n=223)

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



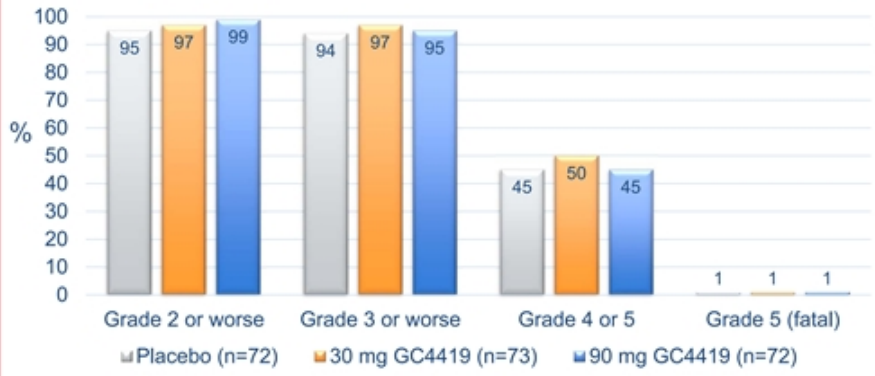
Tumor Outcomes Maintained – 2 year follow-up



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

Safety Summary – Randomized 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%

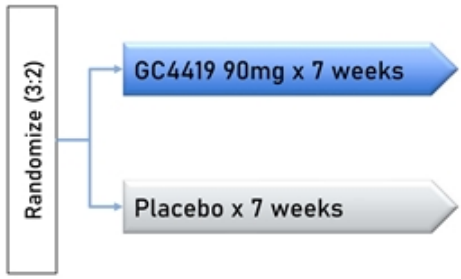
Anderson et al, J Clin Oncol 2019 Dec 1; 37(34):3256-3265

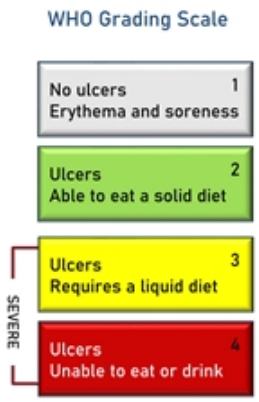
ROMAN: Phase 3 Confirmatory Trial Enrolling

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





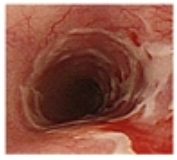
[1] LRC = locoregional control, DM-free = free of distant mets, PFS = Progression-Free Survival, OS = Overall Survival

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

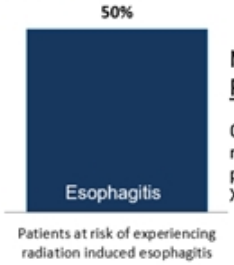


Compendial Listing

AESOP: 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

Large Commercial Opportunities Addressing Clear Unmet Needs

Severe Oral Mucositis & Esophagitis

Galera Therapeutics, Inc

Severe Oral Mucositis Head & Neck Cancer	IMRT Centers Have Infusion Capabilities	SOM Common and Costly	Targeted Salesforce in U.S.	Esophagitis in Lung Cancer
42k Patients	**77% of Centers[1]**	**~$32,000**	**~40 Reps**	**50k Patients**
Radiation oncologists report severe oral mucositis is most burdensome side effect of HNC RT treatment	37% IMRT centers currently infuse drugs Additional 40% coordinate with medical oncology to infuse patients	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	Focused commercial infrastructure ~2,500 RT sites in US ~60% of patients are treated in ~500 centers[2]	50% IMRT Patients get ≥ Grade 2 esophagitis[3] SOM efficacy seen by radiation oncologists as supportive for esophagitis[4]

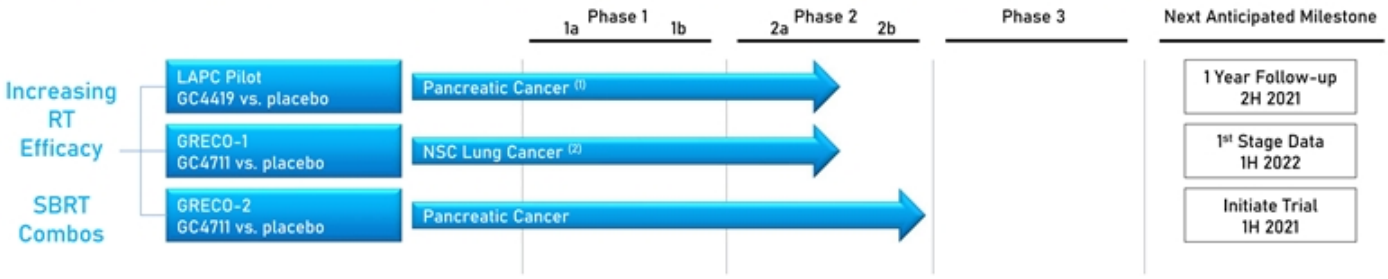
[1]Primary market research with 67 IMRT centers in the US [2]Medicare Claims Analysis by Galera in 2019 [3]NCI or RTOG grading scales, [4]Galera Market Research (150 Radiation Oncologists), SOM = Severe Oral Mucositis

Galera Therapeutics, Inc

Increasing SBRT Efficacy

(Stereotactic Radiotherapy)

Increasing SBRT Efficacy– Large Unmet Medical Need



US Market Potential

Cancer	US Target Patient Population		
	Annual Incidence	Subset	Patients
Pancreatic Cancer	57,000	Locally-Advanced LAPC	18,000
NSC Lung Cancer	175,000	Central Tumors or Peripheral >3cm	42,000

[1]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
[2]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 +/- GC471

Unmet Medical Need with Limited Treatment Options in Pancreatic Cancer

Locally Advanced Pancreatic Cancer (LAPC)

Lethal Common Cancer

Increasing Number of Pancreatic Cancer Patients Diagnosed Each Year

- The most lethal common cancer: 5-year survival 9-13%[1,2]
- Over 30% present with locally advanced unresectable or borderline resectable

Novel Therapies Needed

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

- 60% of patients fail induction therapy within 12 months[3]
- 60% on FOLFIRINOX develop Grade 3-5 toxicity[3]

SBRT is Accepted Tx Option

SBRT Use is increasingly used for locoregional control (by NCCN and others)[4]

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

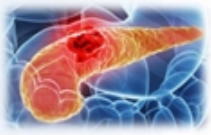
[1] 2019 SEER Data [2] Epidemiology of Pancreatic Cancer: Global Trends, Etiology and Risk Factors, Rawla P et al. World J Oncol. 2019 Feb; 10(1): 10–27.
[3] Suker M., Beumer B.R., Sadot E., Marthey L., Faris J.E., Mellon E.A. The Lancet Oncology. 2016;17(6):801–810. [4] NCCN = National Comprehensive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

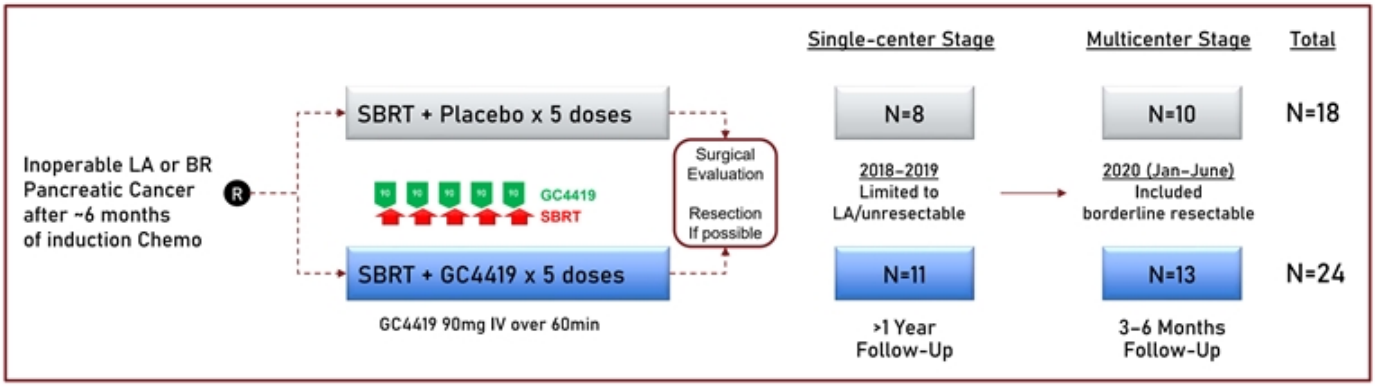
Pilot Phase 1/2 in Pancreatic Cancer: SBRT +/- GC4419

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

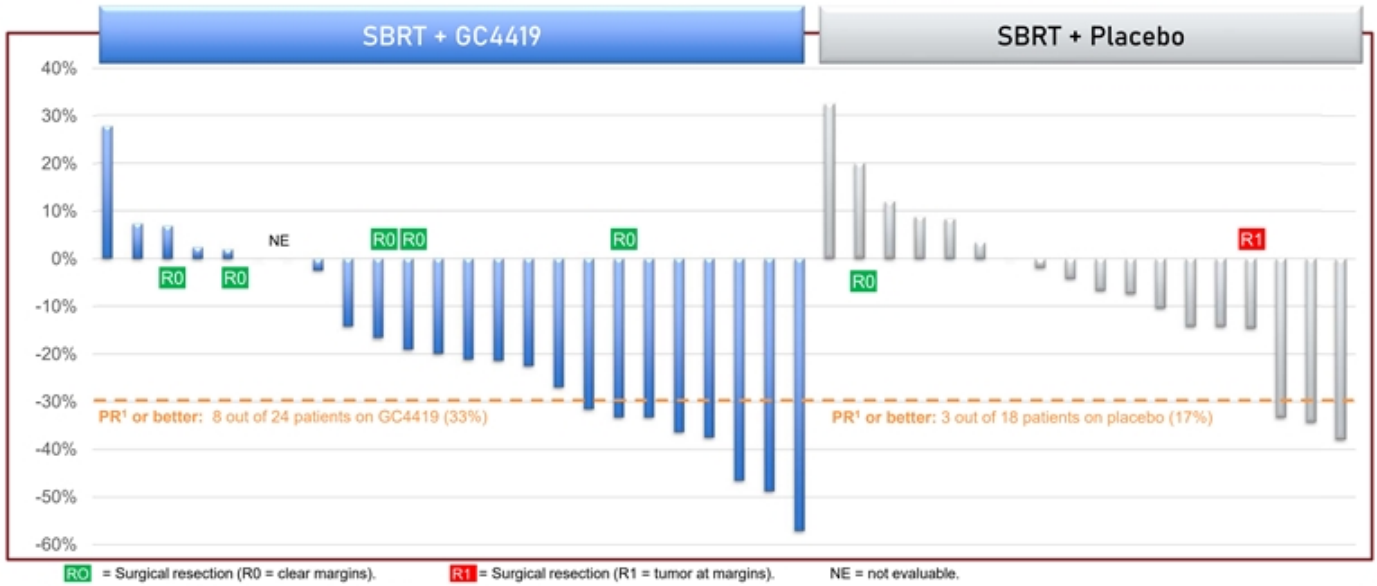




[1]LO-ET = Late-Onset Efficacy-Toxicity (Jin IH, Liu S, Thall PF, Yuan Y. J Am Stat Assoc 2014;109:525-36) SBRT = stereotactic body radiation therapy, LA = Locally Advanced, BR = Borderline Resectable ORR = Overall Response Rate, LRC = Locoregional Failure, DM = Distant Metastases, PFS = Progression-Free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

GC4419 Demonstrated Improved Local Tumor Response in SBRT Field

Waterfall plot of best response through August 24, 2020; follow-up ongoing (ITT, n=42)



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

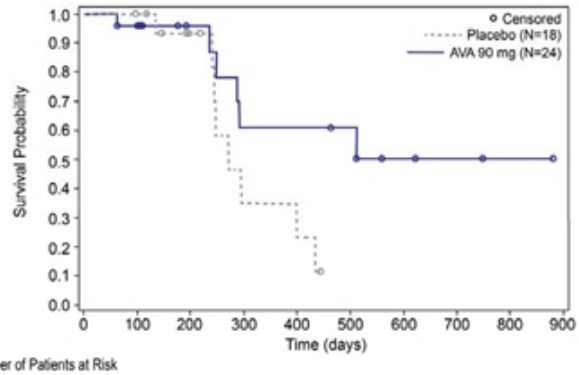
[1] *Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)*

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

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

N=42

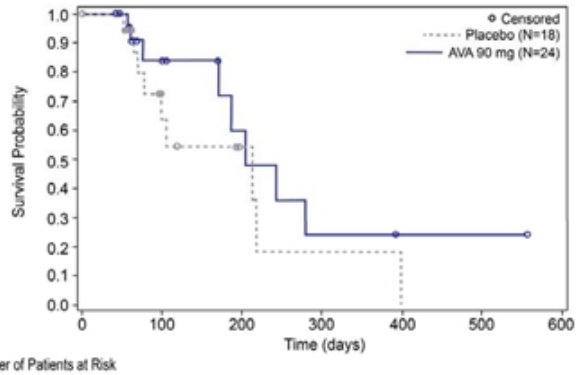
Overall Survival (OS)



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

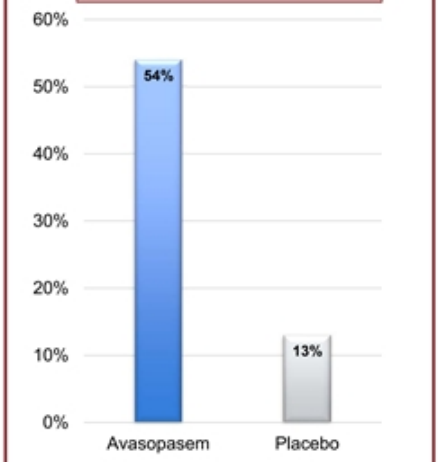
Log Rank *P* value = 0.29, HR = 0.6

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

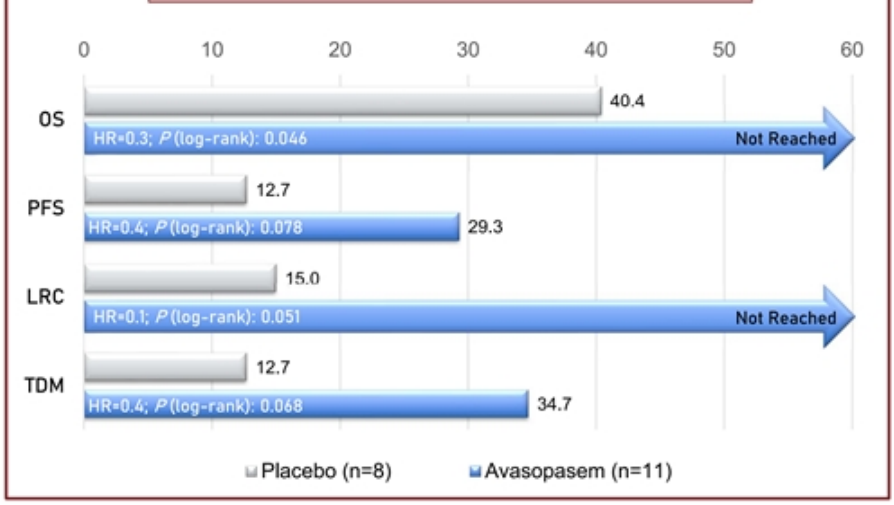
AVA = GC4419 or Avasopasem

Favorable Efficacy Across Multiple Anti-Cancer Measures in Patients Followed for >1 Year (ITT, n=19)

Best Response Rate



Medians (Weeks From SBRT)



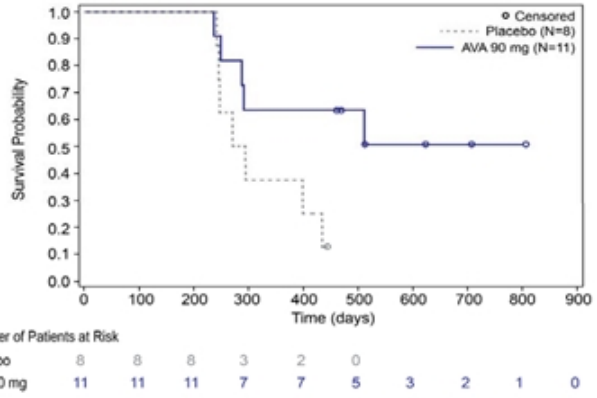
HR = Hazard ratio; LRC = locoregional control; OS = overall survival, PFS = progression-free survival, TDM = time to distant metastases.

Encouraging Survival Maintained in Patients Followed for >1 Year

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

N=19

Overall Survival (OS)

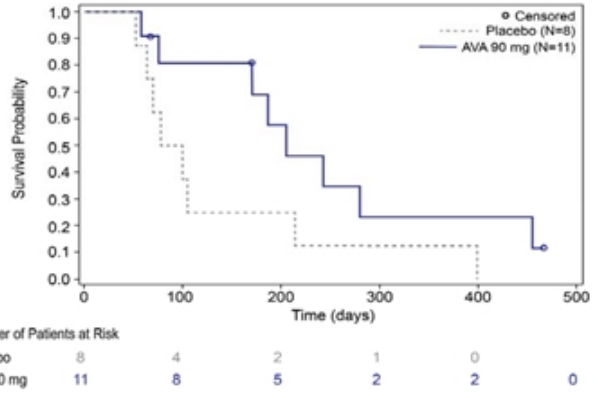


Number of Patients at Risk

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

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*

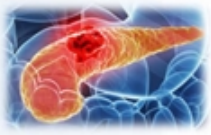
AE = adverse event; GI = gastrointestinal

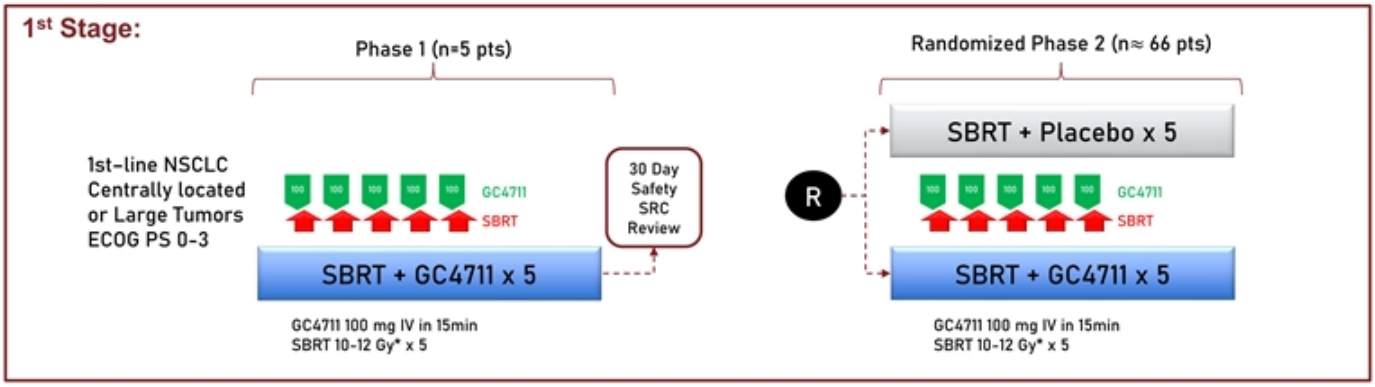
GRECO-1: Ongoing Phase 1b/2 Trial in Locally Advanced NSCLC

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





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

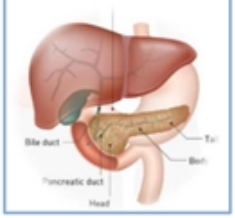
GRECO = Galera Radiotherapy Efficacy Cancer Optimization, NSCLC = Non-Small Cell Lung Cancer; ECOG PS = Eastern Cooperative Group Performance Status

GRECO-2: Initiating Randomized Phase 2b Trial in LAPC

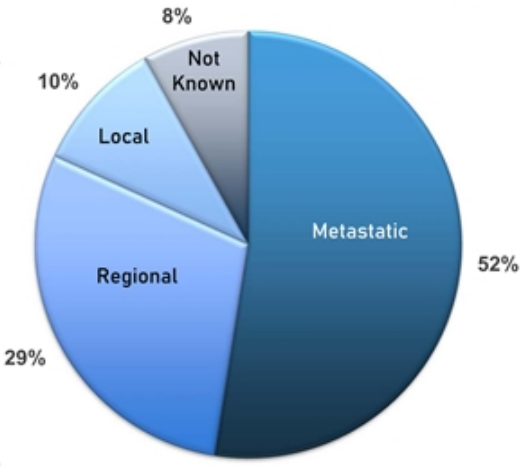
5-Year Survival is ~10%

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

9-13% 5-year Survival



GRECO-2
Double-Blind
Placebo-controlled
Randomized
Phase 2b trial
(SBRT +/- GC4711)



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 = Galera Radiotherapy Efficacy Cancer Optimization

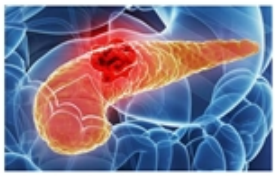
Corporate Highlights

Reducing IMRT Toxicity

Phase 3 ROMAN Results with Avasopasem
- Severe Oral Mucositis in Head & Neck Cancer
- Robust Phase 2b data → Breakthrough Therapy Designation

Increasing SBRT Efficacy

Complete Survival Results from Pancreatic Cancer Pilot
- 1-Year data on all patients from randomized LAPC trial
- Promising data from this trial was presented in 2020



Planning US Launch

Large Market Opportunities with High Unmet Medical Need
- Building commercial team for US launch of avasopasem
- US Target Patient Population of Lead Indication is 42,000

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APPENDIX

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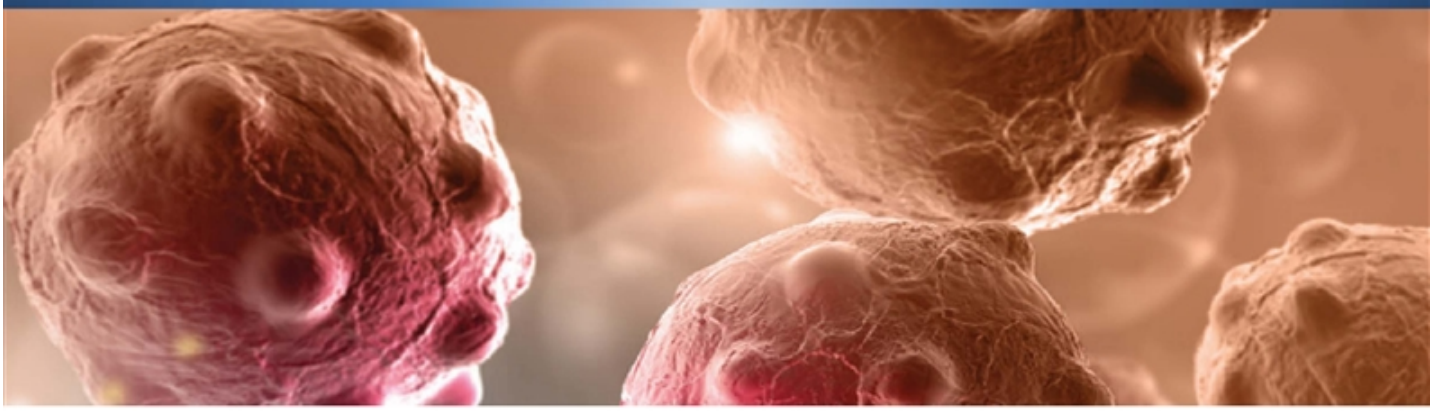
Back-up Preclinical Slides

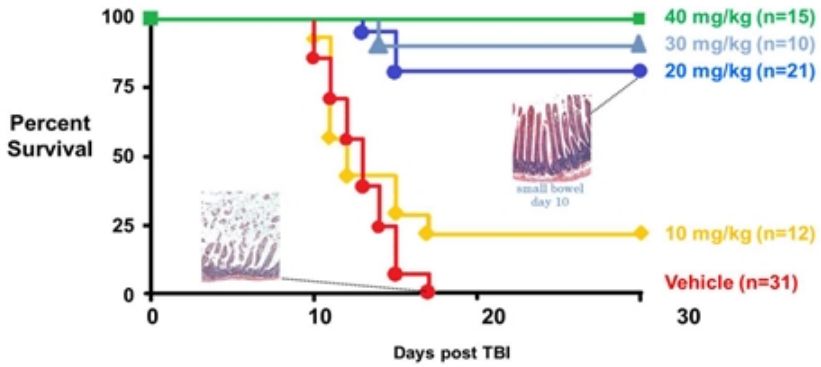


Dismutase Mimetics Reduce Radiation Toxicities

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

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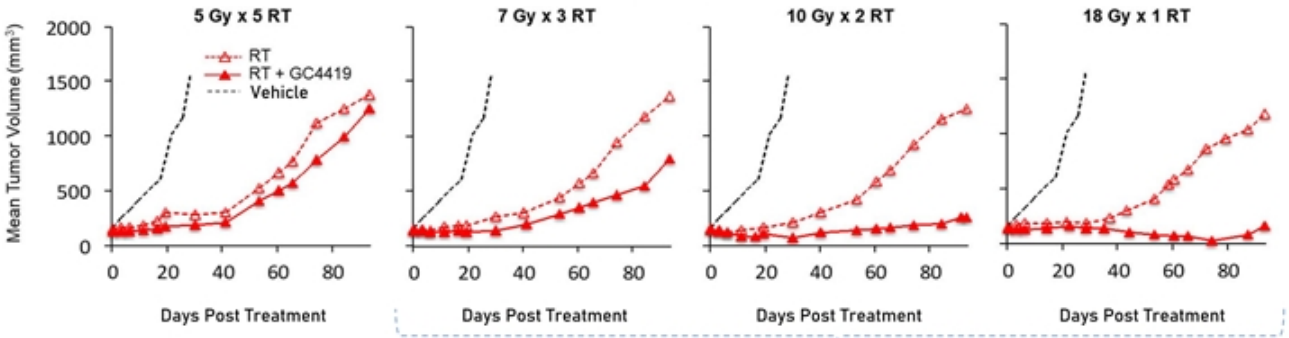
Increase Radiotherapy Efficacy

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



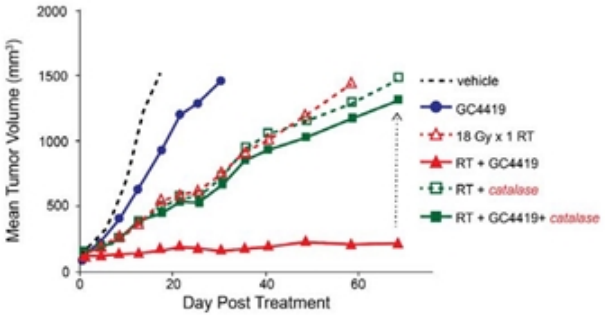
SBRT
Stereotactic Body Radiation Therapy

Courtesy of M Story (UTSW)

Increasing Anti-Cancer Efficacy via H_2O_2

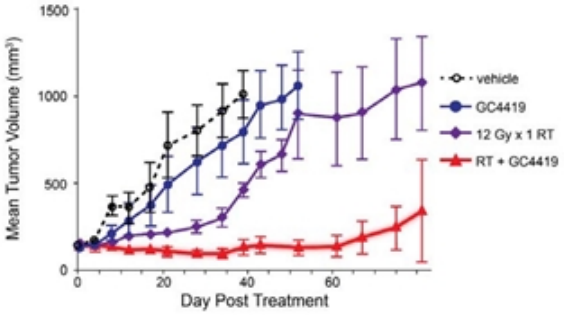
Tumor tissue H_2O_2 reduced when doxycycline added, losing the synergy

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



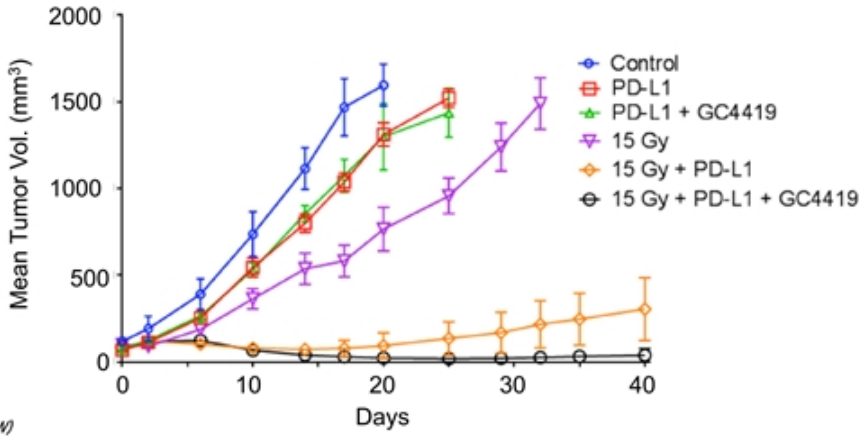
Sishc et al, AACR, 2018
Sishc, et al, AACR Pancreatic Cancer, 2019

Dismutase Mimetics Also Enhance Immuno-Radiotherapy in Preclinical Models

Increase IO + SBRT Efficacy

SBRT + Checkpoint Inhibitor therapy of syngeneic tumors (LLC) in mice

- GC4419 enhances tumor response to SBRT + anti-PD-L1, PD-1 or CTLA-4
- Also appeared to reduce metastasis & increase response in unirradiated secondary tumors



Courtesy of M Story (UTSW)

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Back-up Pilot Phase 1/2 LAPC Trial Data

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

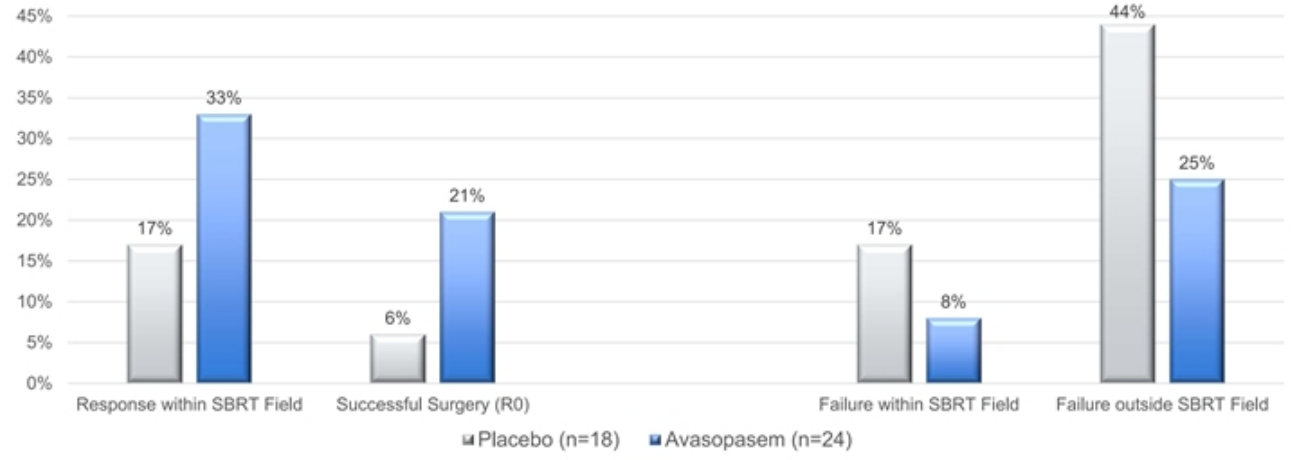
ECOG = Eastern Cooperative Oncology Group Performance Status Criteria
CA 19-9 = Carbohydrate Antigen 19-9 is a tumor marker for pancreatic cancer

SBRT + GC4419 Demonstrated Better Preliminary Outcomes Than SBRT + PBO

Galera Therapeutics, Inc

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

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

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)

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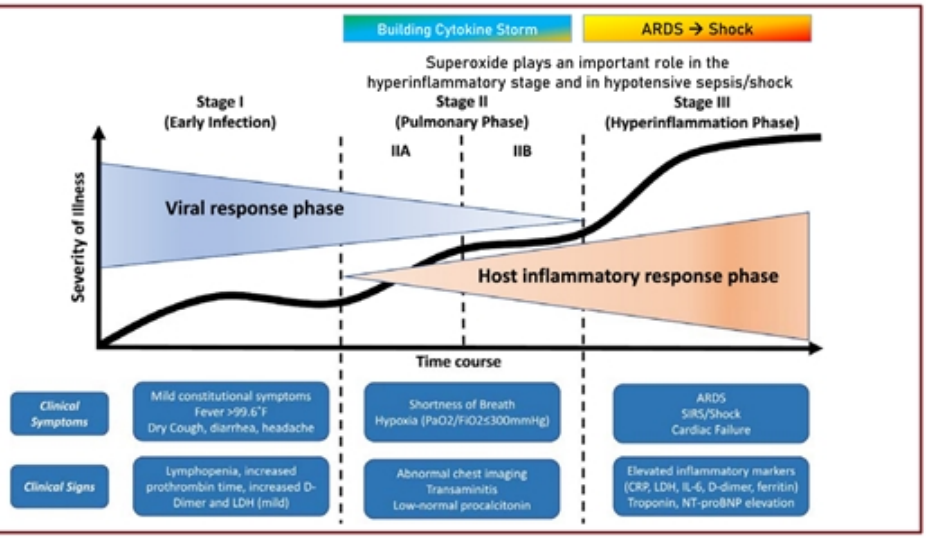
COVID-19 Trial

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

Randomize (1:1)

- Avasopasem 90mg x 7 days BID + SSC
- PBO + Standard Supportive Care (SSC)

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

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Backup Commercial Slides

77% of the IMRT Centers Have the Ability to Infuse Today

Adoption Archetype Determinants	RadOncs Enhance Capabilities to Administer GC4419 (Segment 1A)	RadOncs Add Capabilities to Administer GC4419 (Segment 1B)	MedOncs Administer GC4419 with RadOnc Coordination (Segment 2)	RadOncs Unlikely to Use GC4419 (Segment 3)
GC4419 Infusion Owner	RadOnc	RadOnc	MedOnc	–
Patient Volume	↑ HIGH	↑ HIGH	– MODERATE	↓ LOW
RadOnc IV Administration Capability	↑ HIGH	↓ LOW	↓ LOW	↓ LOW
MedOnc Infusion Constraints	– MODERATE	– MODERATE	↓ LOW	↑ HIGH
Ease of Coordination Today	– MODERATE	– MODERATE	↑ HIGH	↓ LOW
Likelihood to Rx GC4419	↑ **HIGH**	↑ **HIGH**	– **MODERATE**	↓ **LOW**
Total Sample Distribution *(N)*	**37%** *(25)*	**14%** *(9)*	**40%** *(27)*	**9%** *(6)*

Segment 1 — *Segment 1A and 1B share similar attitudes and behaviors with the only exception being current infusion capacity and hence future needs to add capacity. These 2 segments are hence clubbed together as "Segment 1" for metrics where there is no difference*

Primary market research with 67 IMRT centers in the US

SBRT Commonly Used for Central and Peripheral NSCLC Tumors

Potential Opportunity for SBRT + GC4711

NSCLC

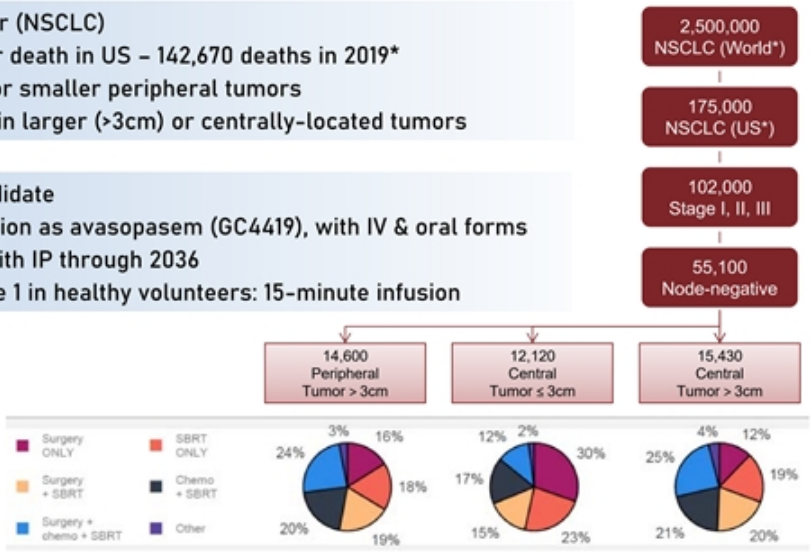
Non-Small Cell Lung Cancer (NSCLC)

- 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