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): November 10, 2020

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 2.02. Results of Operations and Financial Condition.

On November 10, 2020, Galera Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01. Regulation FD Disclosure.

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 November 10, 2020, 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 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information contained in Items 2.02 and 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 and 99.2 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 exhibits relating to Items 2.02 and 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on November 10, 2020
99.2	Corporate Slide Presentation of Galera Therapeutics, Inc. dated November 10, 2020

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: November 10, 2020

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

Galera Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Updates

Presented Promising Interim Data from Placebo-controlled Pilot Dismutase Mimetic SBRT Combination Trial for Pancreatic Cancer

Announced Planned Phase 2b GC4711 SBRT Combination Trial for Pancreatic Cancer (GRECO-2)

Initiated Randomized Phase 1/2 GC4711 SBRT Combination Trial for NSCLC (GRECO-1)

Remain on Track with Ongoing Phase 3 ROMAN Trial and Other Radiation-Induced Toxicity Trials of Avasopasem

MALVERN, Pennsylvania, November 10, 2020 – Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer, today announced financial results for the third quarter ended September 30, 2020, and provided business updates.

"We continue to make great strides advancing the clinical development of our small molecule superoxide dismutase mimetics' ability to address radiation toxicities and augment the anti-cancer efficacy of radiation," said Mel Sorensen, M.D., President and CEO of Galera. "We are delighted with the encouraging data from our placebo-controlled trial of GC4419 in combination with stereotactic body radiation therapy (SBRT) for patients with locally advanced pancreatic cancer (LAPC), which were presented during a late-breaker session at the American Society for Radiation Oncology (ASTRO) 2020 Annual Meeting. The findings are the first clinical evidence supporting our extensive preclinical science that showed synergy of our dismutase mimetics with SBRT. In this first trial with the addition of a dismutase mimetic to SBRT in patients, we observed better tumor responses, saw more patients succeed in going to surgical resection, and are particularly pleased by the initial signal in survival. With these promising early activity results in hand, coupled with the preliminary safety findings of the combination, we look forward to continuing to advance the potential of our dismutase mimetics to enhance the anti-cancer efficacy of SBRT and improve outcomes for cancer patients. We have initiated the GRECO-1 Phase 1/2 trial of GC4711 with SBRT in non-small cell lung cancer (NSCLC), and also anticipate initiating a Phase 2b trial of GC4711 with SBRT in pancreatic cancer (GRECO-2) in the first half of 2021. Our most advanced program, the ROMAN Phase 3 trial, continues to enroll well and we look forward to reporting topline results in the second half of 2021."

Third Quarter 2020 and Recent Corporate Highlights

- In October, presented interim efficacy and safety data from the randomized, double-blind, multicenter, placebo-controlled pilot Phase 1/2 clinical trial of avasopasem manganese (GC4419) in combination with SBRT in patients with LAPC at ASTRO. In the analysis of the intent-to-treat population, multiple endpoints to date show a positive trend in favor of improved anti-

cancer efficacy with avasopasem compared to placebo. While many of the patients are early in their follow-up post treatment, addition of the dismutase mimetic to SBRT appears to improve overall survival (OS) versus placebo (HR=0.4, 95% CI: 0.12-1.11; median OS not yet reached for avasopasem vs. 38.7 weeks for placebo; p=0.06). Best overall response within the SBRT field was partial response, according to modified RECIST criteria, or better in 33% of avasopasem patients versus 17% of placebo patients. Five patients in the avasopasem arm and two in the placebo arm were surgically resected. Among the resected avasopasem patients, all five achieved clear margins (R0), compared to only one of the two in the placebo arm. Progression-free survival hazard ratio as of the cut-off date also appears to favor the avasopasem arm (HR=0.6, 95% CI: 0.23-1.56; p=0.29). Toxicity was comparable across both treatment arms, with no significant differences in overall or Grade 3 GI toxicity post-SBRT. The data presented included all patients followed for a minimum of three months and 19 for more than one year, with data through August 24, 2020. The Company plans to provide an update on this trial with at least one year of follow-up on all patients in the second half of 2021.

- In October, announced that the first patient had been dosed in the Phase 1/2 GRECO-1 trial of GC4711 in combination with SBRT in patients with central or large peripheral NSCLC tumors. GC4711 is Galera's second highly selective small molecule superoxide dismutase mimetic candidate and is being developed specifically for use in combination with SBRT. Following a safety run-in cohort, up to 66 NSCLC patients with locally advanced disease will receive GC4711 with SBRT or placebo with SBRT over five consecutive weekdays in a first stage of the randomized, double-blind, placebo-controlled Phase 2 portion of the GRECO-1 trial. A second stage is planned to add a checkpoint inhibitor to the SBRT combination. The GRECO-1 trial is supported in part by a recently awarded Small Business Innovation Research grant (4R44CA206795-02) from the National Cancer Institute of the National Institutes of Health. The Company anticipates reporting topline data from the first stage of this trial in the first half of 2022.
- In October, hosted a virtual Key Opinion Leader (KOL) event featuring Sarah Hoffe, M.D., Section Head of GI Radiation Oncology and Senior Member at Moffitt Cancer Center. Dr. Hoffe provided an overview of the management of patients with localized pancreatic cancer, including the current clinical treatment paradigm and the use of SBRT.
- In September, announced the first patient had been dosed in a pilot Phase 2 clinical trial of avasopasem to evaluate its ability to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19. The Company anticipates reporting topline data from this trial in the first half of 2021.
- Continued enrollment in multiple clinical trials of avasopasem for radiation-induced toxicities, including the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of severe oral mucositis induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), the Phase 2a EUSOM multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, as well as the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The Company remains on track to announce topline data from the ROMAN trial in the second half of 2021.

Third Quarter 2020 Financial Highlights

- Research and development expenses were $12.1 million in the third quarter of 2020, compared to $11.0 million for the same period in 2019. The increase was primarily attributable to avasopasem development costs due to increased expenses in the Phase 3 ROMAN trial, additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer and the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC. In addition, employee-related costs also increased due to increased headcount and share-based compensation expense. The increases were partially offset by decreased avasopasem preclinical spend and decreased GC4711 development expenses.
- General and administrative expenses were $3.9 million in the third quarter of 2020, compared to $1.8 million for the same period in 2019. The increase was primarily the result of employee-related costs from increased headcount and share-based compensation expense, and increased insurance, professional fees and other operating costs as a result of becoming a public company.
- Galera reported a net loss of $(17.1) million, or $(0.69) per share, for the third quarter of 2020, compared to a net loss of $(13.4) million, or $(51.43) per share, for the same period in 2019.
- As of September 30, 2020, Galera had cash, cash equivalents and short-term investments of $89.2 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the expected payments from Blackstone in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the amended royalty agreement, will enable Galera to fund its operating expenses and capital expenditure requirements into the second half of 2022.

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Galera's lead product candidate is avasopasem manganese (GC4419), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem is being studied in the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in the EUSOM Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19. A pilot Phase 1/2 trial of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer has completed enrollment and reported interim results, with follow-up ongoing. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera's second dismutase mimetic product candidate, GC4711, is being developed specifically to augment the anti-cancer efficacy of SBRT, and is currently being studied in the GRECO-1 Phase 1/2 clinical trial in combination with SBRT in patients with non-small cell lung cancer. Galera is headquartered in Malvern, PA. For more information, please visit **www.galeratx.com**.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding expectations surrounding our growth and the continued advancement of our product pipeline, the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates, plans and timing for the commencement of and the release of data from Galera's clinical trials, expected payments from Blackstone, and the sufficiency of Galera's cash, cash equivalents and short-term investments. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause Galera's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: Galera's limited operating history; anticipating continued losses for the foreseeable future; needing substantial funding and the ability to raise capital; Galera's dependence on avasopasem manganese (GC4419); uncertainties inherent in the conduct of clinical trials; difficulties or delays enrolling patients in clinical trials; the FDA's acceptance of data from clinical trials outside the United States; undesirable side effects from Galera's product candidates; risks relating to the regulatory approval process; failure to capitalize on more profitable product candidates or indications; ability to receive Breakthrough Therapy Designation or Fast Track Designation for product candidates; failure to obtain regulatory approval of product candidates in the United States or other jurisdictions; ongoing regulatory obligations and continued regulatory review; risks related to commercialization; risks related to competition; ability to retain key employees and manage growth; risks related to intellectual property; inability to maintain collaborations or the failure of these collaborations; Galera's reliance on third parties; the possibility of system failures or security breaches; liability related to the privacy of health information obtained from clinical trials and product liability lawsuits; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; environmental, health and safety laws and regulations; the impact of the COVID-19 pandemic on Galera's business and operations, including preclinical studies and clinical trials, and general economic conditions; risks related to ownership of Galera's common stock; and significant costs as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" 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 could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any forward-looking statements speak only as of the date of this press release and are based on information available to Galera as of the date of this release, and Galera assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Galera Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 12,133	$ 11,040	$ 40,225	$ 29,057
General and administrative	3,945	1,816	11,384	5,466
Loss from operations	(16,078)	(12,856)	(51,609)	(34,523)
Other income (expense), net	(1,000)	(495)	(2,543)	(735)
Net Loss	(17,078)	(13,351)	(54,152)	(35,258)
Accretion of redeemable convertible preferred stock to redemption value	—	(2,108)	—	(6,178)
Net loss attributable to common stockholders	$ (17,078)	$ (15,459)	$ (54,152)	$ (41,436)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (51.43)	$ (2.18)	$ (137.85)
Weighed average common shares outstanding, basic and diluted	24,874,805	300,597	24,840,822	300,597

Galera Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited, in thousands)

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 89,151	$ 112,290
Total assets	98,075	123,376
Total current liabilities	10,503	9,694
Total liabilities	73,380	53,768
Total stockholders' equity	24,695	69,608

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Exhibit 99.2

Galera Therapeutics, Inc

Transforming Radiotherapy

with

Dismutase Mimetics

November 2020

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 Trial**

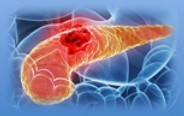
Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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

Increase H_2O_2 in tumors

SBRT
Stereotactic Body RT

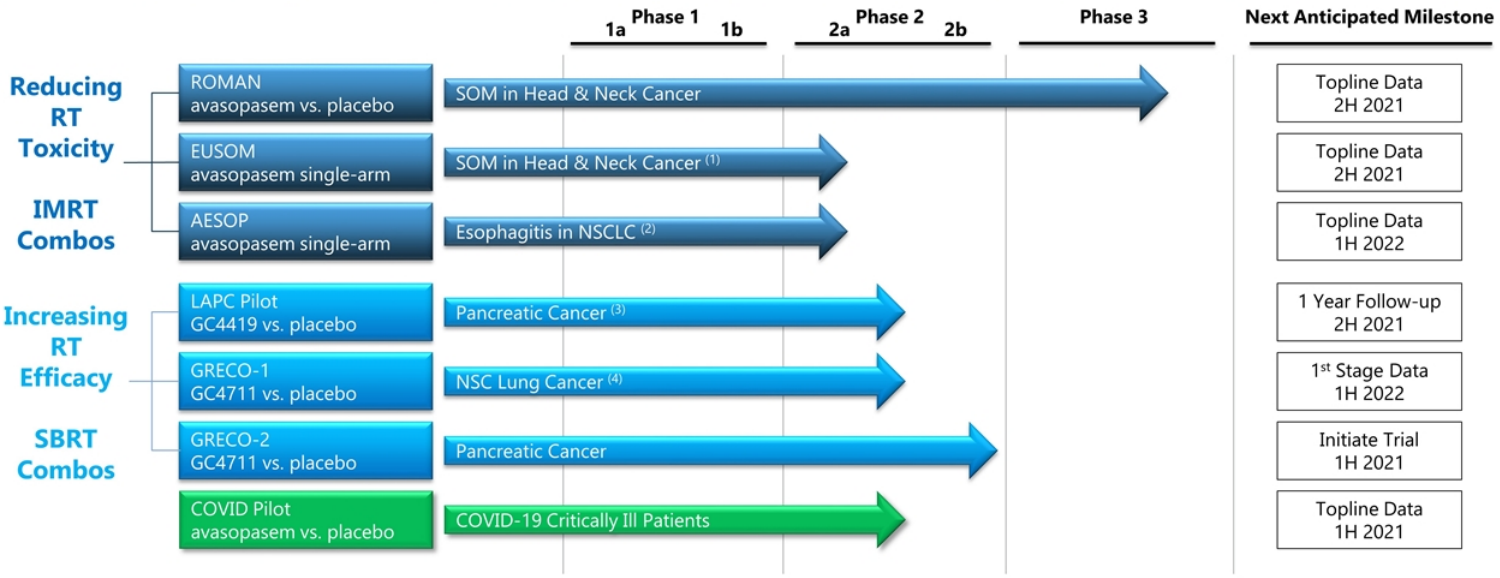
Potential to Increase Efficacy

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

Galera Therapeutics, Inc

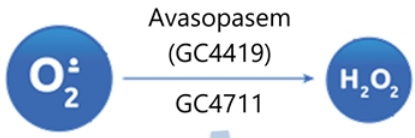
Dismutase Technology

Unique Technology

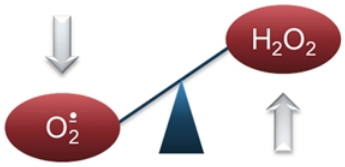
Dismutase Mimetics

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



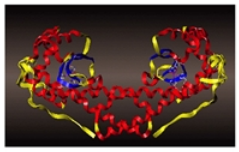
$O_2^{\bullet}$ more damaging to normal cells than cancer cells

H_2O_2 more toxic to cancer cells than normal cells

Galera's Dismutase Mimetics

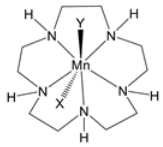
Native SOD Enzymes

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



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

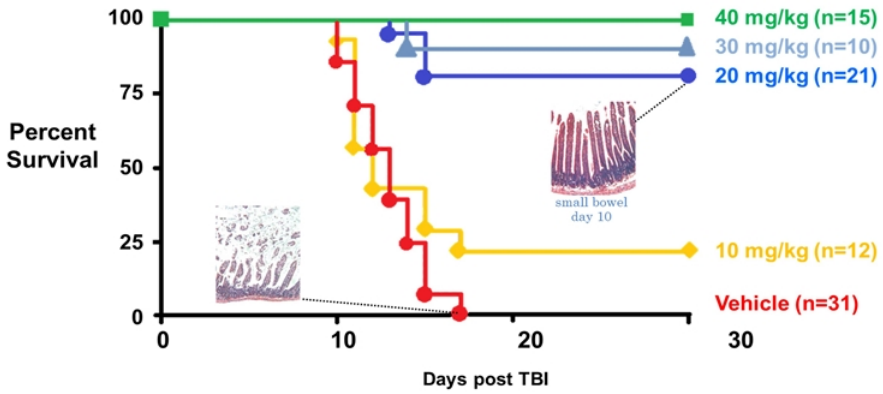
Speed	Selectivity	Stability	Safety	Synthesis
Comparable to native SODs ($2x10^7$ molecules per sec)	Interact with superoxide alone, not other reactive oxygen species	Firmly hold Mn atom in macrocyclic ring	Well-tolerated preclinically and clinically	Efficient & cost-effective manufacturing process

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



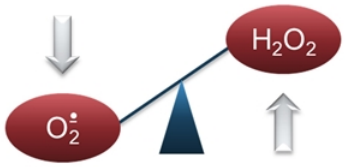
Thompson, et al., Free Radical Research, 44(5):529-540, 2010
Galera internal data

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

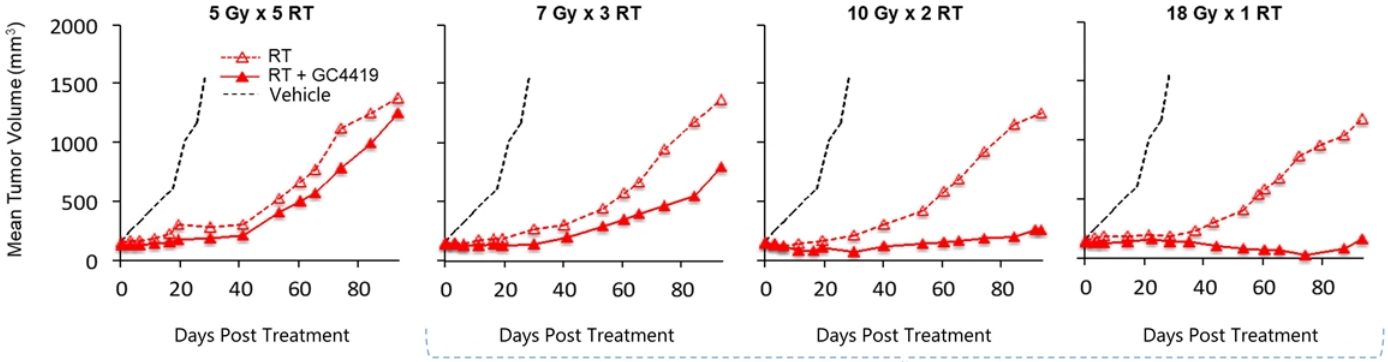
Increase Radiotherapy Efficacy

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



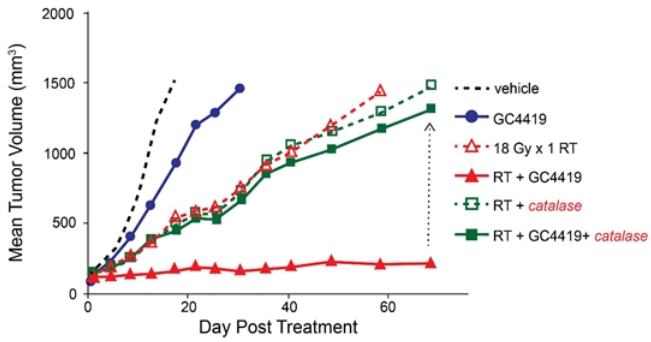
SBRT
Stereotactic Body Radiation Therapy

Courtesy of M Story (UTSW)

…Increasing Anti-Cancer Efficacy via H_2O_2

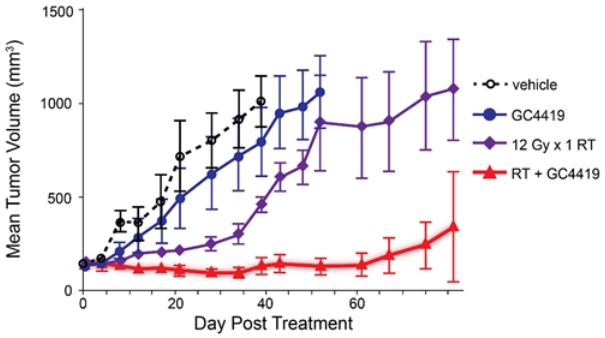
Tumor tissue H_2O_2 reduced when doxycycline added, losing the synergy

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

Galera Therapeutics, Inc

Reducing Toxicity of IMRT – Clinical Data

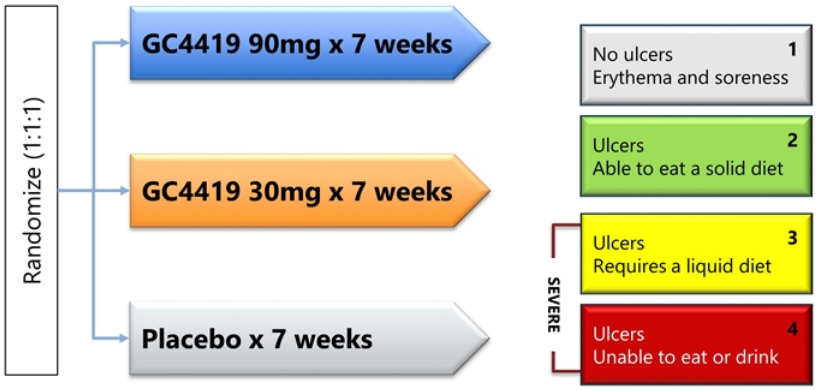
(Intensity Modulated Radiotherapy)

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

Supportive trial to the ROMAN Phase 3 for the NDA

Trial Design

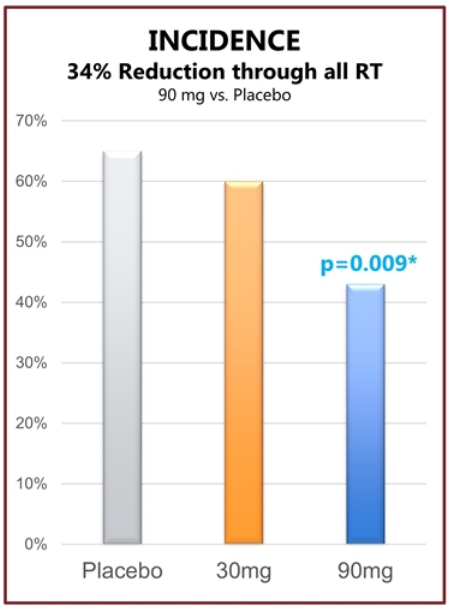
Treatment	• Avasopasem (GC4419) 90mg, 30mg, or placebo • 60 minute IV infusion, Mon-Fri. • Ending <60 mins pre-RT
Population	• Patients with HNC • Locally-advanced, squamous cell • Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	• Tumor HPV Status: positive or negative • Cisplatin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

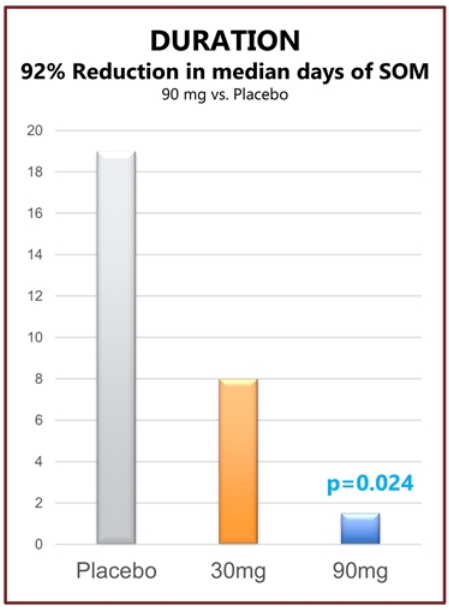


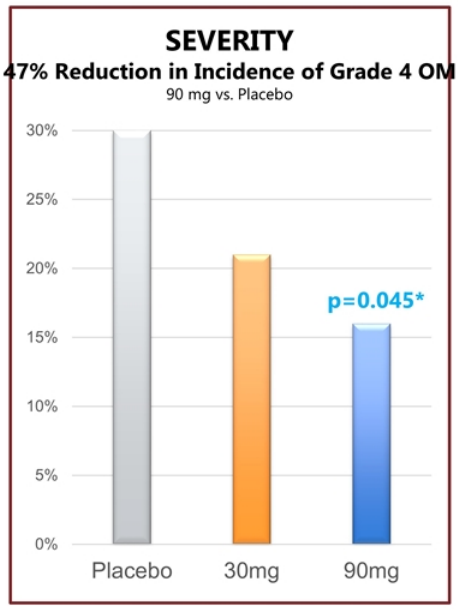
Anderson et al, JCO, 2019

Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg







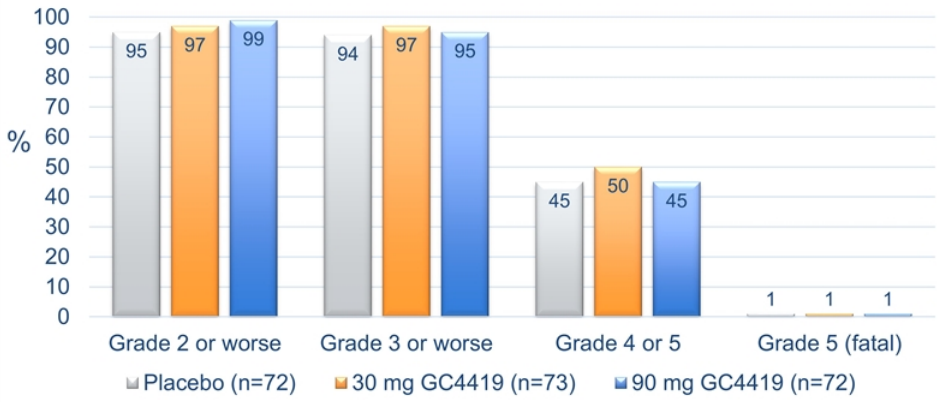
Primary endpoint was duration - defined as # days from 1st occurrence of grade 3 or 4 SOM until the 1st event of grade 2 or less (there being no subsequent grade 3 or 4 events.)

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

SEVERE

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

Galera Therapeutics, Inc

Increasing SBRT Efficacy – Clinical Data

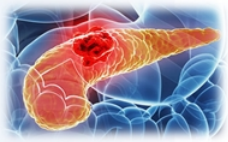
(Stereotactic Radiotherapy)

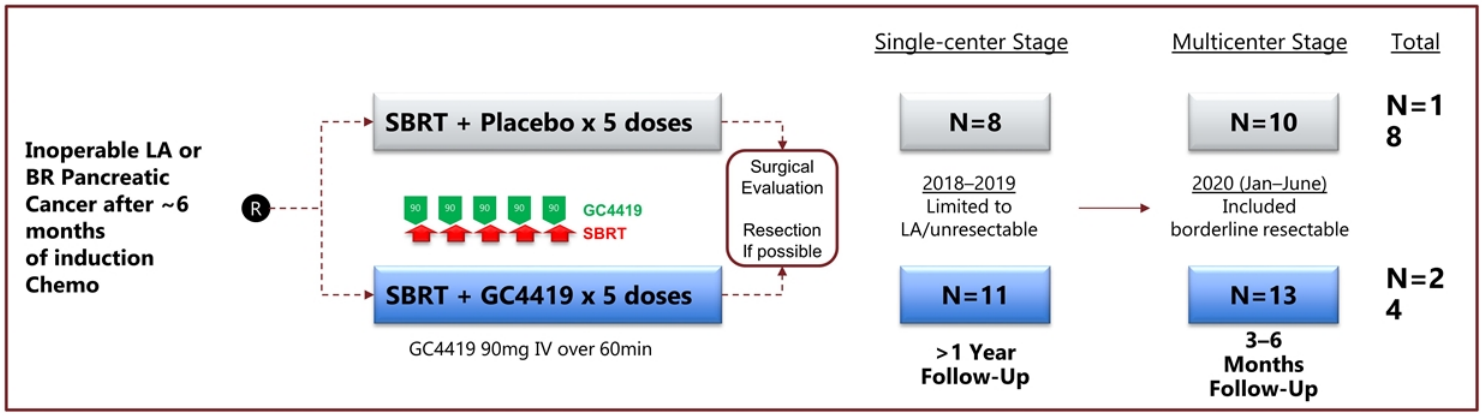
Pilot Phase 1/2 in Pancreatic Cancer: SBRT +/- GC4419

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)

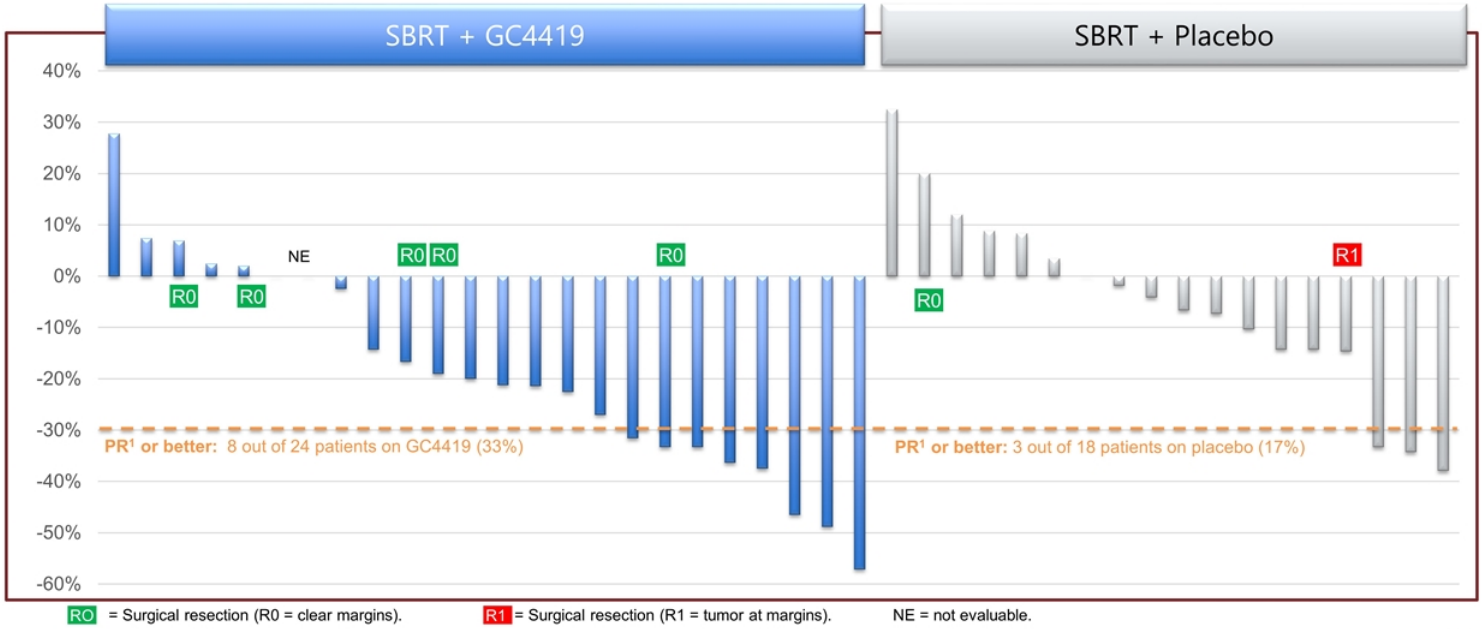
	Placebo (n=18)	Avasopasem (n=24)
Acute Adverse Events (up to 90 days post SBRT)		
Patients with acute Grade 3+ AEs*	4 (22%)	6 (25%)
Grade 3 acute GI toxicity**	2 (11%)	2 (8%)
Late Adverse Events (91 days–1 year post SBRT)		
Patients with late Grade 3+ AEs	5 (28%)	7 (29%)

**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	

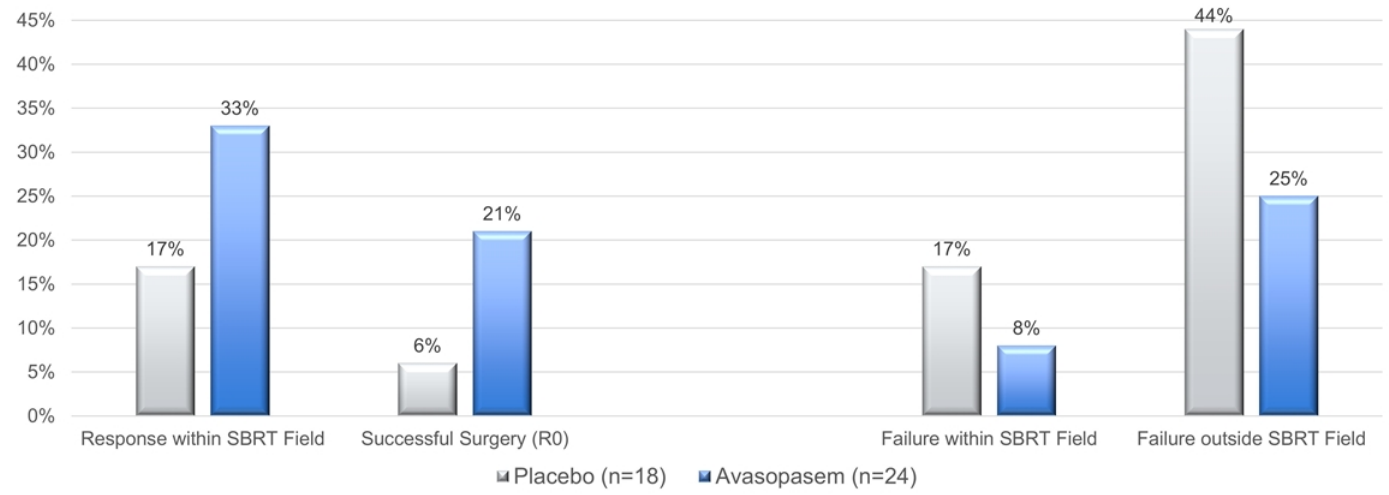
- No significant perioperative complications after SBRT for all 7 patients

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



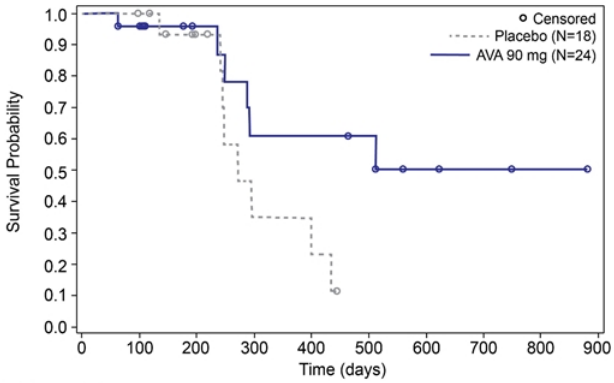
Data through August 24, 2020; follow-up ongoing

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)

Overall Survival (OS)



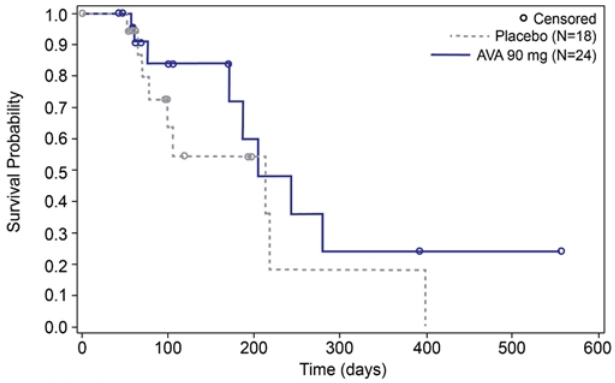
Number of Patients at Risk

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

N=42

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

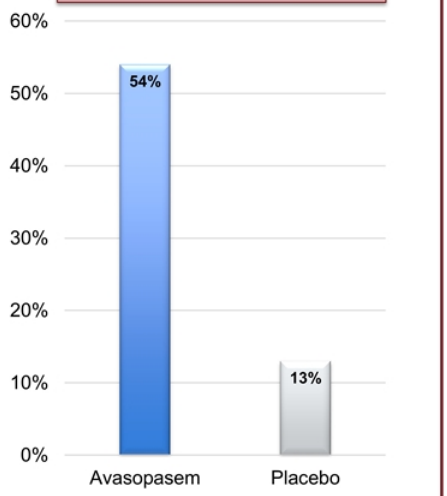
Log Rank *P* value = 0.29, HR = 0.6

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

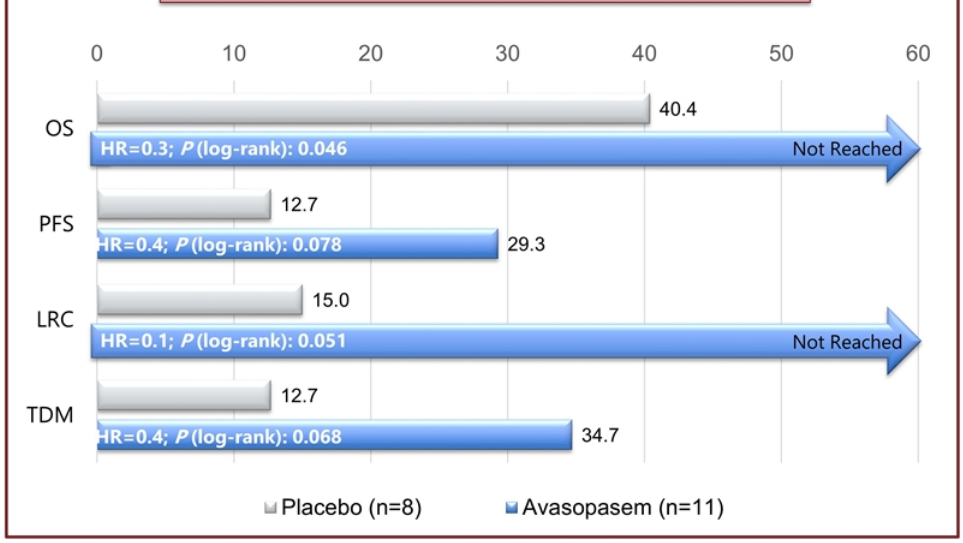
AVA = GC4419 or Avasopasem

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

Best Response Rate



Medians (Weeks From SBRT)

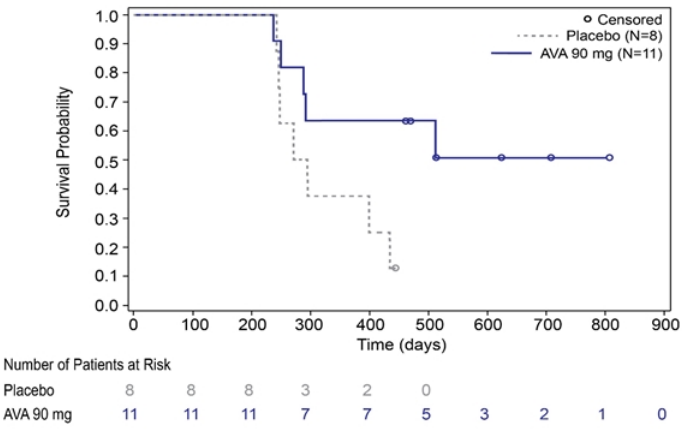


HR = Hazard ratio; LRC = locoregional control; OS = overall survival, PFS = progression-free survival, TDM = time to distant metastases.

Encouraging Survival in Patients Followed for >1 Year

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

Overall Survival (OS)



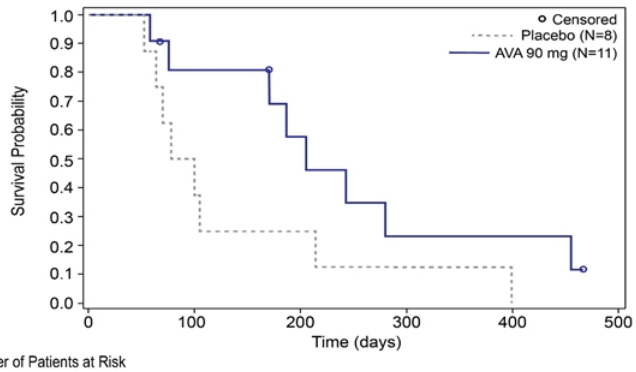
Number of Patients at Risk

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

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, 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

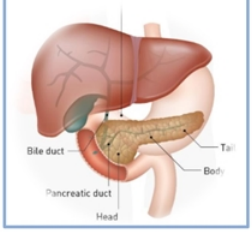
Comparison of Hazard Ratios (95% Confidence Intervals)	Initial Stage Pts (n=19)	All Patients (n=42)
Overall Survival (OS)	0.3 (0.09-1.05)	0.4 (0.12-1.11)
Progression-Free Survival (PFS)	0.4 (0.15-1.14)	0.6 (0.23-1.56)
Loco-Regional Control (LRC)	0.1 (0.01-1.37)	0.2 (0.02-2.22)
Time to Distant Mets (TDM)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

Pancreatic Cancer Population in US

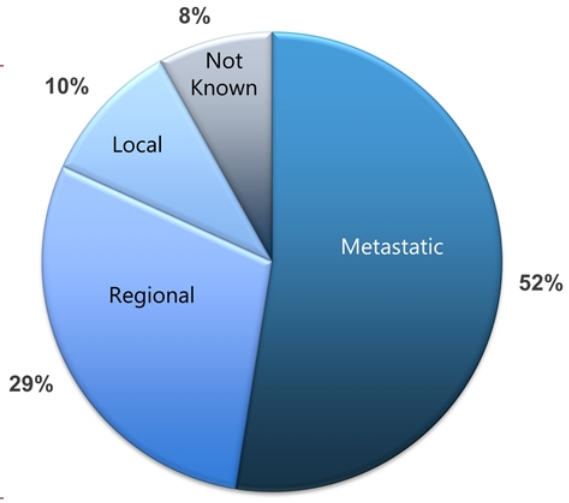
5-Year Survival is ~10%

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

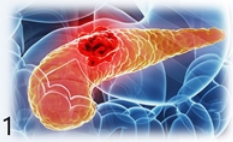
[1] 2019 SEER Data [2] Epidemiology of Pancreatic Cancer: Global Trends, Etiology and Risk Factors, Rawla P et al. World J Oncol. 2019 Feb; 10(1): 10–27
***GRECO** = **G**alera **R**adiotherapy **E**fficacy **C**ancer **O**ptimization*

GRECO-1 for Lung Cancer SBRT +/- GC4711

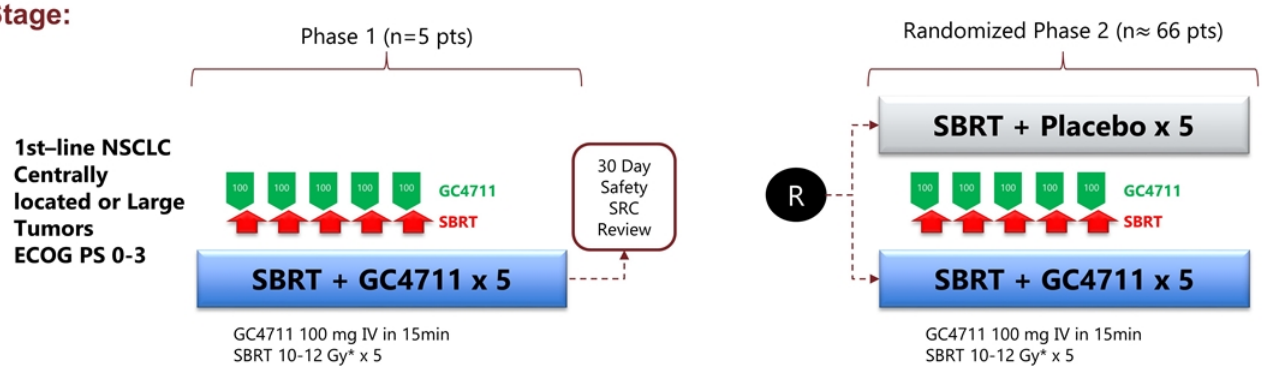
SBRT GC4711 Combo Trial

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:



**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

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

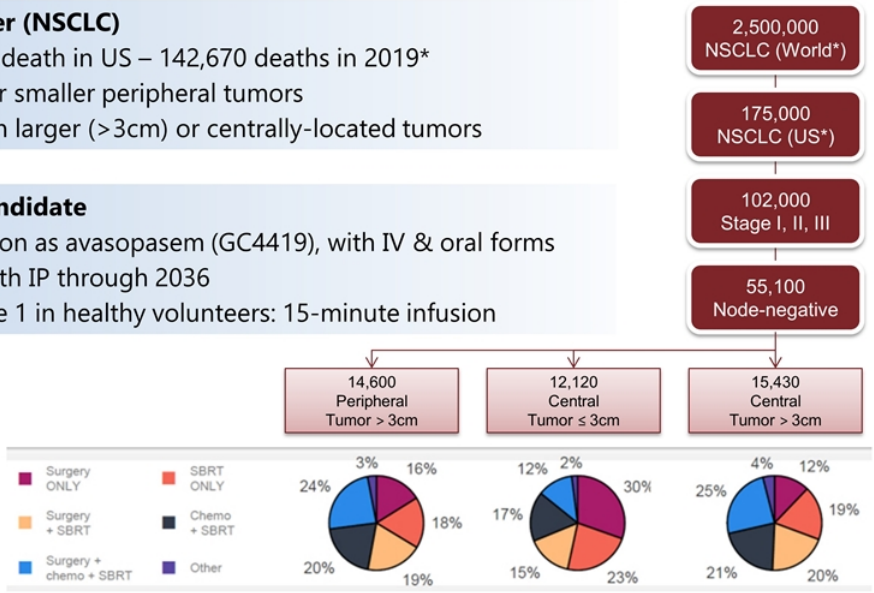
Non-Small Cell Lung Cancer (NSCLC)

- 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

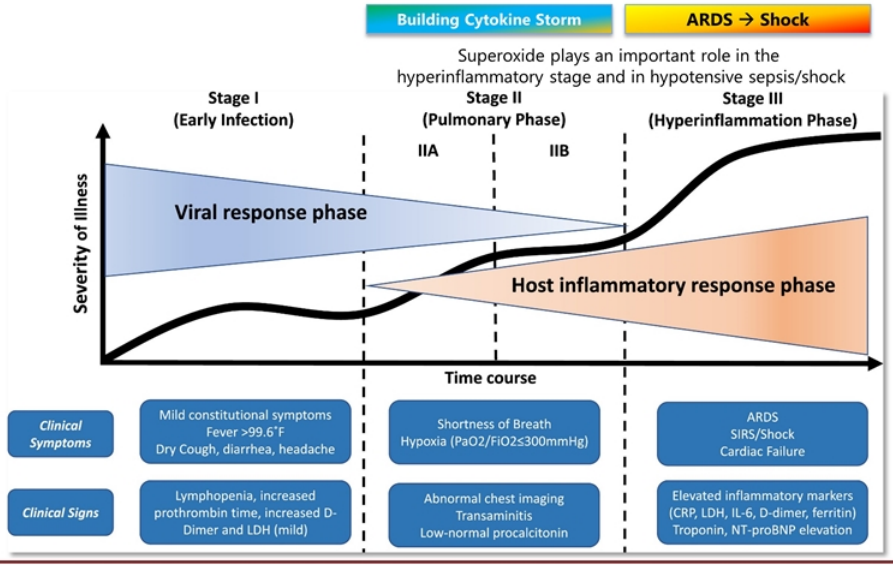
Galera Therapeutics, Inc

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

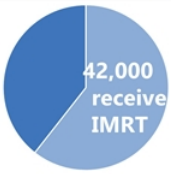
Galera Therapeutics, Inc

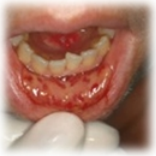
Appendix

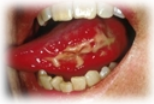
Oral Mucositis in HNC – Large Unmet Medical Need

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

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

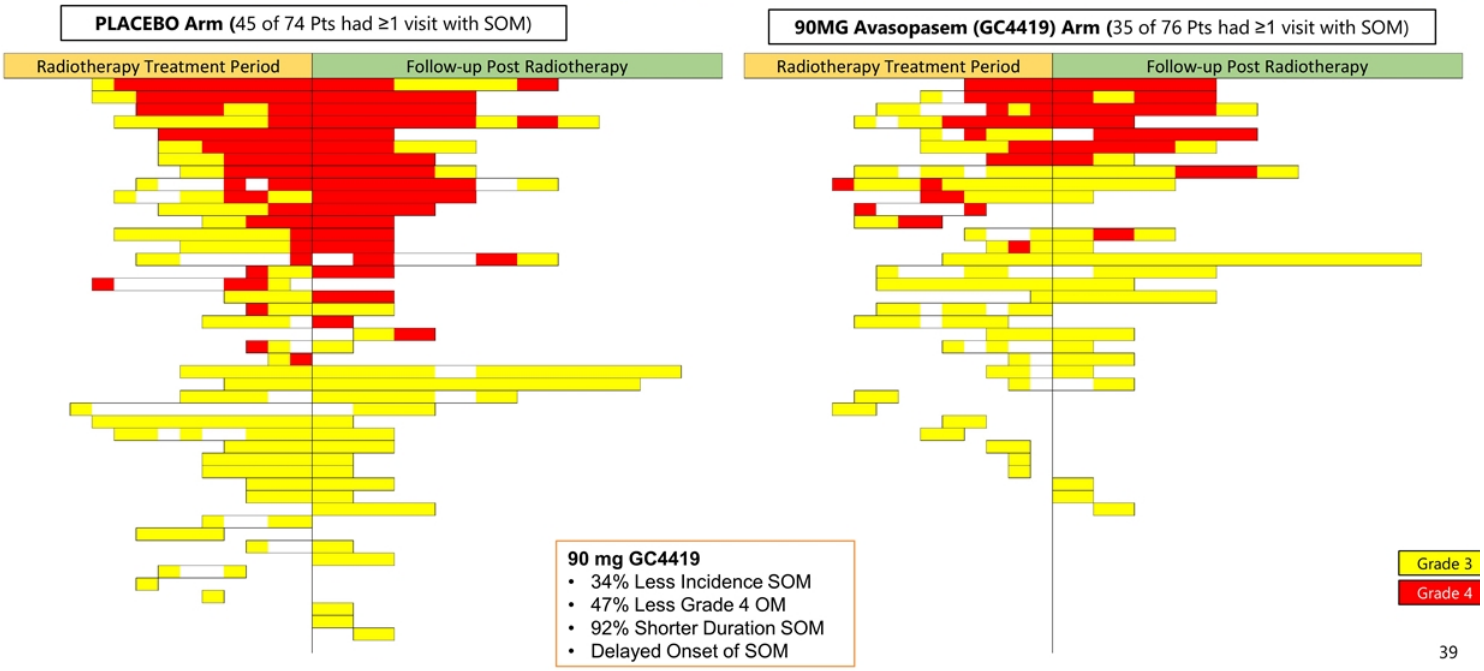
Current Treatments

MASCC / ISOO Guidelines for HNC OM

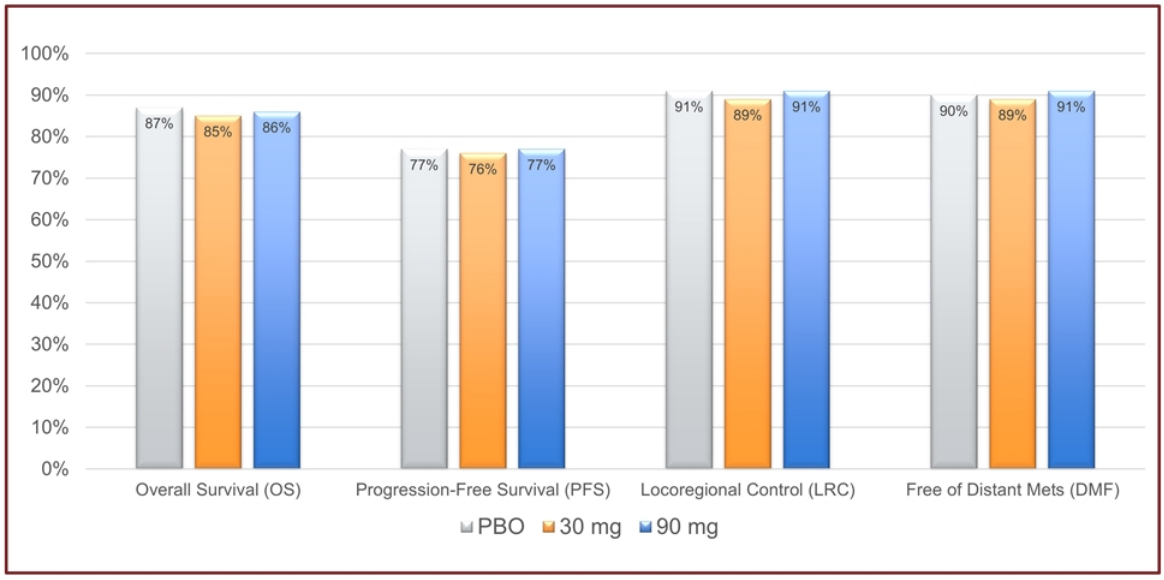
Treatment Approach	Recommended for HNC OM due to RT?
Basic oral care	✓
Anti-microbials, coating agents, anesthetics, & analgesics (0.2% morphine mouthwash)	✓
Anti-inflammatories, benzydamine	?
Low level laser & other light therapy	?
Cryotherapy for 5-FU chemotherapy	✗
Natural & other agents	✗

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

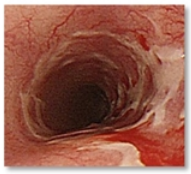
OS = Overall Survival, PFS = Progression-Free Survival, LRC = LocoRegional Control, DMF = Free of Distant Metastases

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