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): May 12, 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 May 12, 2020, Galera Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 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 May 12, 2020, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at *www.galeratx.com*. A copy of the 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 Exhibits 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 Item 2.02 and Item 7.01, respectively, shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 12, 2020
99.2	Corporate Slide Presentation of Galera Therapeutics, Inc. dated May 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: May 12, 2020

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

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

ROMAN Phase 3 Trial Topline Data Readout Guidance Updated to 2H21 Due to Impact of COVID-19

Amendment to Royalty Agreement for Additional $37.5M Extends Cash Runway into 2H22

Locally Advanced Pancreatic Cancer Phase 1b/2a Trial Topline Data Readout and Initiation of NSCLC Anti-cancer Phase 1b/2a Trial Both Remain On Track for 2H20

MALVERN, Pennsylvania, May 12, 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 first quarter ended March 31, 2020, and provided business updates.

“Despite these unprecedented times, we have continued to progress patient enrollment in our three ongoing clinical trials of lead candidate avasopasem manganese (GC4419),” said Mel Sorensen, M.D., President and CEO of Galera. “The COVID-19 pandemic has delayed the initiation of our Phase 2a trial in Europe in patients with head and neck cancer indefinitely, which we planned to start in the first half of this year. As a result, we are increasing the size of the Phase 3 ROMAN trial for the treatment of severe oral mucositis (SOM) in patients with locally advanced head and neck cancer to ensure we are positioned to achieve our targeted number of patients for the NDA safety database, and are updating our guidance for completing enrollment to the first half of 2021 and for reporting topline data to the second half of 2021. Investigator enthusiasm remains high and we are confident in our ability to complete our ongoing trials and maintain our supply chain. In addition, we’re pleased to announce that we added $37.5 million in funding under our amended royalty agreement with Blackstone Life Sciences (formerly Clarus Ventures) which further strengthens our financial foundation and extends our cash runway into the second half of 2022.”

“In the near term, we are looking forward to avasopasem data being presented at ASCO, and are preparing to initiate an anti-cancer efficacy trial of our second product candidate, GC4711, in combination with stereotactic body radiation therapy (SBRT) in non-small cell lung cancer (NSCLC) in the second half of this year. We will continue to carefully monitor the COVID-19 situation and remain committed to thoughtfully executing our clinical programs to realize the potential of our pipeline in addressing radiation toxicities and improving the anti-cancer effect of radiation while prioritizing the health and safety of our partners and trial participants.”

Clinical Program Updates

Galera will continue to assess the rapidly evolving impacts of COVID-19 on clinical programs and operations.

Radiation-induced toxicity clinical trials:

- Updated guidance for topline data from the Phase 3 ROMAN clinical trial of avasopasem for the treatment of SOM in patients with locally advanced head and neck cancer receiving radiotherapy to the second half of 2021. COVID-19 has delayed the initiation of the Phase 2a multi-center trial in Europe in patients with head and neck cancer indefinitely. This trial was expected to enroll up to 70 patients and contribute to the safety database for avasopasem for SOM in head and neck cancer. As a result, in order to ensure we are positioned to maintain the size of the safety database, the ROMAN trial target enrollment has been increased to 450 patients.
- Continued enrollment in the Phase 2a clinical trial of avasopasem to evaluate its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer.

Anti-cancer efficacy clinical trials:

- Reaffirmed guidance for topline data from the pilot Phase 1b/2a safety and anti-cancer efficacy clinical trial of avasopasem in combination with SBRT in patients with locally advanced pancreatic cancer in the second half of 2020.
- Reaffirmed guidance for initiation of a Phase 1b/2a trial of GC4711 with SBRT in non-small cell lung cancer in the second half of 2020. GC4711 is Galera's second small molecule superoxide dismutase mimetic being developed to increase the anti-cancer efficacy of radiotherapy. This trial will evaluate GC4711 in combination with SBRT and with SBRT plus concurrent checkpoint inhibitor therapy in approximately 75 patients. A primary objective of the trial will be to assess the effects of GC4711 on measures of pneumonitis, or inflammation of the lungs. Other key objectives will include safety, local tumor control, distant metastasis rate, progression-free survival and overall survival.

Corporate Updates

- In May 2020, entered into an amendment to the 2018 royalty purchase agreement with Blackstone Life Sciences, which adds $37.5 million in additional funding to the existing $80 million royalty financing commitment that Blackstone Life Sciences (formerly Clarus Ventures) made in 2018. Under the updated agreement terms, we have agreed to pay Blackstone up to high single-digit percentage future commercial royalties from the sales of avasopasem and GC4711 until the total royalty amount achieves an unchanged fixed single-digit multiple of the aggregate financing sum received, upon which the royalty terminates. Additional information regarding this amendment is included in a Form 8-K filed by the Company with the U.S. Securities and Exchange Commission on May 12, 2020.
- In April 2020, announced three abstracts regarding avasopasem were accepted for presentation at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, taking place May 29-31, 2020. The titles of the abstracts are currently available in the ASCO digital program, with the full abstracts scheduled to be published on May 13, 2020. As previously announced, this includes the presentation titled "Effects of GC4419 (avasopasem manganese) on chronic kidney disease in head and neck cancer patients treated with radiation and cisplatin."

- In April 2020, announced the appointment of Linda B. West to our board of directors. Ms. West brings nearly 40 years of business experience to Galera's board of directors, having served in multiple leadership roles of increasing responsibility for E. I. du Pont de Nemours and Company (DuPont) until her retirement in 2019.
- In March 2020, implemented a work-from-home policy for office-based employees for the safety of employees and their families and to reduce the spread of COVID-19, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratory.

First Quarter 2020 Financial Highlights

- Research and development expenses were $14.3 million in the first quarter of 2020, compared to $8.5 million for the same period in 2019. The increase was primarily attributable to avasopasem development costs due to greater patient enrollment and additional clinical site initiations in the Phase 3 ROMAN trial, additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer, initiation of additional toxicology studies and costs associated with manufacturing scale-up activities. Employee-related costs also increased due to increased headcount and share-based compensation expense.
- General and administrative expenses were $3.6 million in the first quarter of 2020, compared to $1.9 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 $(18.4) million, or $(0.74) per share, for the first quarter of 2020, compared to a net loss of $(10.3) million, or $(41.12) per share, for the same period in 2019.
- As of March 31, 2020, Galera had cash, cash equivalents and short-term investments of $120.5 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 manganese is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer, its lead indication, and in the Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The

FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, which successfully completed Phase 1 trials in healthy volunteers. 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, 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, the anticipated direct and indirect impact of COVID-19 on Galera's business and operations, anticipated funding and payments under Galera's amended agreement with Blackstone, and the sufficiency of Galera's cash, cash equivalents and short-term investments, or cash runway. 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 March 31, 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 March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 14,252	$ 8,502
General and administrative	3,566	1,894
Loss from operations	(17,818)	(10,396)
Other income (expense)	(599)	47
Net loss	(18,417)	(10,349)
Accretion of redeemable convertible preferred stock to redemption value	—	(2,011)
Net loss attributable to common stockholders	$ (18,417)	$ (12,360)
Net loss per share of common stock, basic and diluted	$ (0.74)	$ (41.12)
Weighed average common shares outstanding, basic and diluted	24,815,024	300,597

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$120,517	$ 112,290
Total assets	130,813	123,376
Total current liabilities	12,648	9,694
Total liabilities	77,755	53,768
Total stockholders' equity	53,058	69,608

###

Investor Contacts:

Christopher Degnan
Galera Therapeutics, Inc.
610-725-1500
cdegnan@galeratx.com

Chiara Russo
Solebury Trout
617-221-9197
crusso@soleburytrout.com

Media Contact:

Heather Anderson
6 Degrees
919-827-5539
handerson@6degreespr.com

Exhibit 99.

Galera Therapeutics, Inc

Transforming Radiotherapy

with

Dismutase Mimetics

May 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, 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 March 31, 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 – Development Targets

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

IMRT
Intensity Modulated RT

Reducing IMRT Toxicity

Severe Oral Mucositis Head & Neck Cancer (SOM in HNC)

Phase 3 ROMAN

Esophagitis NSC Lung Cancer (NSCLC)

Phase 2 Trial

Normal tissue toxicity limits optimal radiotherapy treatment of tumor

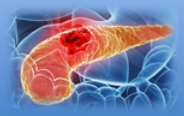
Over half of cancer patients receive radiotherapy as part of their care[1, 2]

Increase H_2O_2 in tumors

SBRT
Stereotactic Body RT

Increasing SBRT Efficacy

Pancreatic Cancer Locally Advanced (LAPC)



Phase 1b/2a SBRT Combo

Lung Cancer Oligometastatic (NSCLC)

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*

Investment Highlights

Lead Product in Phase 3

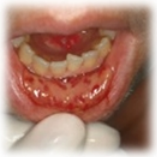
Robust Efficacy in Randomized Phase 2b (n=223)

- Breakthrough Therapy designation
- Single Phase 3 sufficient for registration (n≈450)[1]

Substantial Unmet Medical Need

Radiation-Related Severe Oral Mucositis (SOM)

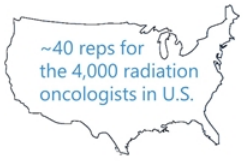
- 65,000 patients/year in US get Head & Neck Cancer
- SOM most burdensome side-effect: 70% of patients



Focused Commercial Opportunity

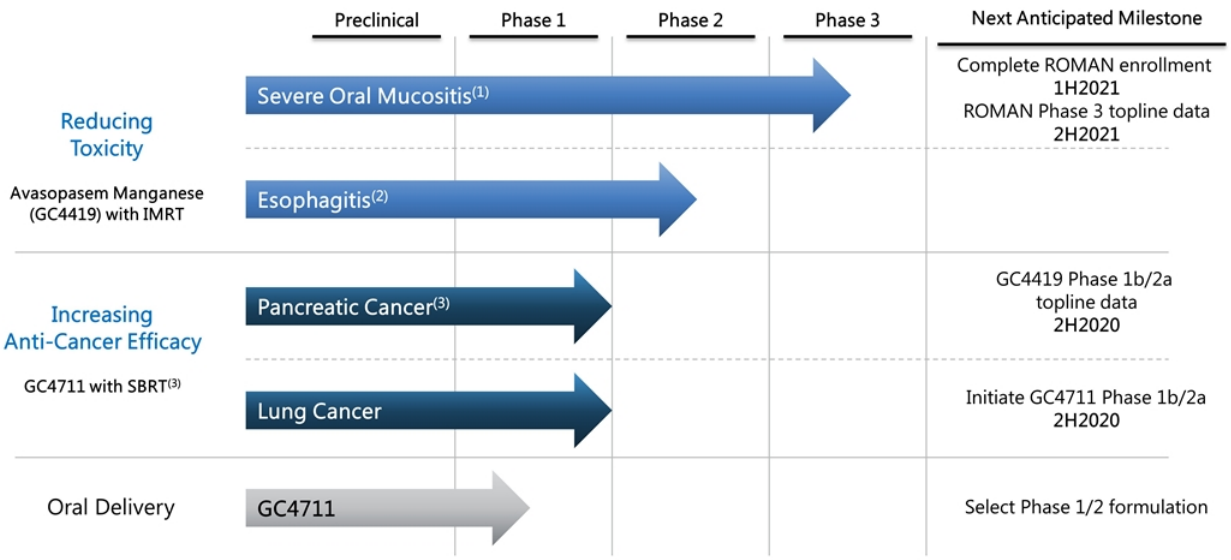
Galera Intends to Commercialize in US

- ~60% treatments in ~500 centers
- Current SOM treatments are marginally effective



[1] COVID-19 has delayed the initiation of the Phase 2a multi-center trial in Europe in patients with head and neck cancer indefinitely. This trial was expected to enroll up to 70 patients and contribute to the safety database for avasopasem for SOM in HNC. As a result, in order to maintain the size of the safety database, the ROMAN trial target enrollment has been increased to 450 patients.

Clinical Stage Pipeline



(1) We also plan to conduct a Phase 2a multi-center trial in Europe assessing the safety of 90 mg avasopasem (GC4419) in patients with HNC undergoing standard-of-care radiotherapy. COVID-19 has delayed the initiation of the trial indefinitely. We will continue to monitor and assess the COVID-19 pandemic in Europe regarding the initiation of the trial in Europe.
(2) Phase 2a trial in patients with lung cancer building on avasopasem (GC4419) safety and tolerability findings in patients with HNC SOM studies.
(3) Observations from our Phase 1b/2a pilot trial of avasopasem (GC4419) in combination with SBRT in patients with LAPC whose tumor cannot be resected will be used to help develop GC4711 to increase the anti-cancer efficacy of SBRT.

Galera Therapeutics, Inc

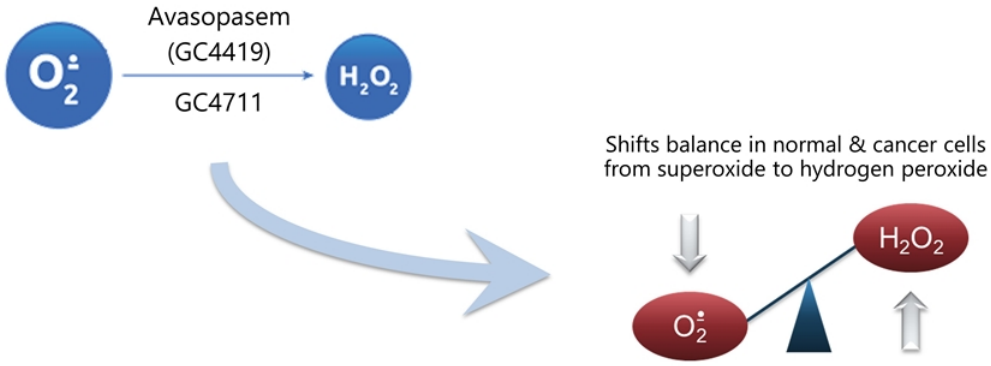
Dismutase Technology

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)

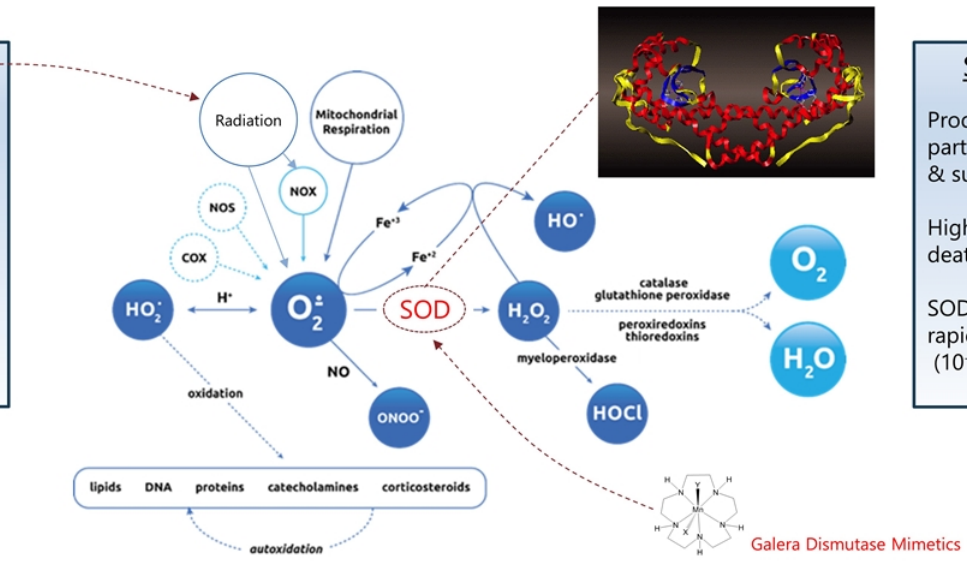


Radiation & Superoxide

Radiation

Produces bursts of superoxide, causing
- Radiolysis of water
- Stimulation of NOX, etc.
- Inflammatory response

RT-induced superoxide overwhelms SODs, resulting in normal tissue damage



Galera Dismutase Mimetics

Superoxide ($O_2^{\bullet}$)

Produced by every cell as part of cellular respiration & substrate for HOCl.

Highly toxic & leads to cell death.

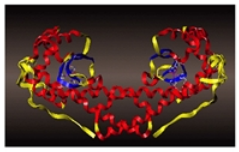
SOD enzymes evolved to rapidly convert $O_2^{\bullet}$ to H_2O_2 (10^{-7} seconds)

Galera's Dismutase Mimetics

Natural SOD Enzymes

Limitations of Natural SOD Enzymes

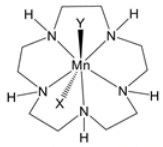
- Large size prevents entry into cells
- Immunogenicity & short half-lives
- Inactivation/inhibition by reactive oxygen species



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

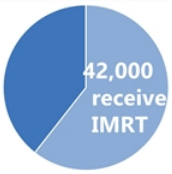
Reducing Toxicity of IMRT

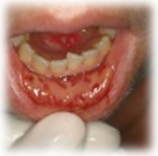
(Intensity Modulated Radiotherapy)

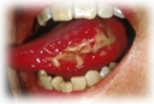
Oral Mucositis in HNC – Large Unmet Medical Need

SOM and Head & Neck Cancer

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







Can Have Devastating Complications

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

WHO Grading Scale

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

SEVERE

Current Treatments are Marginally Effective

MASCC / ISOO Guidelines for HNC OM

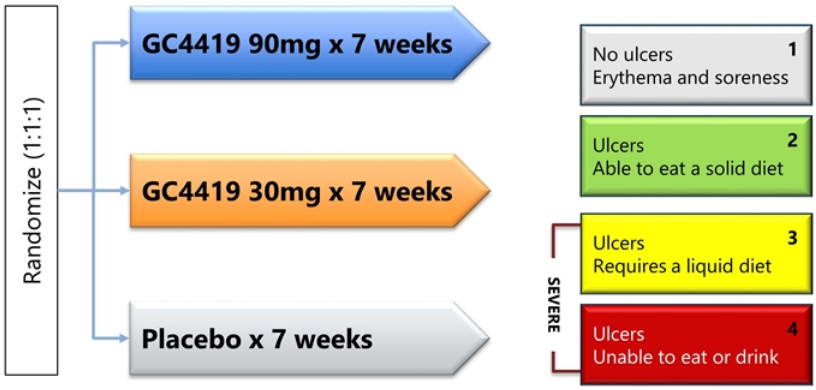
Treatment Approach	Recommended for HNC OM due to RT?
Basic oral care	✓
Anti-microbials, coating agents, anesthetics, & analgesics (0.2% morphine mouthwash)	✓
Anti-inflammatories, benzydamine	?
Low level laser & other light therapy	?
Cryotherapy for 5-FU chemotherapy	✗
Natural & other agents	✗

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

Supportive trial to the ROMAN Phase 3 for the NDA

Trial Design

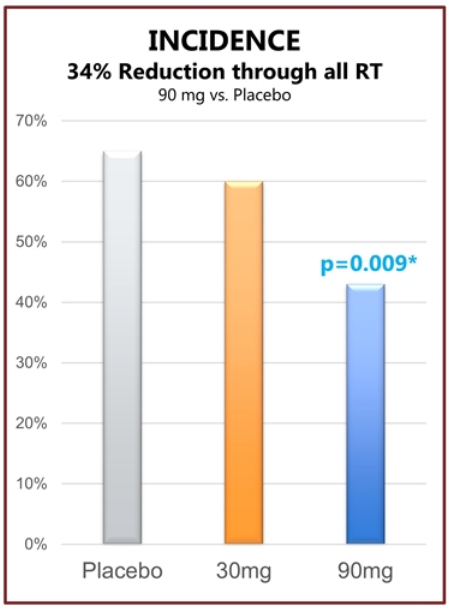
Treatment	• Avasopasem (GC4419) 90mg, 30mg, or placebo • 60 minute IV infusion, Mon-Fri. • Ending <60 mins pre-RT
Population	• Patients with HNC • Locally-advanced, squamous cell • Eligible for SoC – 7 weeks IMRT + cisplatin
Stratification Factors	• Tumor HPV Status: positive or negative • Cisplatin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

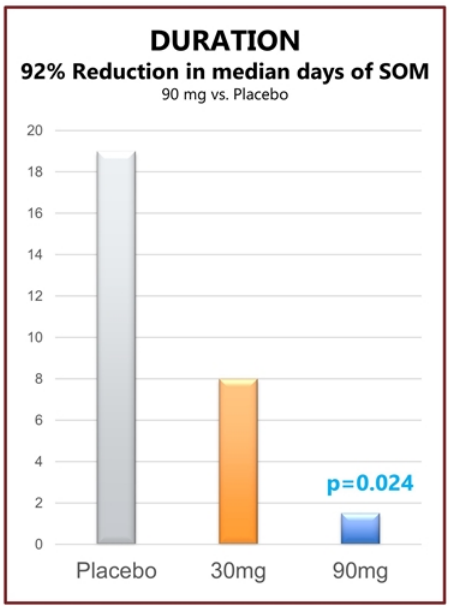


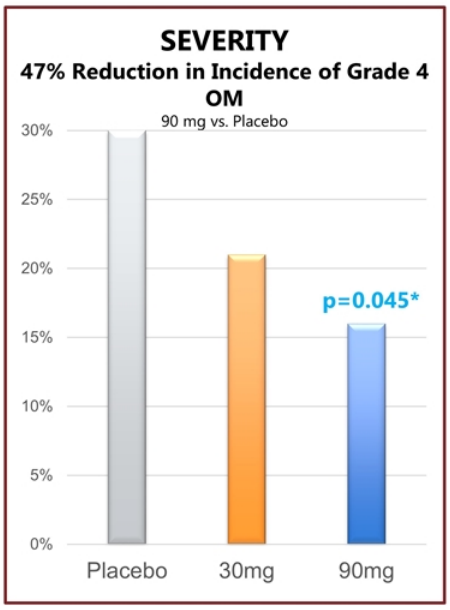
Anderson et al, JCO, 2019

Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg







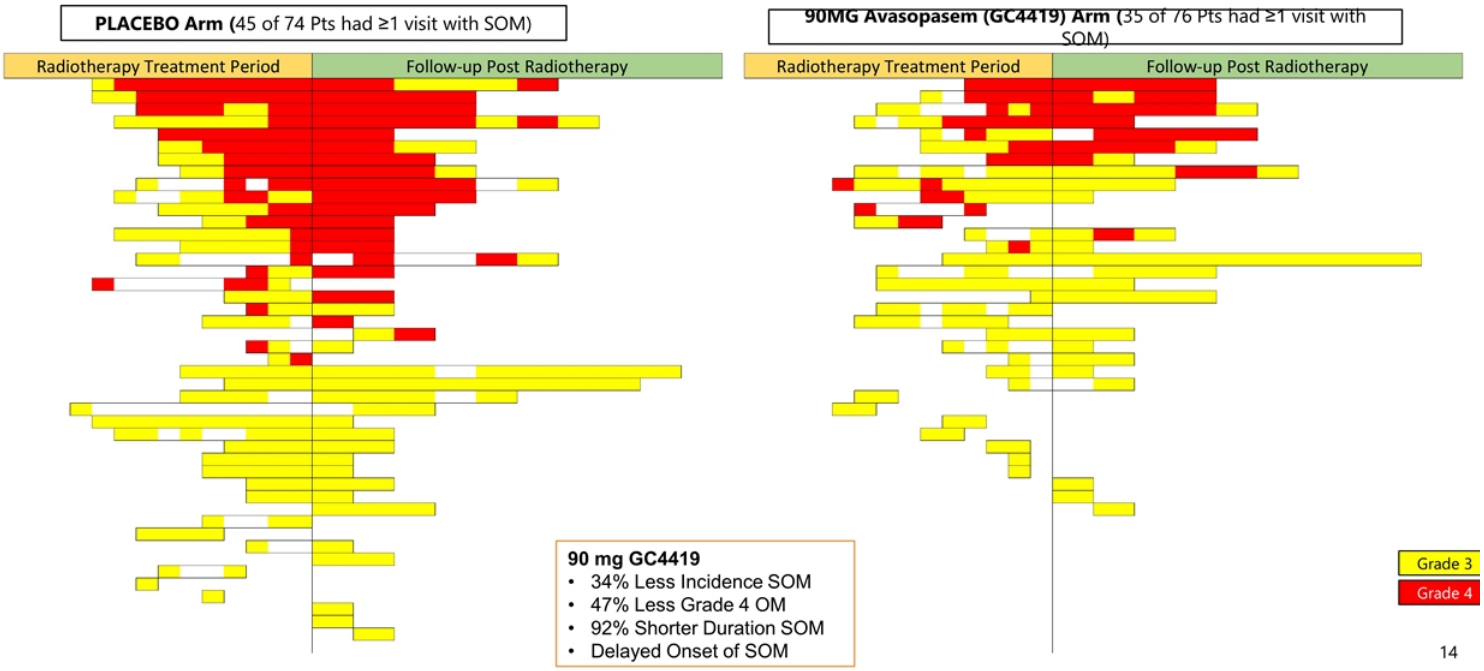
Primary endpoint was duration - defined as # days from 1st occurrence of grade 3 or 4 SOM until the 1st event of grade 2 or less (there being no subsequent grade 3 or 4 events.)

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

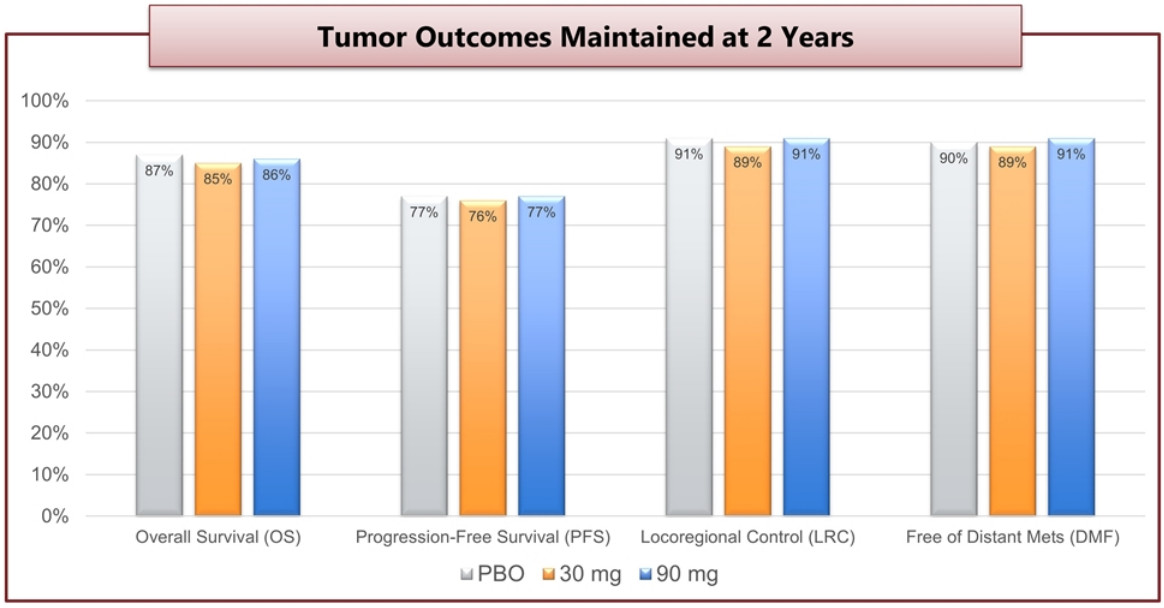
ITT = Intent-To-Treat population (n=223)

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

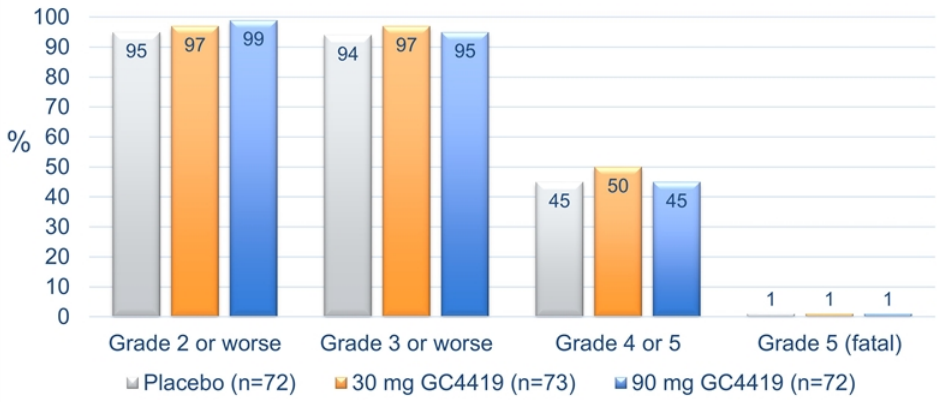


Final ITT Analysis

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

Safety Summary – 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 as expected with Standard 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%

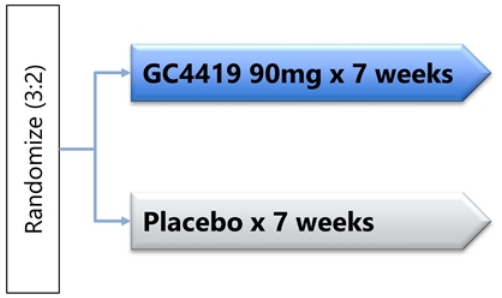
Anderson et al, JCO, 2019

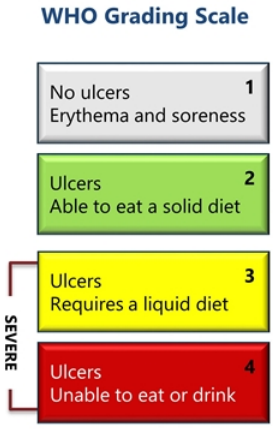
GT-301: The ROMAN Trial- Phase 3 Confirmatory Trial Enrolling

Reduction in Oral Mucositis with Avasopasem Manganese (GC4419)

Trial Design (n≈450 pts)[1]

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[2] – LRC, DM-free, PFS, OS





[1] COVID-19 has delayed the initiation of the Phase 2a multi-center trial in Europe in patients with head and neck cancer indefinitely. This trial was expected to enroll up to 70 patients and contribute to the safety database for avasopasem for SOM in HNC. As a result, in order to maintain the size of the safety database, the ROMAN trial target enrollment has been increased to 450 patients.

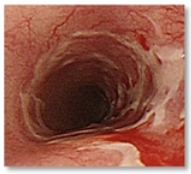
[2] LRC = locoregional control, DM-free = free of distant mets, PFS = Progression-Free Survival, OS = Overall Survival

RT-related Mucositis Beyond Head and Neck Cancer

Mucositis of Esophagus

Radiotherapy-related Esophagitis in Lung Cancer

- Galera's HNC trials 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

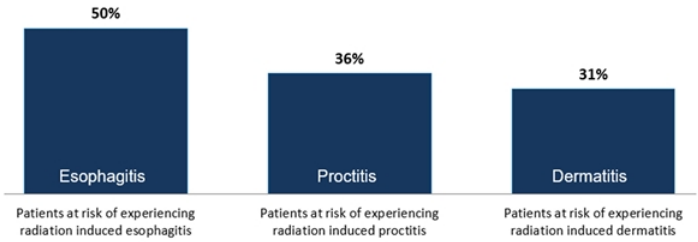


Compendial Listing

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]

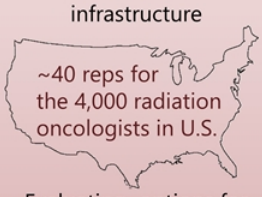
Given the demonstrated ability of Product X to prevent radiation-induced toxicities in the oral mucosa, please indicate how you might use (maximum %) Product X for the following radiation associated conditions?

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

Galera Therapeutics, Inc

Commercial Considerations

Large Commercial Opportunity Addressing Clear Unmet Need

220 Rad Oncs in market research	SOM clear unmet need	SOM common & costly	OM data representative for all mucositis	Targeted salesforce In U.S.
5% of Rad Oncs	**70% get SOM**	**~$32,000**	**4,000 Rad Oncs**	**~40 Reps**
Galera's quantitative market research to date includes ~5% of US radiation oncologists Support significant, rapid uptake of avasopasem (GC4419) for oral mucositis	Rad Oncs report severe oral mucositis is most burdensome side effect of HNC RT treatment 70% of patients get SOM (Grades 3 & 4) with standard-of-care RT & 20-30% get Grade 4	Current approaches inadequate – while frequently used, only 1 in 5 believe they are useful Patients with OM incur ~$32,000 more in medical expenses in first 6 months from start of RT	~2,500 radiotherapy sites in US ~60% of patients are treated in ~500 centers[1] Market research suggests rad oncs view OM data as representative of efficacy in esophagitis	Focused commercial infrastructure  Evaluating options for commercialization outside U.S.

Rad Oncs = Radiation Oncologists, SOM = Severe Oral Mucositis

[1] Medicare Claims Analysis by Galera in 2019

Topical Agents Perform Poorly in Efficacy Attributes

Physicians seek therapy to prevent/reduce the toxicity of radiation

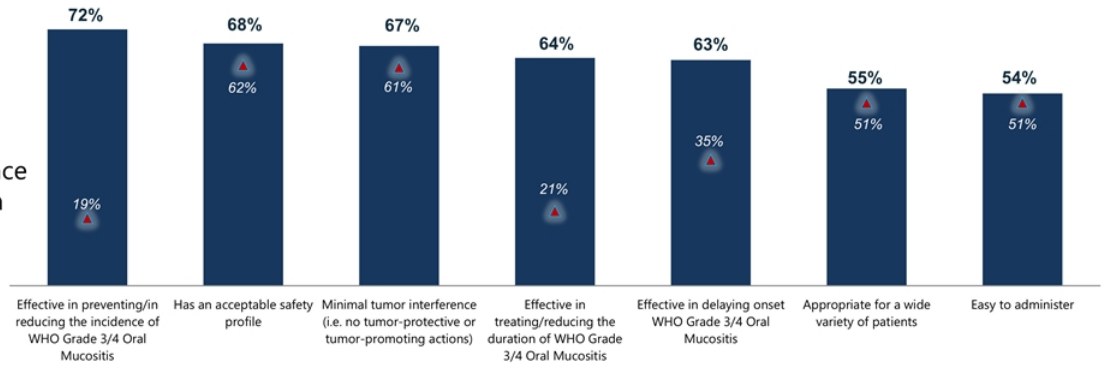
Product Performance

Product Attribute Importance & Topical Performance

- Efficacy in preventing/reducing OM is most important product attribute
- Only 19-21% MDs believe topical agents perform well in preventing or reducing mucositis

Product Importance

Rated in importance when choosing an oral mucositis treatment



Topical Performance

Rated on usefulness for treating oral mucositis

Galera Market Research (150 U.S. Radiation Oncologists)
% MDs that rated these attributes as a 6 or 7 on a 7-point scale

OM Substantially Increases Medical Expenses in Patients with HNC

Health economic analysis of patients with HNC receiving RT or chemo/RT

High Cost Of Oral Mucositis

Identified patients with locally advanced Head & Neck Cancer, treated with RT +/-chemo

- Longitudinal claims analysis[1] assessing costs over a six month period
- Compared healthcare expenses of patients with & without oral mucositis
- Included both in-patient and out-patient expenses associated with a claim

Pts with OM incur **~$32,000** more of medical expenses within first 6 months of start of RT

[1] *Navigant analysis; 40 million member years*

Physicians View Oral Mucositis Data as Potentially Applicable to Other Radiation-Related Toxicities

Other RT-related Mucositis

Avasopasem (GC4419) for other RT-related Toxicities

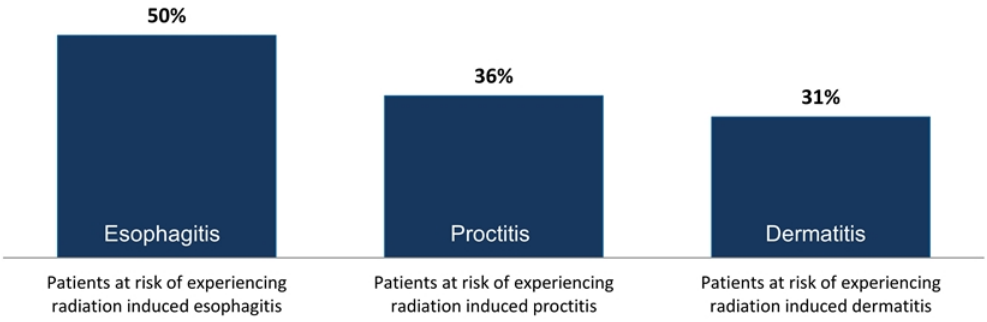
- Over 50% cancer patients will get RT at some time in their treatment
- Several major cancers treated with RT (lung, prostate, breast)
- Largest potential usage for radiation induced esophagitis (out of conditions below)

Question
Patients with Other Conditions

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?

Potential Usage in Other Radiation Associated Conditions

Maximum % of Patients with Other Conditions



Galera Market Research (150 U.S. Radiation Oncologists)

Galera Therapeutics, Inc

Increasing SBRT Efficacy

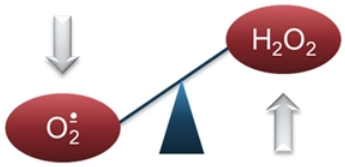
(Stereotactic Radiotherapy)

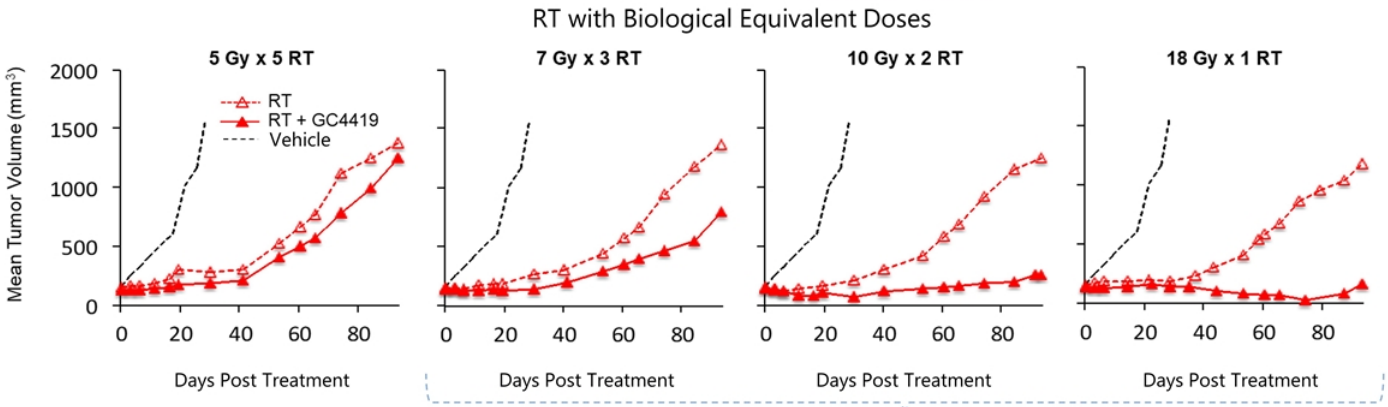
Dismutase Mimetics Increase Anti-Cancer Efficacy with High Fraction-Dose RT

Increase Radiotherapy Efficacy

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

- RT anti-cancer synergy of avasopasem (GC4419) increases with bigger RT fractions
- Bigger fraction → More O_2 → More H_2O_2





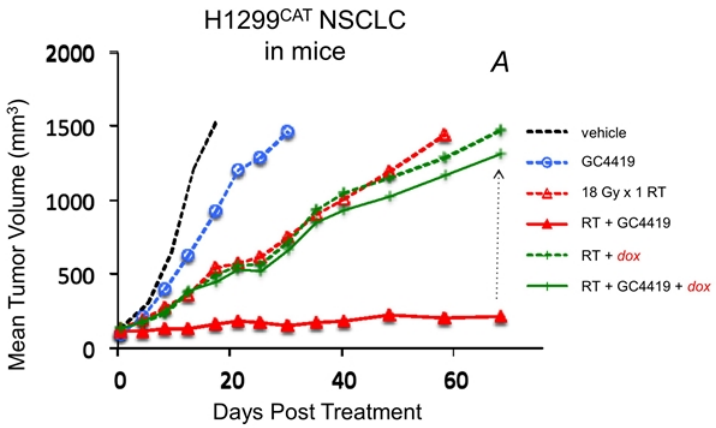
Courtesy of M Story (UTSW)

…Increase Anti-Cancer Efficacy via H_2O_2

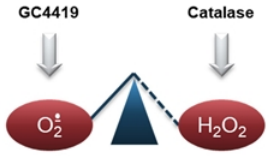
H_2O_2 Drives Increased Efficacy

SBRT Irradiation of human tumor-derived xenografts ($H1299^{CAT}$) in mice

- Engineered to overexpress catalase (disposes of H_2O_2) when induced by doxycycline
- Overexpressing catalase blocks synergy with RT by removing avasopasem (GC4419)-generated H_2O_2



Tumor tissue H_2O_2 reduced when doxycycline added to RT + avasopasem (GC4419)



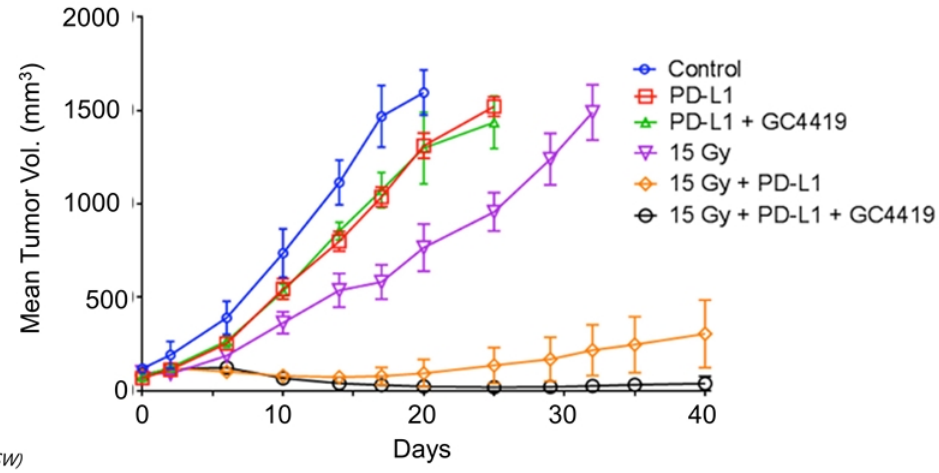
Sishc et al, AACR 2018

...Also Enhance Immuno-Radiotherapy

Increase IO + SBRT Efficacy

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

- Avasopasem (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)

Avasopasem (GC4419) + SBRT Pilot Phase 1b/2a in Pancreatic Cancer

Galera Therapeutics, Inc

Pancreatic Cancer

Locally-Advanced Pancreatic Cancer (LAPC)

- 3rd leading cause of cancer death in US – 45,750 deaths in 2019
- One year survival is 20% & 5-year survival is ~5%
- Placebo-controlled, Adaptive Trial: Escalating SBRT Dose (LO-ET Method[1]) both arms

48 Patient Pilot Trial

Screened After 6 months of induction Chemo

R

SBRT + GC4419 x 5 doses

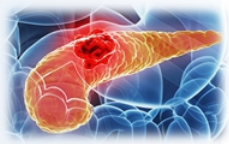
SBRT + Placebo x 5 doses

Evaluated at 2, 3, 6 & 12 months

1° Objective is **MTD of SBRT (at 12 months)**

2° Objectives include

- Progression-Free Survival (PFS)
- Overall Response Rate at 90 days



Trial status as of August 2019

Single-Center: 19 patients treated

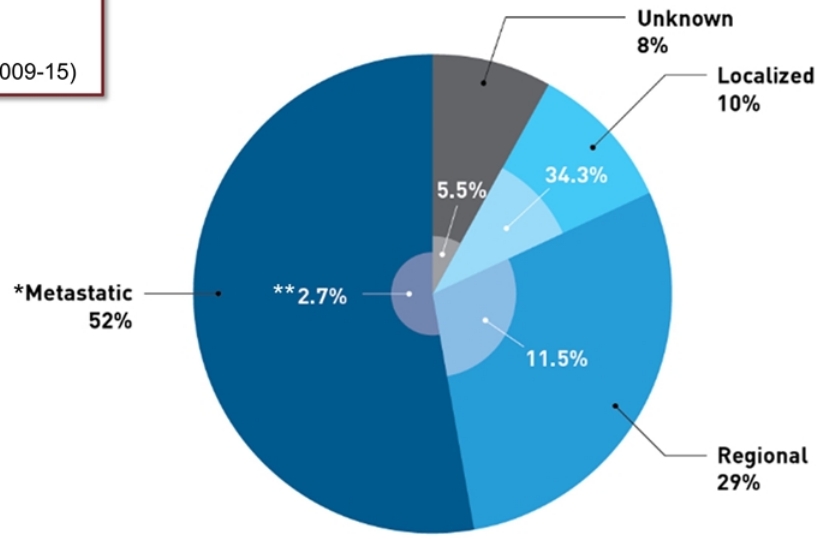
- Numerical differences in favor of avasopasem (GC4419) arm in PFS, local tumor response rate & overall response rate
- Data is preliminary, not yet audited, & subject to change
- Now Multi-Center, targeting 29 more patients

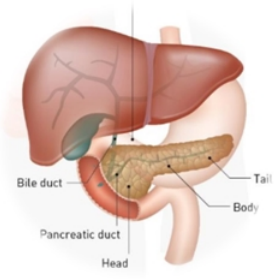
SBRT = Stereotactic Body Radiation Therapy, C Taniguchi & J Herman (MD Anderson),

[1]*LO-ET = Late-Onset Efficacy-Toxicity (*in IH, Liu S, Thall PF, Yuan Y. J Am Stat Assoc 2014;109:525-36)

Potential Eligible Pancreatic Cancer Population

Pancreatic Cancer 2018: US (World)
- Diagnoses 55k (459k)
- Deaths 44k (432k)
- 2/3rds Dx age > 65
- 5-Yr Survival (US) = 9.3% (2009-15)





* Stage at diagnosis; **5 yr survivorship by stage: surwww.seer.cancer.gov/statfacts/html/pancreas.html & https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21492
https://www.ajmc.com/journals/supplement/2019/managed-care-considerations-pancreatic-cancer/current-treatment-landscape--and-emerging-therapies-for-pancreatic-cancer

GC4711 + SBRT Combination in NSC Lung Cancer

GC4711

GC4711 – SBRT Clinical Candidate

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

NSCLC

Non-Small Cell Lung Cancer (NSCLC)

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

Pilot Study

Phase 1b/2a in NSCLC with GC4711 + SBRT

- 1st Stage: 5 fractions of SBRT +/- GC4711
- 2nd Stage: 5 fractions of SBRT + checkpoint inhibitor +/- GC4711
- Endpoints include safety, acute pneumonitis ($DLCO_2$) & PFS

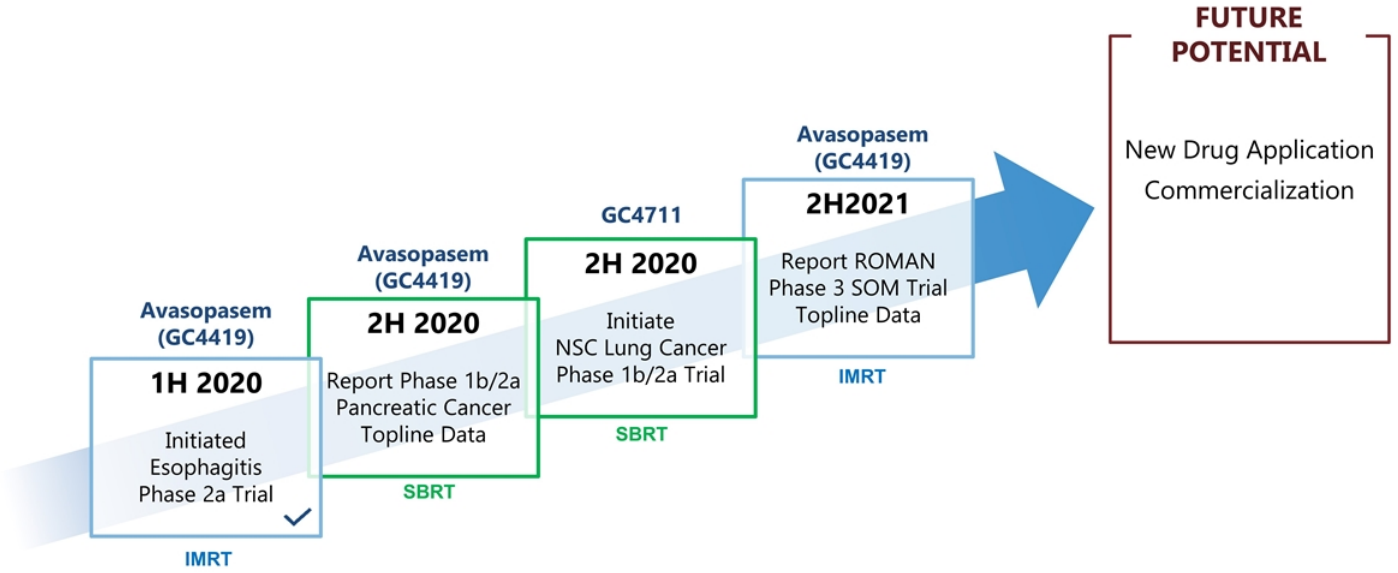
[1] 2019 SEER Data

[2] DLCO = diffusing capacity of the lung for carbon monoxide

Galera Therapeutics, Inc

Summary

Near-term Potential Catalysts to Drive Future Value



Superoxide Dismutase Mimetics – Development Targets

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

IMRT
Intensity Modulated RT

Reducing IMRT Toxicity

Severe Oral Mucositis Head & Neck Cancer (SOM in HNC)

Phase 3 ROMAN

Esophagitis NSC Lung Cancer (NSCLC)

Phase 2 Trial

Normal tissue toxicity limits optimal radiotherapy treatment of tumor

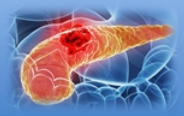
Over half of cancer patients receive radiotherapy as part of their care[1, 2]

Increase H_2O_2 in tumors

SBRT
Stereotactic Body RT

Increasing SBRT Efficacy

Pancreatic Cancer Locally Advanced (LAPC)



Phase 1b/2a SBRT Combo

Lung Cancer Oligometastatic (NSCLC)

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*