

**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): July 14, 2020**

**GALERA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**001-39114**  
(Commission  
File Number)

**46-1454898**  
(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
<b>Common Stock, \$0.001 par value per share</b>	<b>GRTX</b>	<b>The Nasdaq Global Market</b>

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

Emerging growth company

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

**Item 7.01. Regulation FD Disclosure.**

Galera Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On July 14, 2020, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at [www.galeratx.com](http://www.galeratx.com). A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

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

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Corporate Slide Presentation of Galera Therapeutics, Inc. dated July 2020</a>

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: July 14, 2020

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



Transforming Radiotherapy

*with*

Dismutase Mimetics

July 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.



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

Over half of cancer patients receive radiotherapy as part of their care<sup>1, 2</sup>

Increase  $H_2O_2$  in tumors

**IMRT**  
Intensity Modulated RT

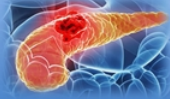

**Reducing Toxicity**

<p><b>Severe Oral Mucositis</b> Head &amp; Neck Cancer (SOM in HNC)</p> 	<p><b>Esophagitis</b> NSC Lung Cancer (NSCLC)</p> 
<p><b>Phase 3</b> ROMAN</p>	<p><b>Phase 2</b> Trial</p>



**SBRT**  
Stereotactic Body RT

**Increasing Efficacy**

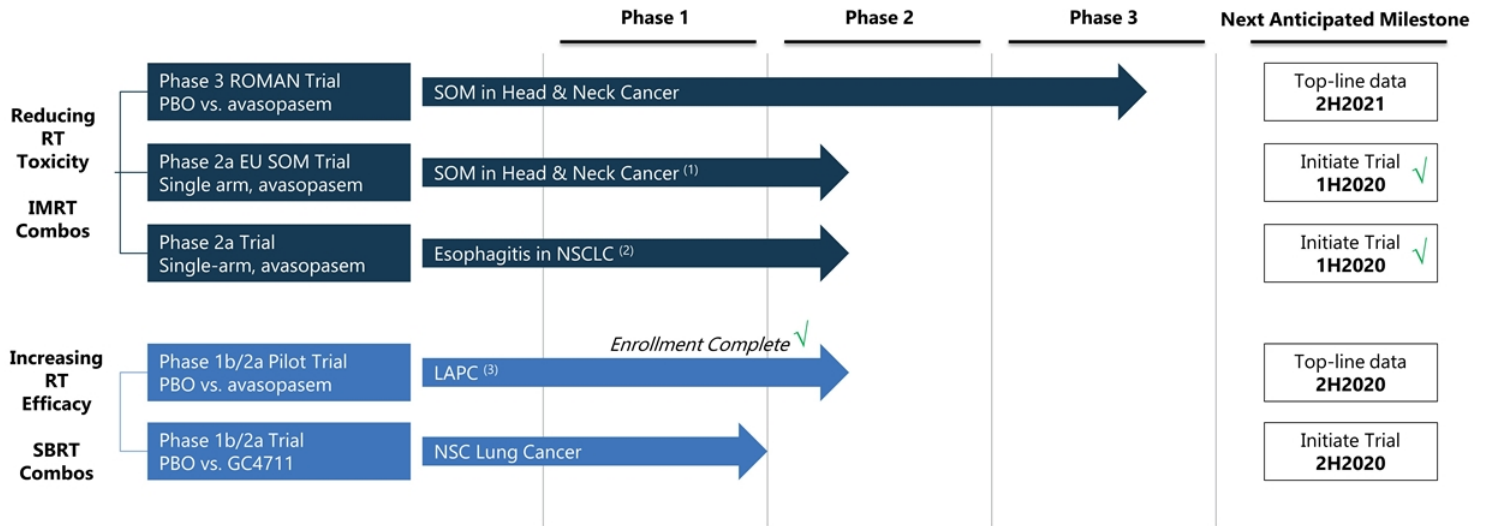
<p><b>Pancreatic Cancer</b> Locally Advanced (LAPC)</p> 	<p><b>Lung Cancer</b> Locally Advanced (LANSCLC)</p> 
<p><b>Phase 1b/2a</b> SBRT Combo</p>	<p><b>Phase 1b/2a</b> SBRT Combo</p>

Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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

<sup>1</sup> Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment... *Cancer*. 2005;104:1129-1137  
<sup>2</sup> Beggs 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 HNC patients in Europe. First patient dosed in June 2020. We continue to monitor the COVID-19 pandemic in Europe regarding enrollment prospects for this trial.  
 (2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings in patients with HNC SOM studies.  
 (3) This first SBRT combination trial used GC4419. Observations from this pilot trial will be used to help develop GC4711 to increase the anti-cancer efficacy of SBRT.

Avasopasem  
In Phase 3

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

- Breakthrough Therapy designation granted by FDA
- Single Phase 3 sufficient for registration (n≈450)

JOURNAL OF  
CLINICAL  
ONCOLOGY

J.Clin.Oncol. 2019 Dec 1; 37(34): 3256-3265.

RT-related  
Toxicity

### Radiation-Related Severe Oral Mucositis (SOM)

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



Anti-Cancer  
Efficacy

### Pilot Phase 1b/2a Anti-cancer Trial in Locally Advanced Pancreatic Cancer

- Randomized, placebo-controlled trial
- Unmet medical need following induction chemotherapy





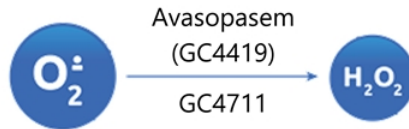
## Dismutase Technology



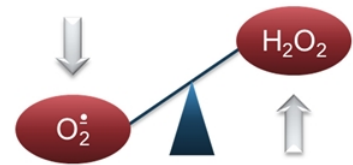
Dismutase Mimetics

### Small Molecule Enzyme Mimetics

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



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

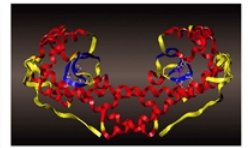




## Native SOD Enzymes

### Native SOD Enzymes

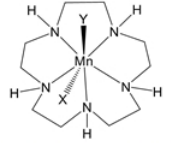
- Overexpression reduces RT toxicity
- Large size, immunogenicity & short half-lives limit bioavailability
- Inactivation/inhibition by reactive oxygen species



## Small Molecule Mimetics

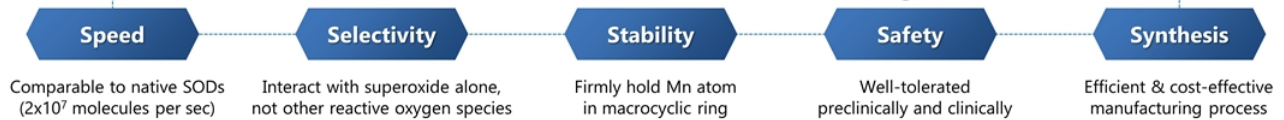
### Challenge: suitable small molecule dismutase mimetics

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



Dismutase Mimetics Core Structure  
Pentaaza Macrocycles

### Small Molecule Dismutase Mimetics with Attractive Drug Characteristics





# Reducing Toxicity of IMRT

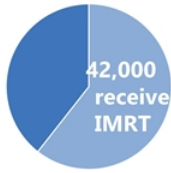
(Intensity Modulated Radiotherapy)





## 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

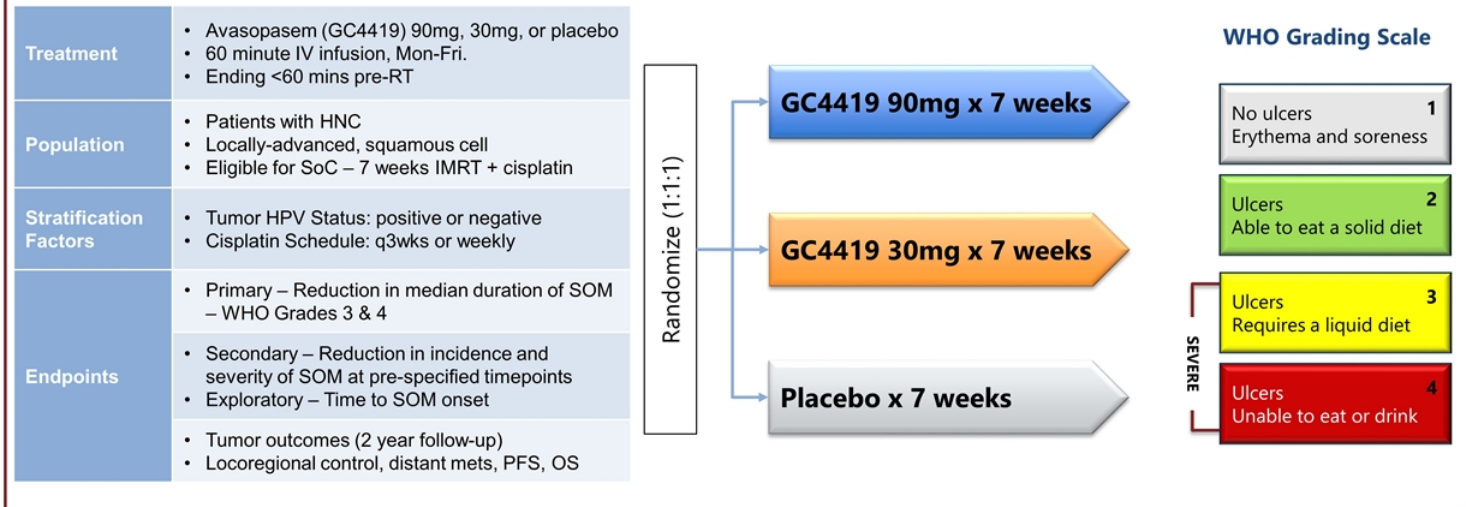
MASCC / ISOO Guidelines for HNC OM

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

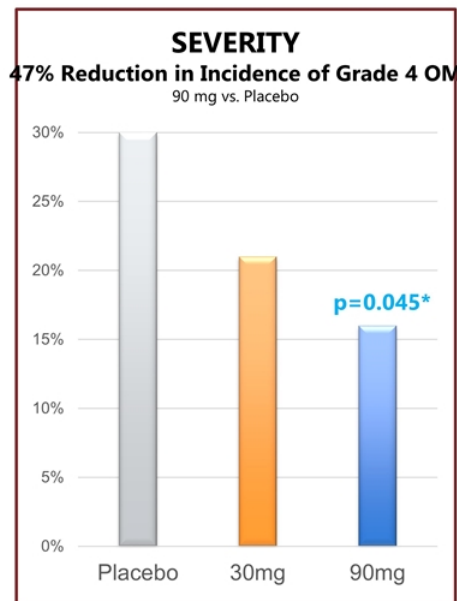
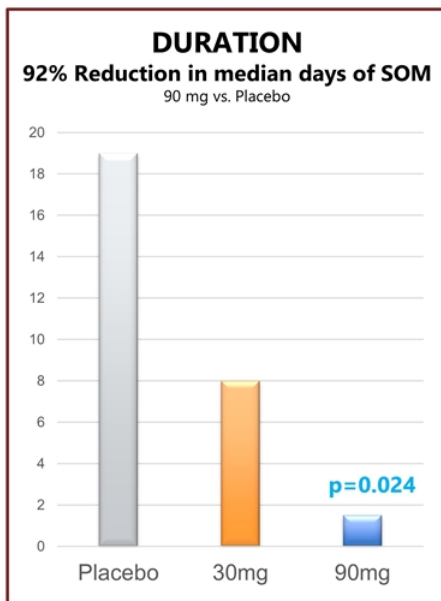
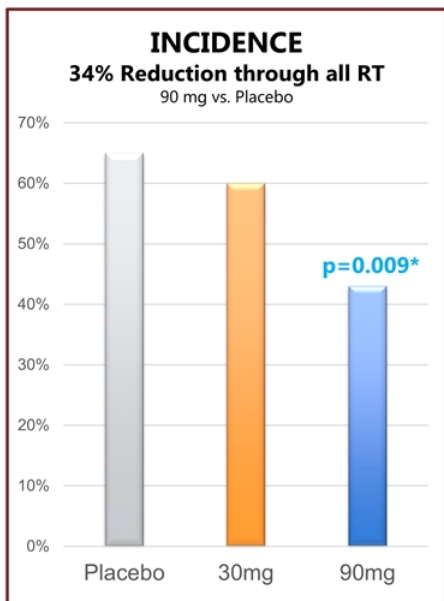
Supportive trial to the ROMAN Phase 3 for the NDA

## Trial Design



# Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg



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

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

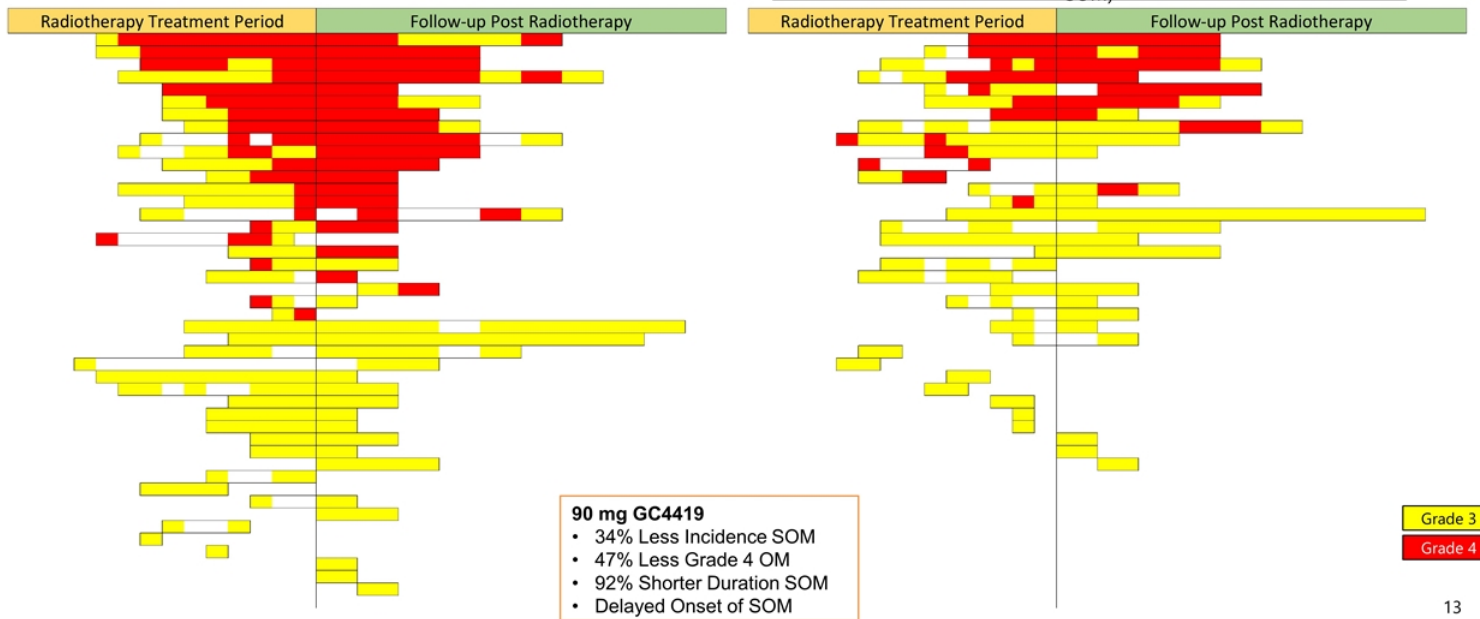
ITT = Intent-To-Treat population (n=223)

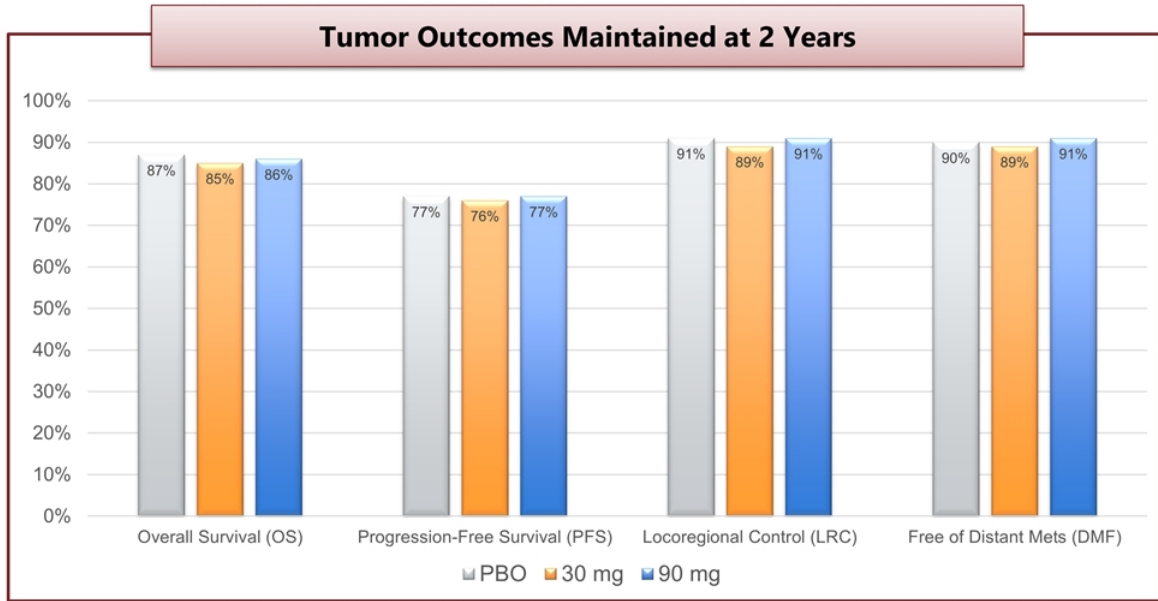
# Efficacy Parameters Better on 90mg arm Compared to Placebo

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

**PLACEBO Arm** (45 of 74 Pts had  $\geq 1$  visit with SOM)

**90MG Avasopasem (GC4419) Arm** (35 of 76 Pts had  $\geq 1$  visit with SOM)

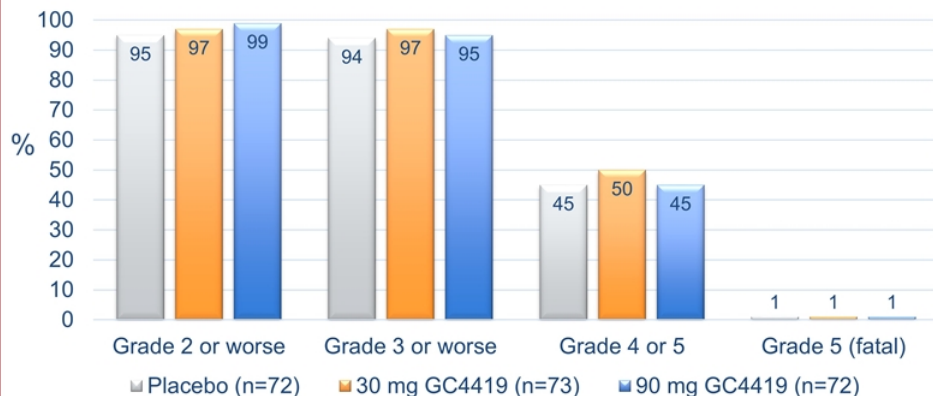




Final ITT Analysis

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

### 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%

## Trial Design (n≈450 pts)

<b>Treatment</b>	<ul style="list-style-type: none"> <li>Avasopasem (GC4419) 90mg or placebo</li> <li>60 minute IV infusion, Mon-Fri</li> <li>Ending &lt;60 mins pre-RT</li> </ul>
<b>Population</b>	<ul style="list-style-type: none"> <li>Patients with Head &amp; Neck Cancer</li> <li>Locally-advanced, squamous cell</li> <li>Eligible for SoC – 7 weeks IMRT + cisplatin</li> </ul>
<b>Stratification Factors</b>	<ul style="list-style-type: none"> <li>Surgery Status: post-op or definitive</li> <li>Cisplatin Schedule: q3wks or weekly</li> </ul>
<b>Endpoints</b>	<ul style="list-style-type: none"> <li>Primary – Reduction in incidence of SOM – WHO Grades 3 &amp; 4</li> <li>Secondary – Reductions in severity of SOM and number of days of SOM experienced</li> <li>Tumor outcomes<sup>1</sup> – LRC, DM-free, PFS, OS</li> </ul>

Randomize (3:2)

GC4419 90mg x 7 weeks

Placebo x 7 weeks

### WHO Grading Scale

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

SEVERE

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

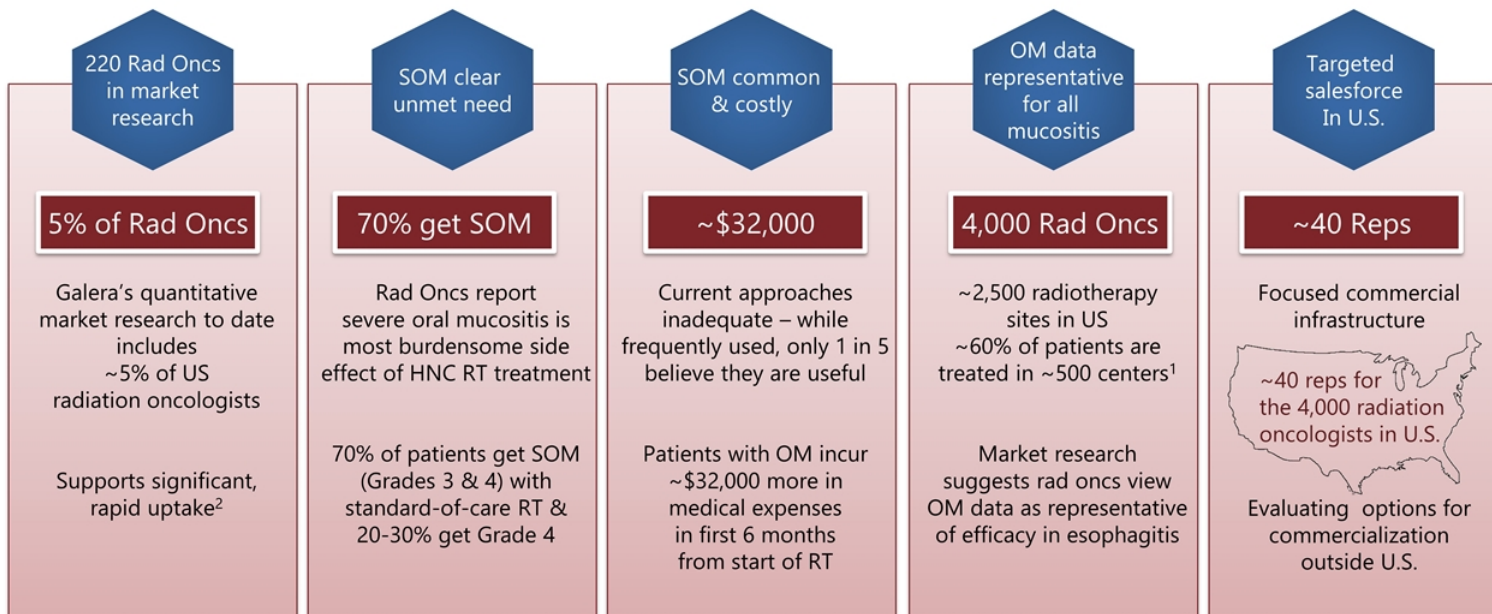


## Commercial Considerations





# Large Commercial Opportunity Addressing Clear Unmet Need



Rad Oncs = Radiation Oncologists, SOM = Severe Oral Mucositis

<sup>1</sup> Medicare Claims Analysis by Galera in 2019 <sup>2</sup>Hypothetical Product X for SOM with a similar profile to avasopasem Phase 2b results

# 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<sup>1</sup> 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

<sup>1</sup> Navigant analysis; 40 million member years

Mucositis of Esophagus

### Radiotherapy-related Esophagitis in Lung Cancer

- SOM efficacy seen by radiation oncologists as supportive for esophagitis<sup>1</sup>
- ~50,000 lung cancer patients are treated with RT, 50% get ≥ Grade 2 esophagitis<sup>2</sup>
- 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.



50%



Esophagitis

Patients at risk of experiencing radiation induced esophagitis

### Market Research Question Patients with Other Conditions<sup>1</sup>

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?

<sup>1</sup>Galera Market Research (150 Radiation Oncologists)

<sup>2</sup> NCI or RTOG grading scales



# Increasing SBRT Efficacy

(Stereotactic Radiotherapy)

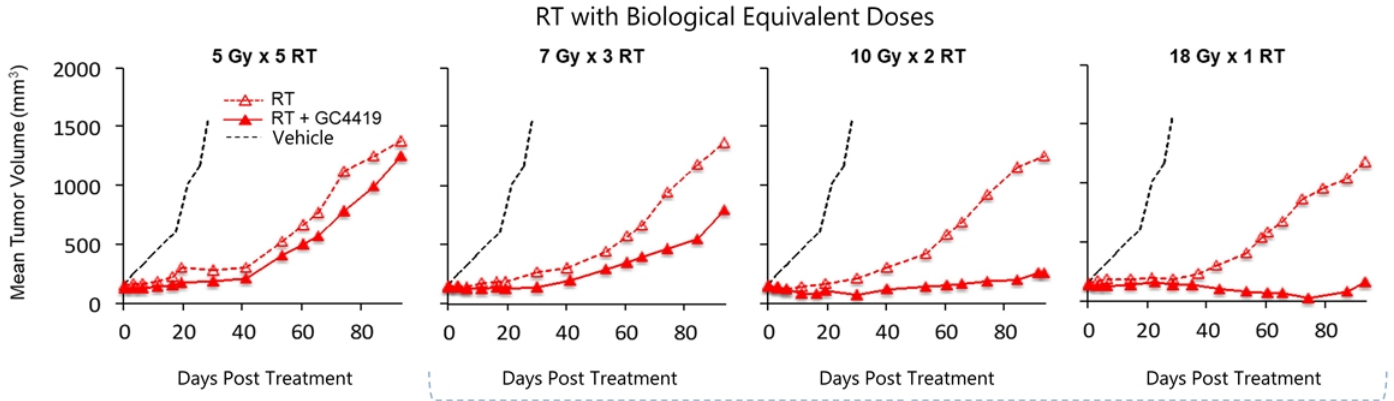
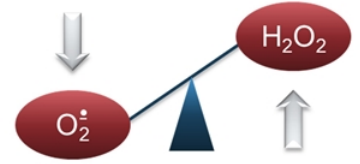


# Dismutase Mimetics Increase Anti-Cancer Efficacy with High Fraction-Dose RT in Preclinical Models

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  $O_2^{\cdot -}$  → More  $H_2O_2$
- Also demonstrated with human pancreatic cancer xenografts



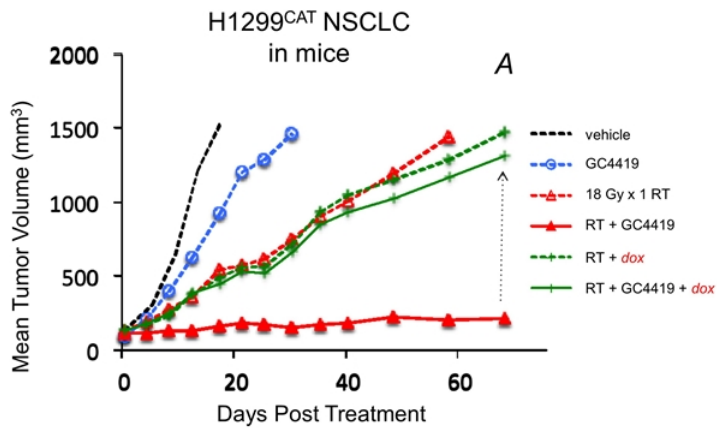
Courtesy of M Story (UTSW)

SBRT  
Stereotactic Body Radiation Therapy

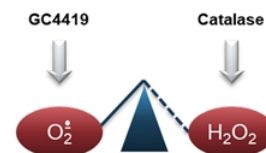
H<sub>2</sub>O<sub>2</sub> Drives Increased Efficacy

## SBRT Irradiation of human tumor-derived xenografts (H1299<sup>CAT</sup>) in mice

- Engineered to overexpress catalase (disposes of H<sub>2</sub>O<sub>2</sub>) when induced by doxycycline
- Overexpressing catalase blocks synergy with RT by removing GC4419-generated H<sub>2</sub>O<sub>2</sub>



Tumor tissue H<sub>2</sub>O<sub>2</sub> reduced when doxycycline added to RT + avasopasem (GC4419)





Target  
Treatment  
Population

## Increasing Number of Pancreatic Cancer Patients Diagnosed Each Year

- 57,000 newly diagnosed/year<sup>1</sup>
- 65% of Stage 2: unresectable (UR) or borderline resectable (BR) at Diagnosis
- 85% of Stage 3: UR or BR at Diagnosis

} 18,000 Pts<sup>2</sup>

Novel  
Therapies  
Needed

## First Line Treatment is Induction Chemotherapy for Over 80% of Patients<sup>2</sup>

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

SBRT is  
Accepted  
Tx Option

## NCCN Recommends SBRT for some Patients with Locally Advanced Pancreatic Cancer (LAPC)<sup>5</sup>

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

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

<sup>3</sup> Acta Oncologica, 2015; 54: 979-985 <sup>4</sup> Suker M., Beumer B.R., Sadot E., Marthey L., Faris J.E., Mellon E.A. The Lancet Oncology. 2016;17(6):801-810.

<sup>5</sup> NCCN = National Comprehensive Cancer Network-2019

**SBRT  
Combo  
Pilot Trial**

**Double-blind, Placebo-controlled, Randomized Adaptive Trial**

- Enrollment of maximum of 24 patients on each arm (LO-ET<sup>1</sup> design)
- Primary objective is MTD of escalating fractions of SBRT
- Secondary objectives include Progression-Free Survival, Overall Response Rate at 90 days

**Trial  
Status**

**Expanded from Single Center (MDA) to Multi-Center (n=5) after First 19 Patients**

- Single-center (n=19) experience: PFS & response rates favored GC4419 arm
- Enrollment completed & last patient treated
- Topline safety and efficacy results will be presented later this year



SBRT = Stereotactic Body Radiation Therapy, C Taniguchi & J Herman (MD Anderson),  
<sup>1</sup>LO-ET = Late-Onset Efficacy-Toxicity (in IH, Liu S, Thall PF, Yuan Y. J Am Stat Assoc 2014;109:525-36)



GC4711

## GC4711 – SBRT Clinical Candidate

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

NSCLC

## Non-Small Cell Lung Cancer (NSCLC)

- Leading cause of cancer death in US – 142,670 deaths in 2019<sup>1</sup>
- 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

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

<sup>1</sup> 2019 SEER Data

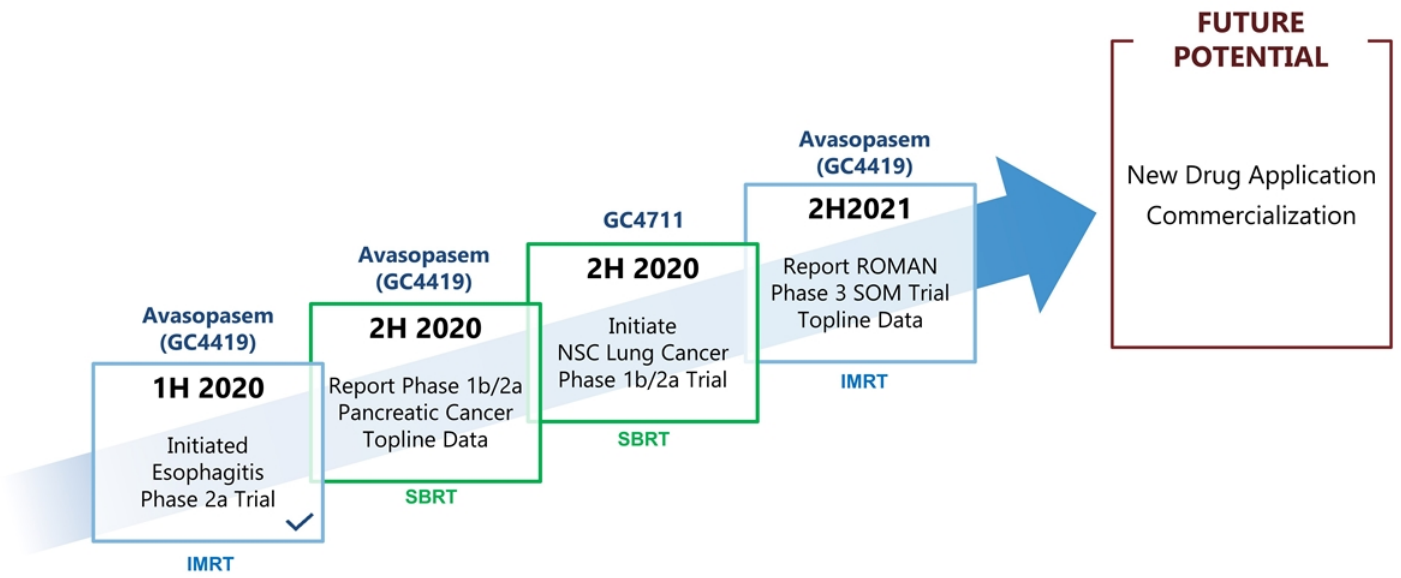
<sup>2</sup> DLCO = diffusing capacity of the lung for carbon monoxide



## Summary



# Near-term Potential Catalysts to Drive Future Value





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

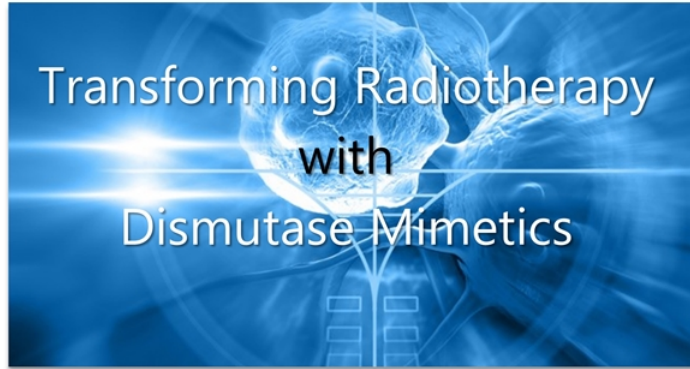
Over half of cancer patients receive radiotherapy as part of their care<sup>1, 2</sup>

Increase  $H_2O_2$  in tumors

**IMRT**  
Intensity Modulated RT

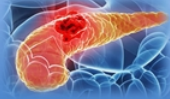

**Reducing Toxicity**

<p><b>Severe Oral Mucositis</b> Head &amp; Neck Cancer (SOM in HNC)</p> 	<p><b>Esophagitis</b> NSC Lung Cancer (NSCLC)</p> 
<p><b>Phase 3</b> ROMAN</p>	<p><b>Phase 2</b> Trial</p>



**SBRT**  
Stereotactic Body RT

**Increasing Efficacy**

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

Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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

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