

**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): September 16, 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
Common Stock, \$0.001 par value per share	GRTX	The Nasdaq Global Market

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

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

Galera Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On September 16, 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 99.1. 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	Corporate Slide Presentation of Galera Therapeutics, Inc. dated September 16, 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: September 16, 2020

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



Transforming Radiotherapy

with

Dismutase Mimetics

September 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 June 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.

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

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

Increase H_2O_2 in tumors

IMRT
Intensity Modulated RT

Reducing Toxicity

<p>Severe Oral Mucositis Head & Neck Cancer (SOM in HNC)</p> <p>Phase 3 ROMAN</p>	<p>Esophagitis NSC Lung Cancer (NSCLC)</p> <p>Phase 2 Trial</p>
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Transforming Radiotherapy
with
Dismutase Mimetics

SBRT
Stereotactic Body RT

Increasing Efficacy

<p>Pancreatic Cancer Locally Advanced (LAPC)</p> <p>Phase 1b/2a SBRT Combo</p>	<p>Lung Cancer Locally Advanced (LANSCLC)</p> <p>Phase 1b/2a SBRT Combo</p>
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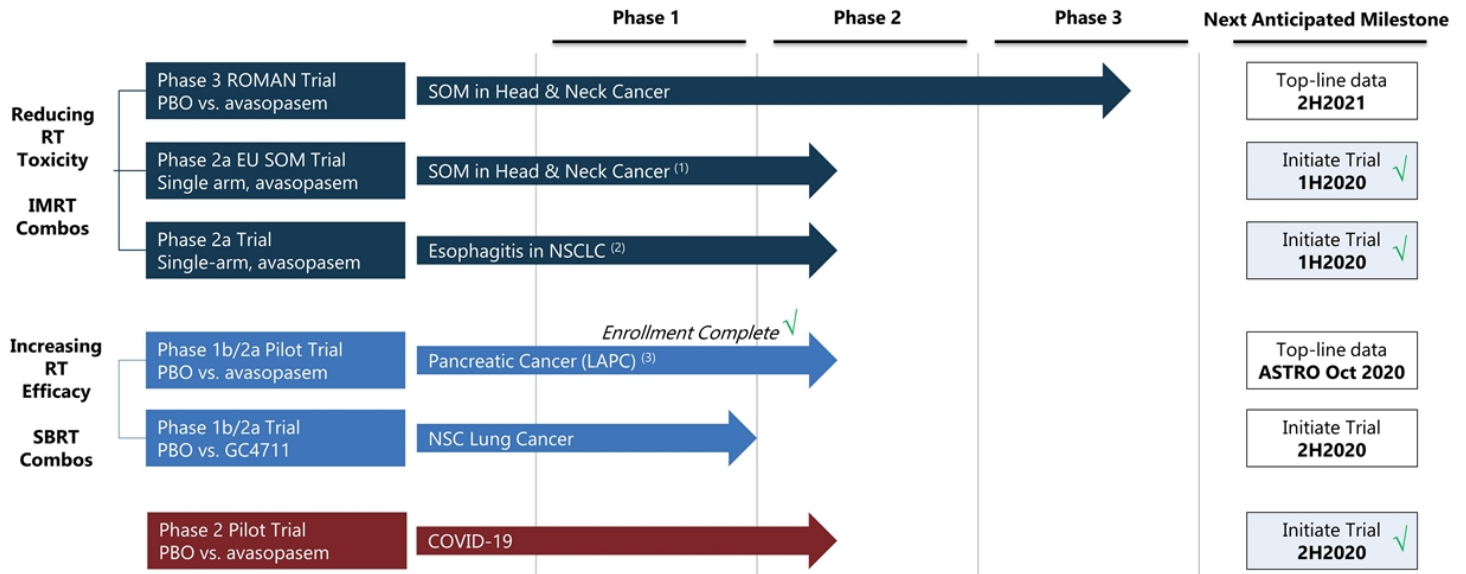
Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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

¹ Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment... *Cancer*. 2005;104:1129-1137

² Begg AC, Stewart FA, Vens C. Strategies to improve radiotherapy with targeted drugs. *Nat Rev Cancer*. 2011;11:239-253

Clinical Stage Pipeline



(1) EUSOM is a single-arm multi-center trial evaluating the safety of avasopasem in 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)



RT-related
Toxicity

Radiation-Related Severe Oral Mucositis (SOM)

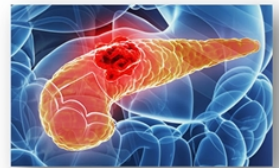
- 65,000 patients/year in US get Head & Neck Cancer
- SOM most burdensome side-effect: 70% of patients



Anti-Cancer
Efficacy

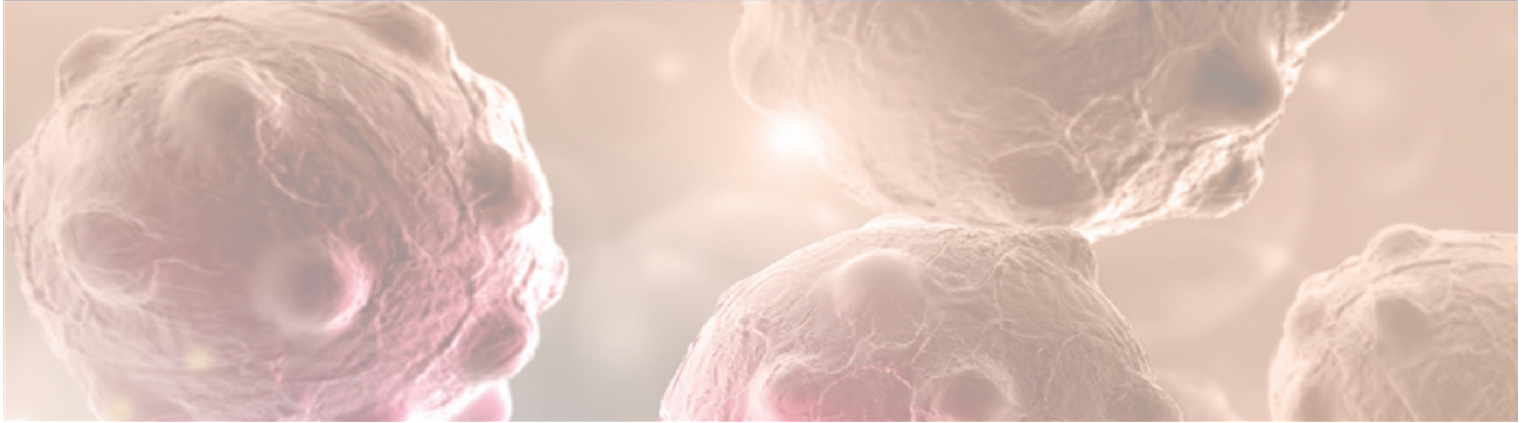
Pilot Phase 1b/2a Anti-cancer Trial in Locally Advanced Pancreatic Cancer

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





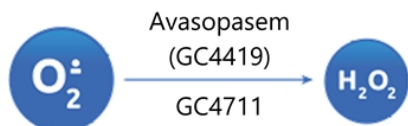
Dismutase Technology



Dismutase Mimetics

Small Molecule Enzyme Mimetics

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



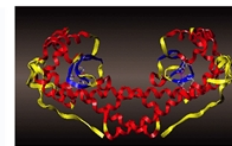
Shifts balance in normal & cancer cells from superoxide to hydrogen peroxide



Native SOD Enzymes

Native SOD Enzymes

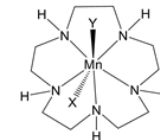
- Overexpression reduces RT toxicity
- Large size, immunogenicity & short half-lives limit bioavailability
- Inactivation/inhibition by reactive oxygen species



Small Molecule Mimetics

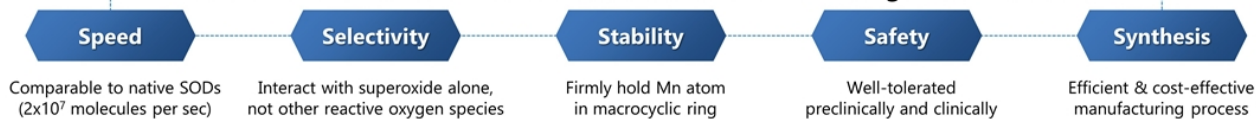
Challenge: suitable small molecule dismutase mimetics

- 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





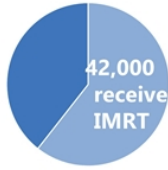
Reducing Toxicity of IMRT

(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

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**

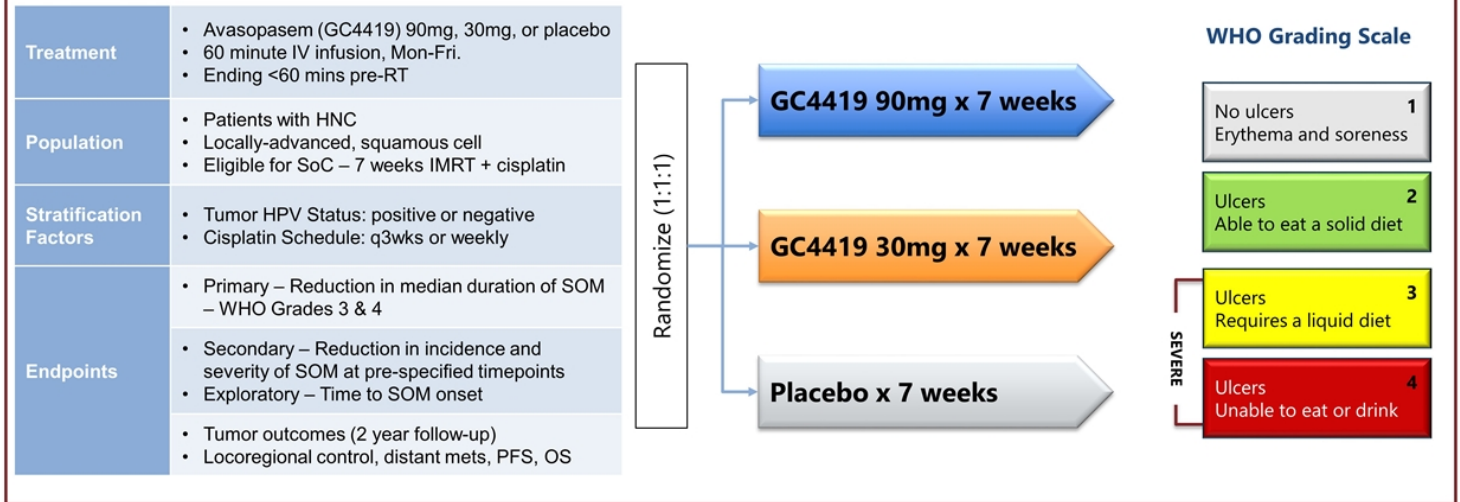
- Treatment interruption**
Each week of treatment delay decreases tumor control by >10%
- Increased economic burden**
OM Dx → ~\$32,000 in additional medical expenses in first 6 months from RT start

Current Treatments

MASCC / ISOO Guidelines for HNC OM

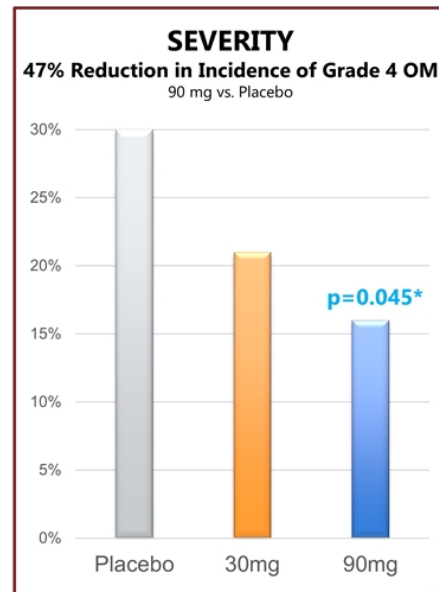
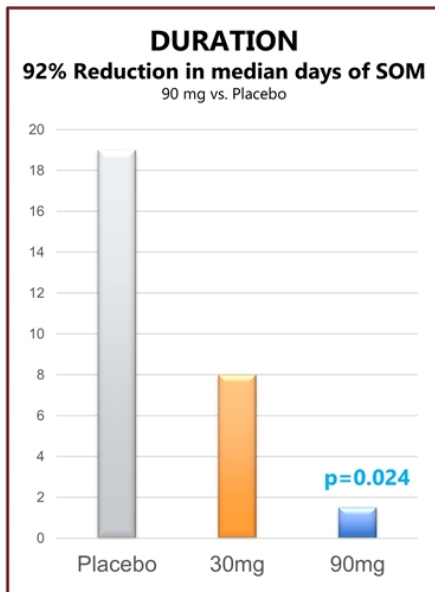
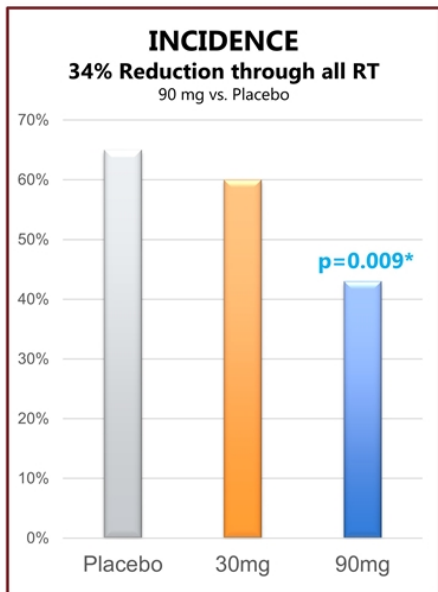
Treatment Approach	Recommended for HNC OM due to RT?
Basic oral care	✓
Anti-microbials, coating agents, anesthetics, & analgesics (0.2% morphine mouthwash)	✓
Anti-inflammatories, benzydamine	?
Low level laser & other light therapy	?
Cryotherapy for 5-FU chemotherapy	✗
Natural & other agents	✗

Trial Design



Consistent Efficacy Across All SOM Parameters

And consistent dose response: 90mg > 30mg



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

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

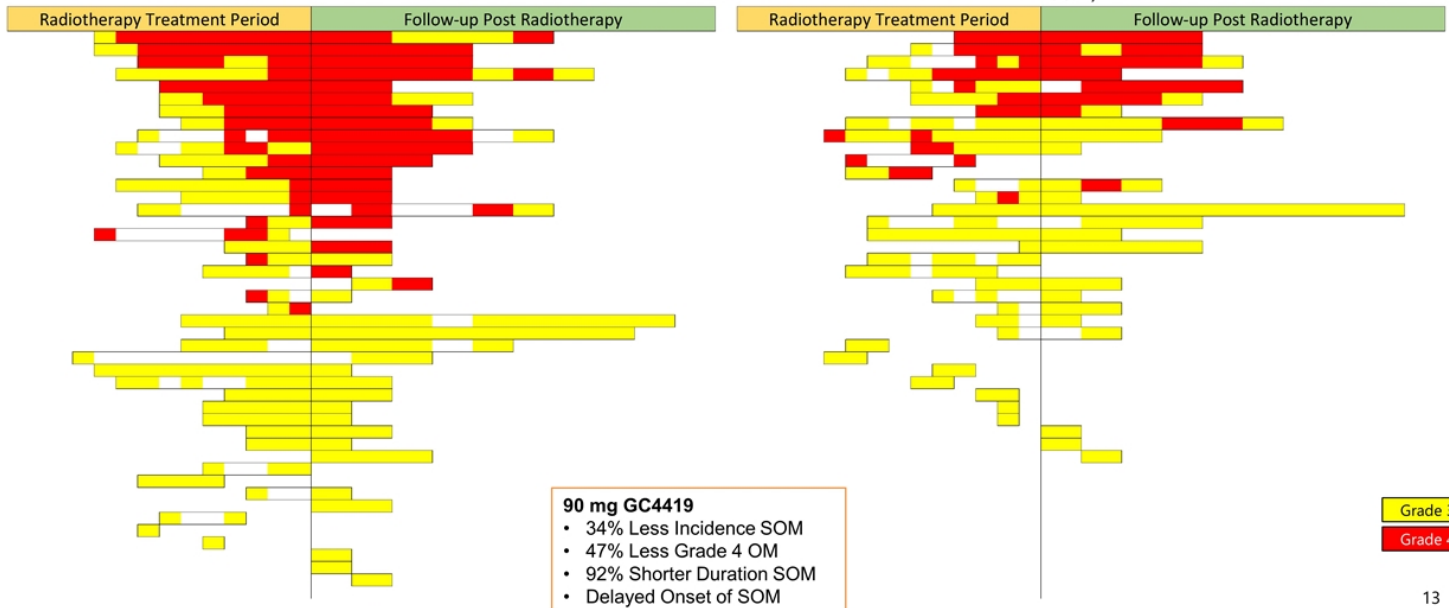
ITT = Intent-To-Treat population (n=223)

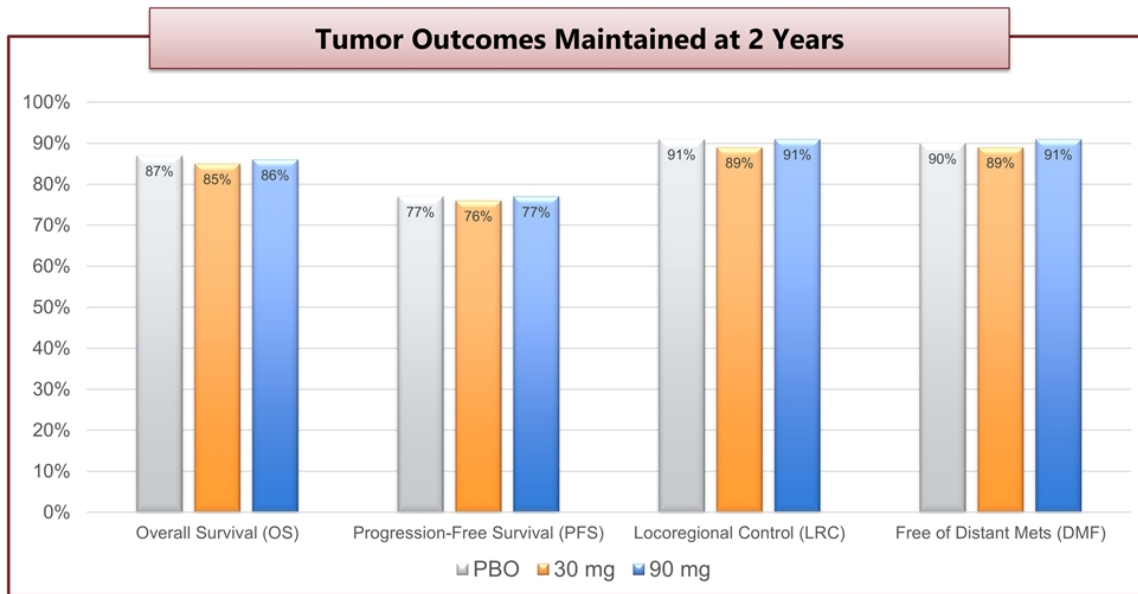
Efficacy Parameters Better on 90mg arm Compared to Placebo

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

PLACEBO Arm (45 of 74 Pts had ≥ 1 visit with SOM)

90MG Avasopasem (GC4419) Arm (35 of 76 Pts had ≥ 1 visit with SOM)

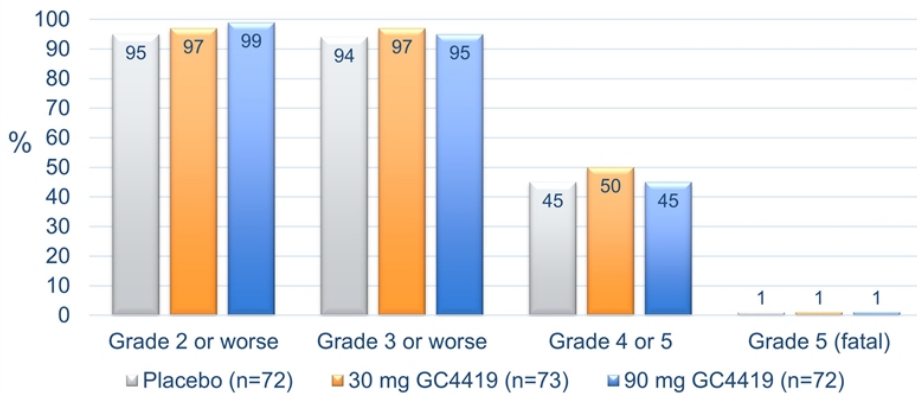




Final ITT Analysis

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

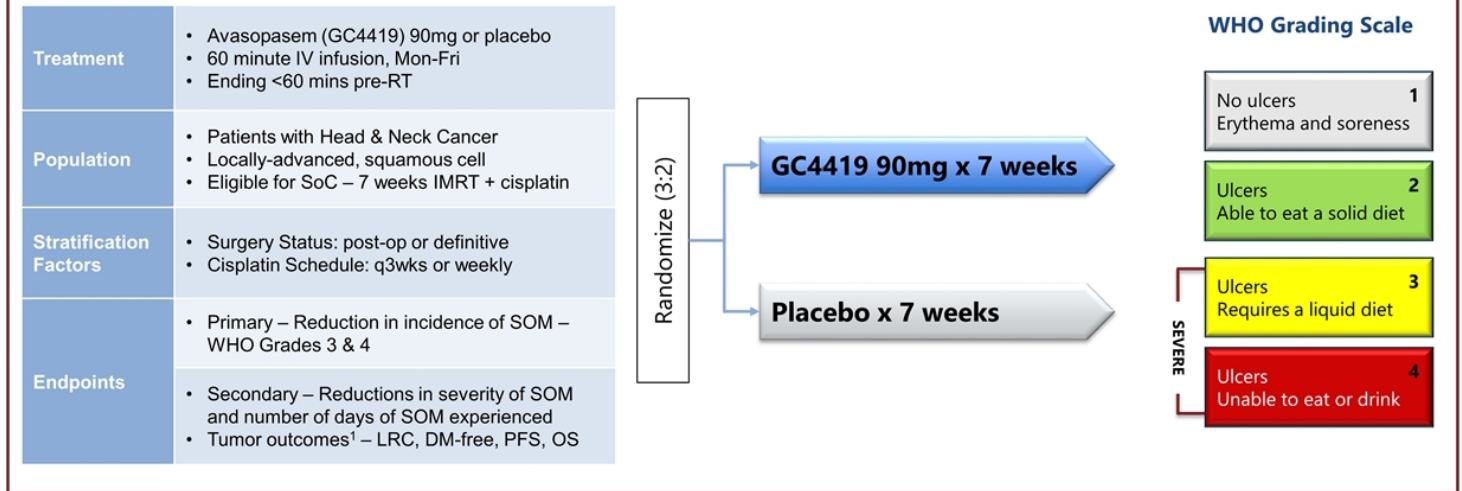


Avasopasem (GC4419) was well tolerated at both doses

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)

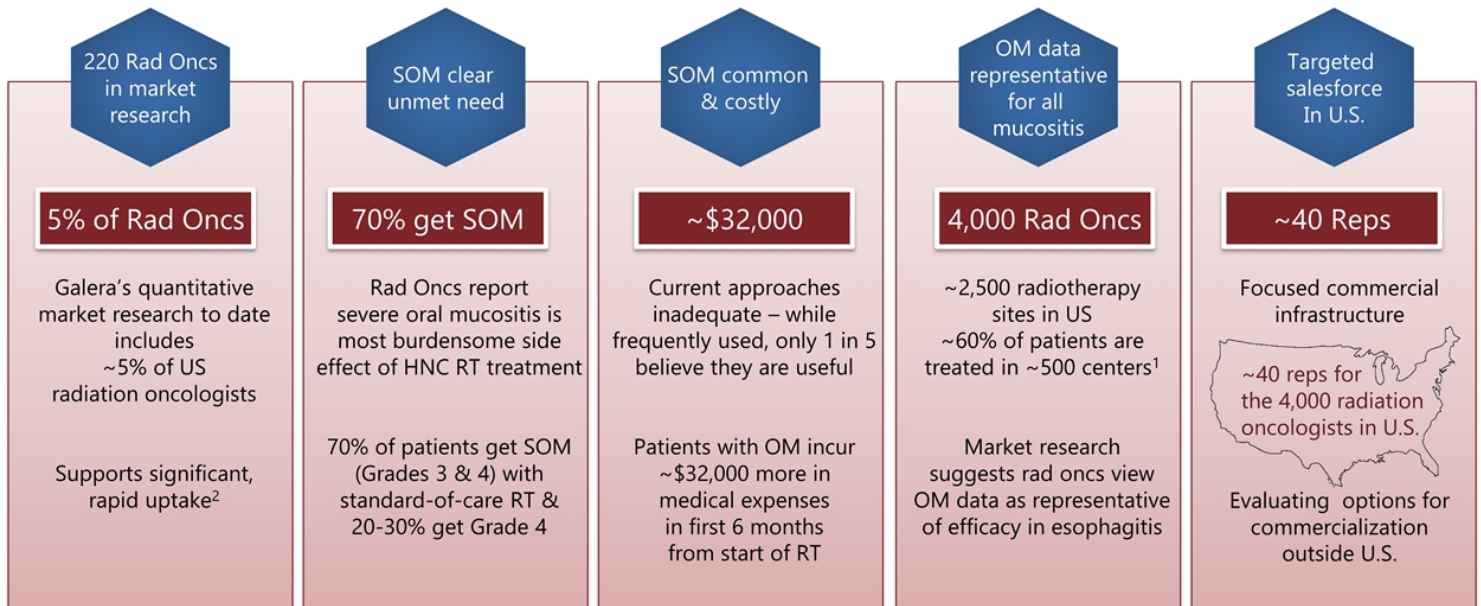


¹ LRC = locoregional control, DM-free = free of distant mets, PFS = Progression-Free Survival, OS = Overall Survival

Commercial Considerations



Large Commercial Opportunity Addressing Clear Unmet Need



Rad Oncs = Radiation Oncologists, SOM = Severe Oral Mucositis

¹ Medicare Claims Analysis by Galera in 2019 ²Hypothetical 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 analysis¹ 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



Radiotherapy-related Esophagitis in Lung Cancer

- SOM efficacy seen by radiation oncologists as supportive for esophagitis¹
- ~50,000 lung cancer patients are treated with RT, 50% get ≥ Grade 2 esophagitis²
- Effects: inability to swallow, severe pain, ulceration, bleeding & hospitalization



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 Conditions¹

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

¹Galera Market Research (150 Radiation Oncologists)

² NCI or RTOG grading scales



Increasing SBRT Efficacy

(Stereotactic Radiotherapy)

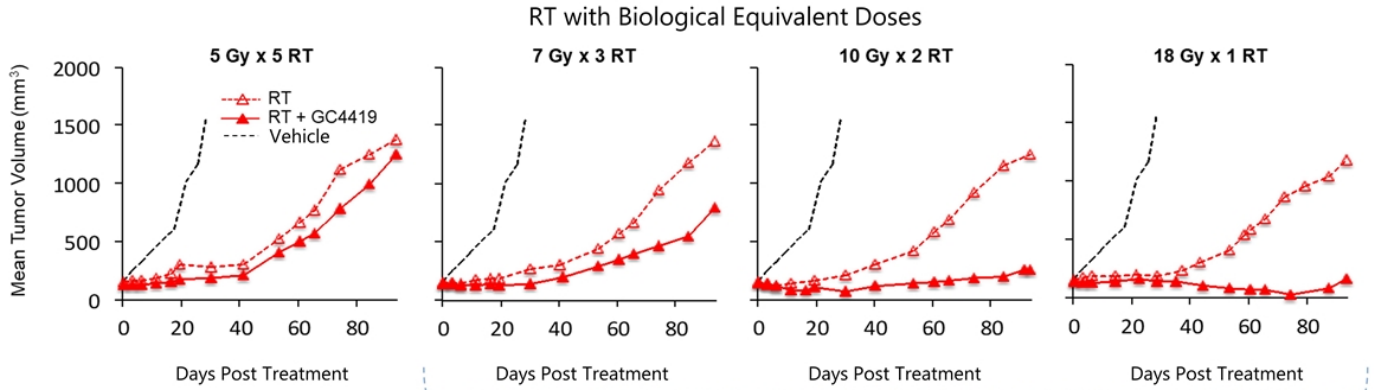
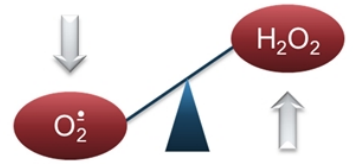


Dismutase Mimetics Increase Anti-Cancer Efficacy with High Fraction-Dose RT in Preclinical Models

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



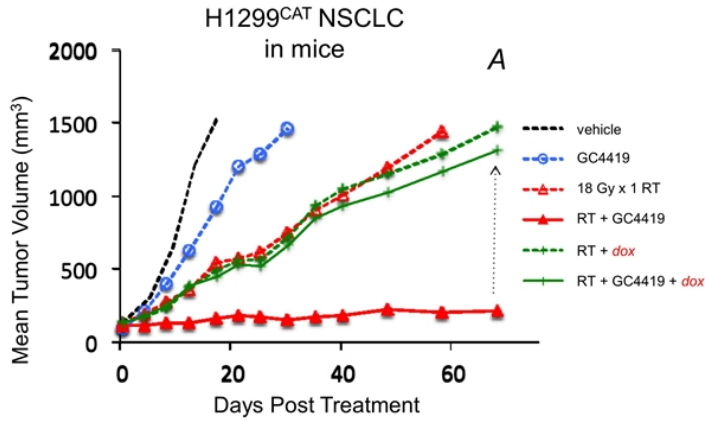
Courtesy of M Story (UTSW)

SBRT
Stereotactic Body Radiation Therapy

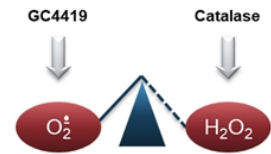
H₂O₂ Drives Increased Efficacy

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

- Engineered to overexpress catalase (disposes of H₂O₂) when induced by doxycycline
- Overexpressing catalase blocks synergy with RT by removing GC4419-generated H₂O₂



Tumor tissue H₂O₂ reduced when doxycycline added to RT + avasopasem (GC4419)



Target Treatment Population

Increasing Number of Pancreatic Cancer Patients Diagnosed Each Year

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

} 18,000 Pts²

Novel Therapies Needed

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

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

SBRT is Accepted Tx Option

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

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

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

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

⁵ NCCN = National Comprehensive Cancer Network-2019

**SBRT
Combo
Pilot Trial**

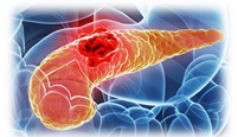
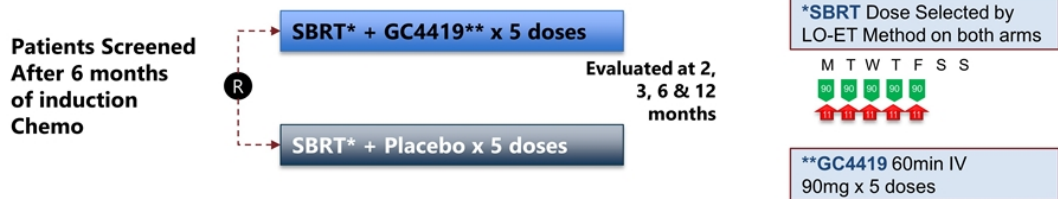
Double-blind, Placebo-controlled, Randomized Adaptive Trial

- Enrollment of maximum of 24 patients on each arm (LO-ET¹ design)
- Primary objective is 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 at 2020 ASTRO Annual Meeting (Late October)



SBRT = Stereotactic Body Radiation Therapy, C Taniguchi & J Herman (MD Anderson),
¹LO-ET = Late-Onset Efficacy-Toxicity (Lin 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 2019¹
- 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 (DLCO²) & PFS

¹ 2019 SEER Data

² DLCO = diffusing capacity of the lung for carbon monoxide



COVID-19 Trial

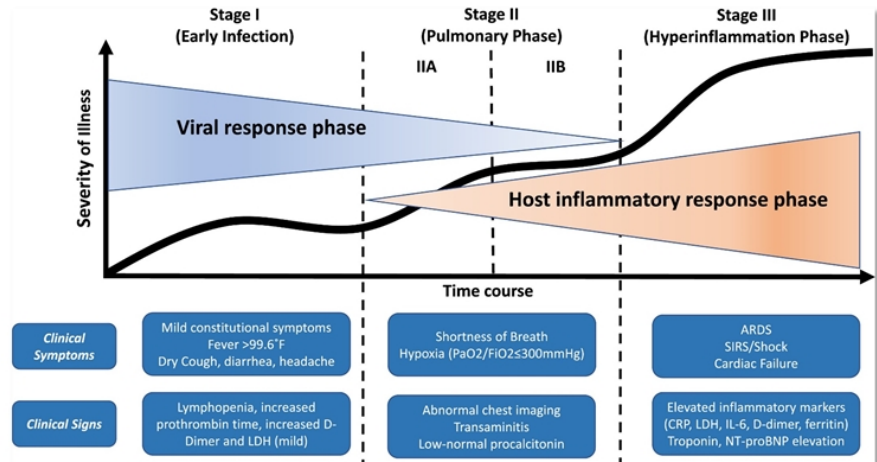


Superoxide plays a central role in pathophysiology of acute respiratory distress syndrome (ARDS)

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

Building Cytokine Storm ARDS → Shock

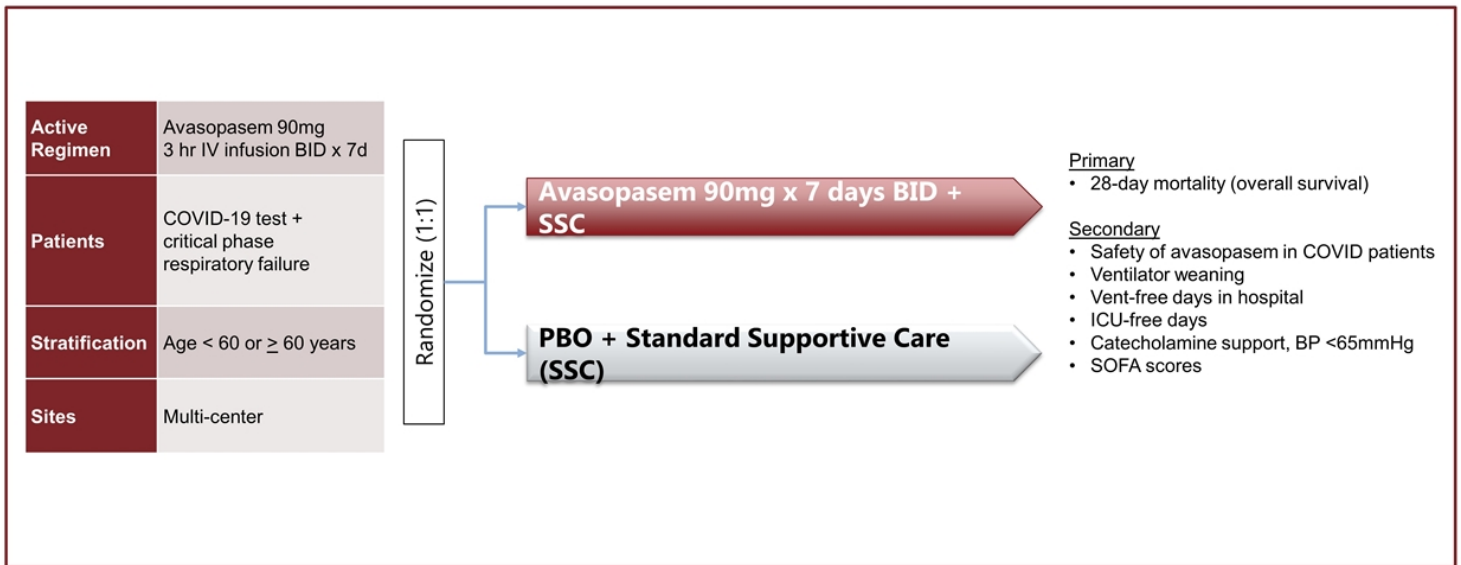
Superoxide plays an important role in the hyperinflammatory stage and in hypotensive sepsis/shock



Siddiqi & Mehra, *J Heart Lung Transplant*, 2020; 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

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

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



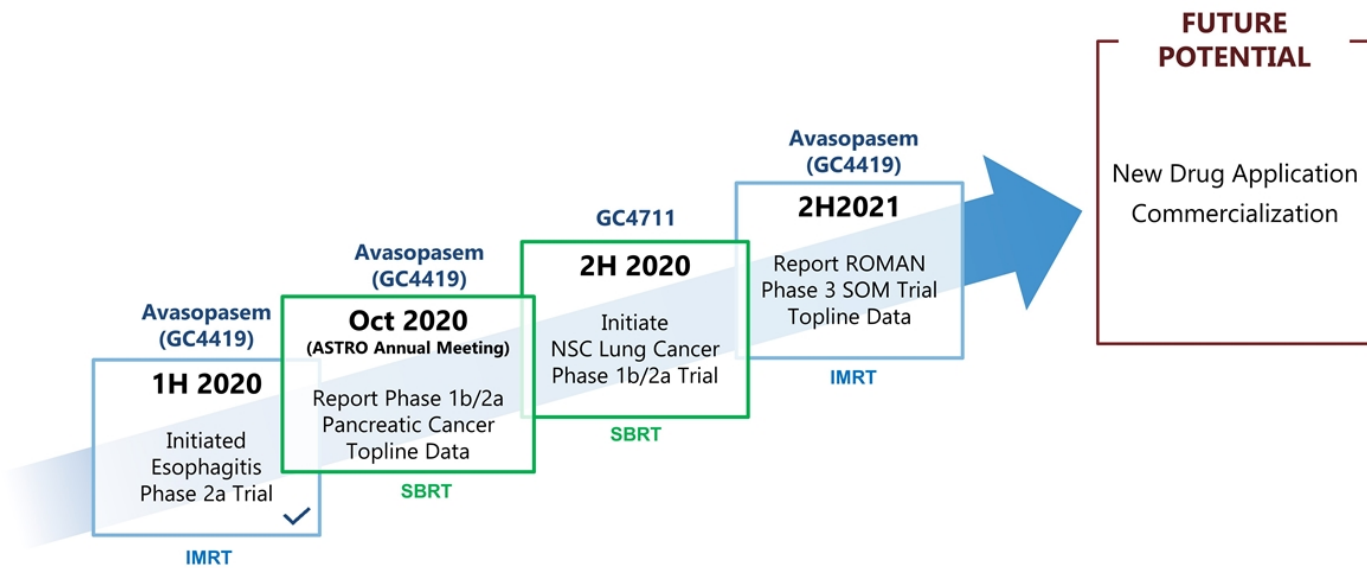
SSC = Standard Supportive Care
SOFA = Sequential Organ Failure Assessment



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^{1, 2}

Increase H_2O_2 in tumors

IMRT
Intensity Modulated RT

Reducing Toxicity

<p>Severe Oral Mucositis Head & Neck Cancer (SOM in HNC)</p> <p>Phase 3 ROMAN</p>	<p>Esophagitis NSC Lung Cancer (NSCLC)</p> <p>Phase 2 Trial</p>
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SBRT
Stereotactic Body RT

Increasing Efficacy

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Normal tissue toxicity limits optimal radiotherapy treatment of tumor

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

¹ Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment... *Cancer*. 2005;104:1129-1137

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