# 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 8, 2021**

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

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

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

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☒

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

**Item 7.01. Regulation FD Disclosure.**

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

The information contained in Item 7.01 of this Current Report on 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 8.01. Other Events.**

On September 8, 2021, the Company announced final results from its Phase 1/2 pilot trial of its dismutase mimetic candidate, GC4419, versus placebo, in patients with unresectable or borderline resectable locally advanced pancreatic cancer (LAPC), who are undergoing stereotactic body radiation therapy (SBRT). The results include a minimum of one year of follow up on all 42 patients enrolled in the trial.

In the trial, improvements were observed in overall survival (HR=0.48; 95% CI: 0.20-1.14; p=0.090), progression-free survival (HR=0.46; 95% CI: 0.22-0.98; p=0.040), local tumor control (HR=0.30; 95% CI: 0.08-1.10; p=0.055) and time to distant metastases (HR=0.39; 95% CI: 0.16-0.93; p=0.028). 46% of patients in the active arm were alive at last follow-up (11 out of 24) compared to 33% in the placebo arm (6 out of 18). As previously reported, 29% of patients in the active arm achieved a 30% or greater decrease in primary tumor size (partial response) compared to 11% of patients in the placebo arm. GC4419 was well tolerated, with similar rates of early and late adverse events in the active and placebo arms.

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

(d) Exhibits

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

| Exhibit No | Description |
|---|---|
| 99.1 | Corporate Slide Presentation of Galera Therapeutics, Inc. dated September 8, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the inline XBRL document) |

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 8, 2021

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

# Transforming **radiotherapy** for patients with cancer

September 2021

Galera Therapeutics, Inc

# Forward-Looking Statements

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

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

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

# Radiation Therapy – Key Role in Cancer Treatment

Over 50% of all cancer patients receive radiation therapy as part of their treatment

**IMRT**

**Intensity Modulated Radiation Therapy**

Low doses for weeks
(~2 Gy/day)

Most used form of external beam RT

Toxicity

**Galera's Goal**

**Radioprotection**

**SBRT**

**Stereotactic Body Radiation Therapy**

High doses for days
(>5 Gy/day)

Cutting edge form of external beam RT

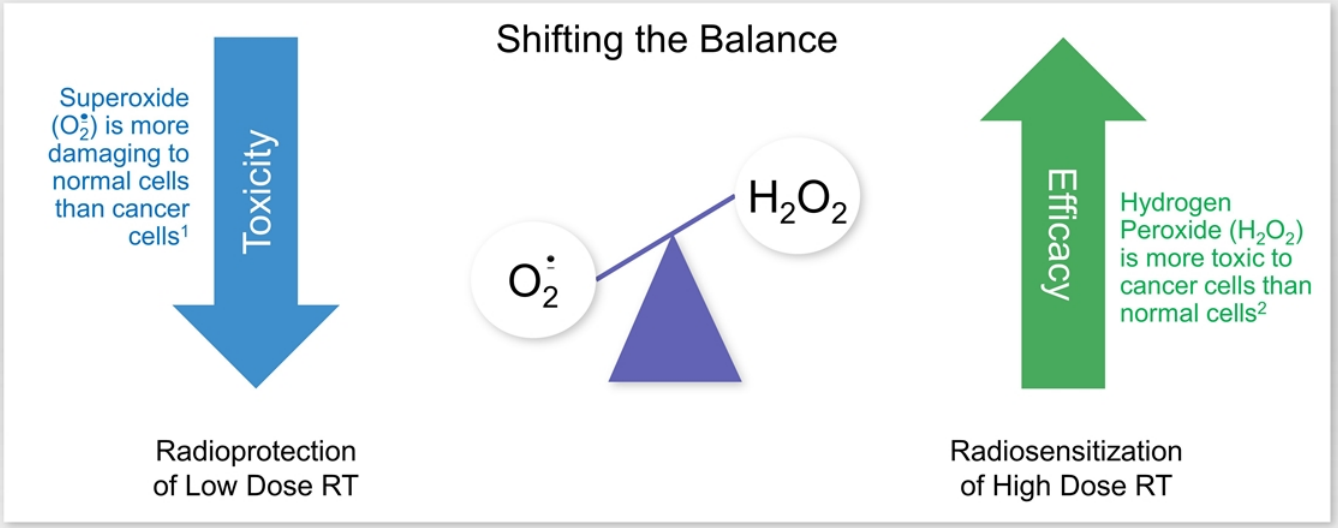
**Galera's Goal**

**Radiosensitization**

Efficacy

# Galera's Technology: Dismutase Mimetics

Mechanism of action is to convert RT-induced burst of Superoxide to Hydrogen Peroxide




[1]Sonis S. Drug Design, Development and Therapy 2021:15 1021–1029
[2]Park WH: Oncol Rep 40: 1787-1794, 2018

# Transforming Radiotherapy

## Avasopasem Reducing IMRT Toxicity

Breakthrough Therapy with Phase 3 Fully Enrolled

Severe Oral Mucositis In Head & Neck Cancer

Esophagitis in Lung Cancer

## GC4711 Increasing SBRT Efficacy

Encouraging Survival Data in Pancreatic Cancer Trial[1]

Pancreatic Cancer Locally Advanced

Lung Cancer Locally Advanced

## Large Markets with High Unmet Need

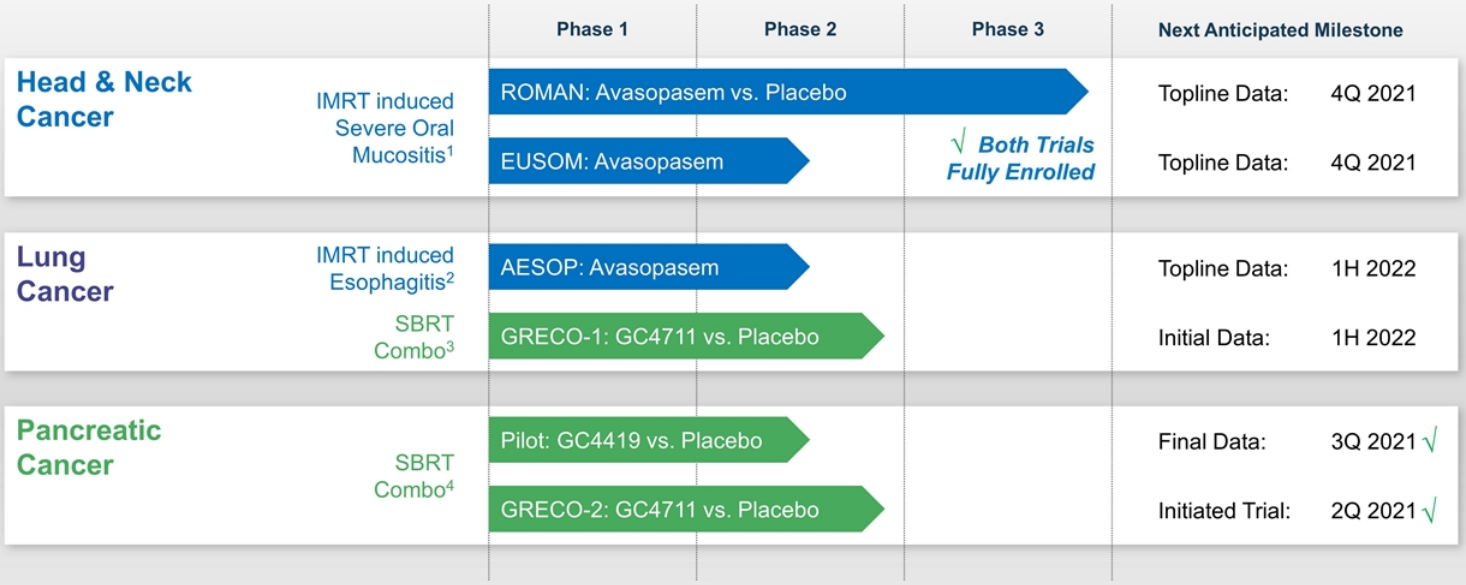
18 Million New Cancers in World in 2020[2] (1.9M in US)

Radiotherapy needed by over half of patients with cancer

Galera building US commercial team for Avasopasem Launch

[1]The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT
[2]Global Cancer Statistics. Sung H et al. CA Cancer J Clin 2021;0:1–41 (excluding nonmelanoma skin cancer)
[3]US Cancer Statistics Siegel RL et al. CA Cancer J Clin 2021;71:7–33

# Robust Pipeline




[1]EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe
[2]Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
[3]Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711
[4]The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

# Reducing
# IMRT Toxicity

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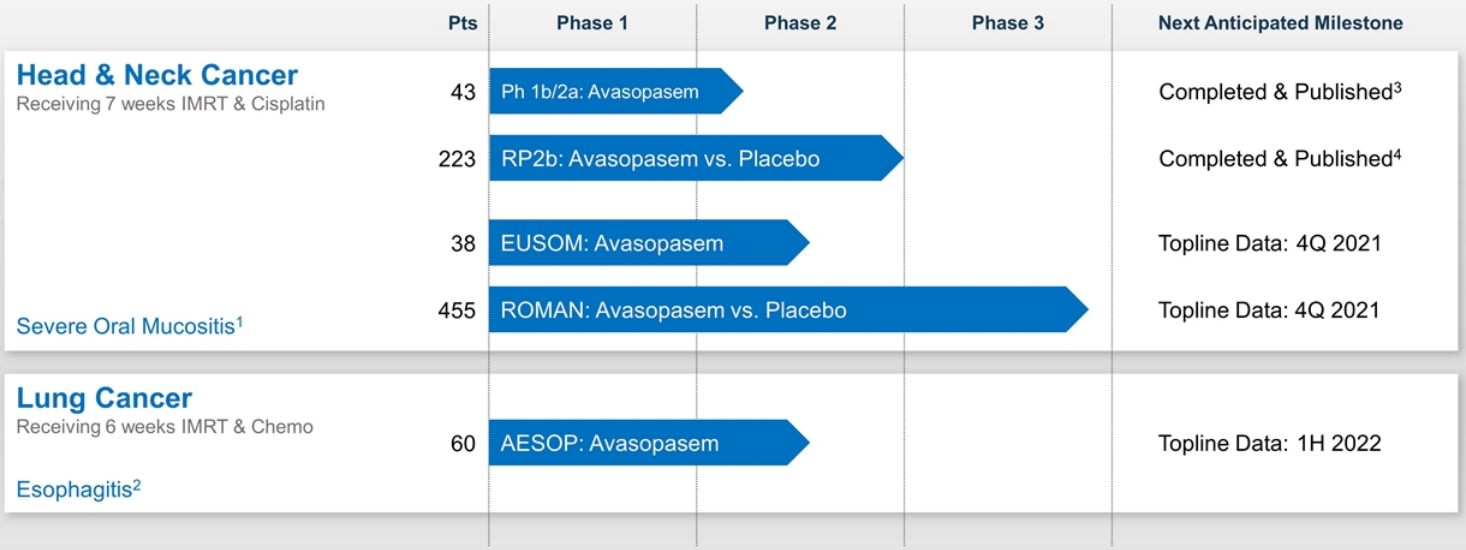
# Radioprotection Programs

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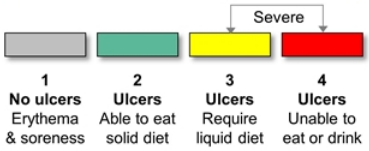
[2]Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
[3]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435
[4]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.

# Severe Oral Mucositis in Head & Neck Cancer

The most burdensome toxicity of standard-of-care chemoradiotherapy (radiotherapy & cisplatin)

## 70% Patients Get SOM (Grade 3 or 4 OM)

WHO Grading System




## Current Approaches Lack Efficacy

MASCC Guidelines focus only on symptoms[1]

- Basic Oral care
- Opioids, anesthetics
- Coating agents
- Benzydamine
- Anti-inflammatories

## Physicians Consider Topicals Ineffective

Market Research with 150 Radiation Oncologists[2]

- Only 20% of physicians believe topical agents perform well for oral mucositis

[1]Elad S et al, MASCC/ISOO Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. Cancer 2020;126:4423-4431
[2]Galera Market Research

# 455 Patient ROMAN Phase 3 Trial – Results this Year

## Fully Enrolled Randomized Placebo-Controlled Severe Oral Mucositis Trial

### Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks
- 70% expected to get SOM

### Treatment

- Avasopasem 90mg x 7 weeks
- R — Randomized 3:2
- Placebo x 7 weeks

- 60-minute IV infusion just before IMRT
- Multicenter (North America)

### Endpoints

- Primary: Reduction in the incidence of SOM
- Secondary: Reduction in SOM duration & severity

# Avasopasem: First-to-Market Potential

## Avasopasem Prevents RT Injury

Patients get avasopasem before each RT dose

Blocks initiating injury in normal cells from RT burst of superoxide

Does not interfere with RT anti-cancer efficacy

## Avasopasem has BTD for Oral Mucositis

FDA Breakthrough Therapy Designation

BTD granted for oral mucositis in February 2018

Based on robust Phase 2b data in 223 patients

## 455 Patient ROMAN Phase 3 Trial

Data anticipated 4Q 2021

Enrollment complete

Single Phase 3 sufficient for NDA with Phase 2b as supportive

# 223 Patient Phase 2b Trial – Robust Results

## Randomized Placebo-Controlled Severe Oral Mucositis (SOM) Trial

### Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks
- 70% expected to get SOM

### Treatment

- Avasopasem 90mg x 7 weeks
- R
- Avasopasem 30mg x 7 weeks
- Placebo x 7 weeks

- 60-minute IV infusion just before IMRT
- Multicenter (North America)

### Endpoints

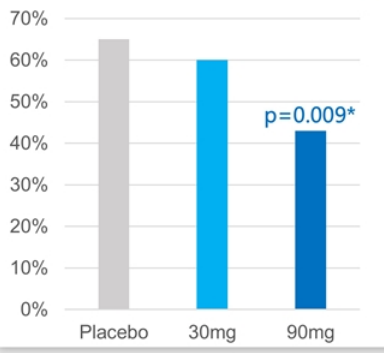
- Primary: Reduction in SOM duration
- Secondary: Reduction in SOM incidence & severity

# Consistent and Encouraging Results

## Across SOM Endpoints

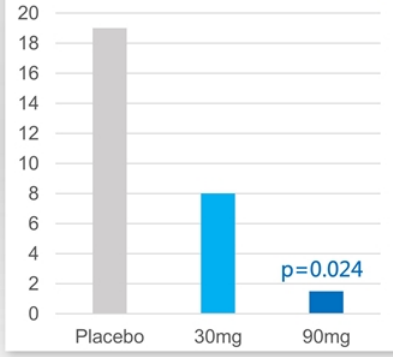
### Incidence

**34%** Reduction in SOM incidence



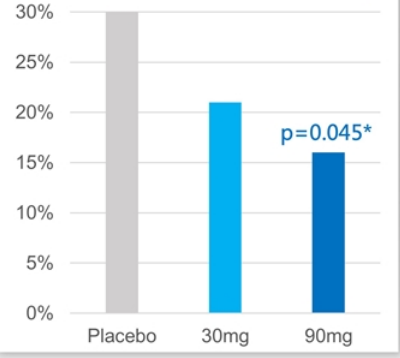

### Duration

**92%** Reduction in median days of SOM



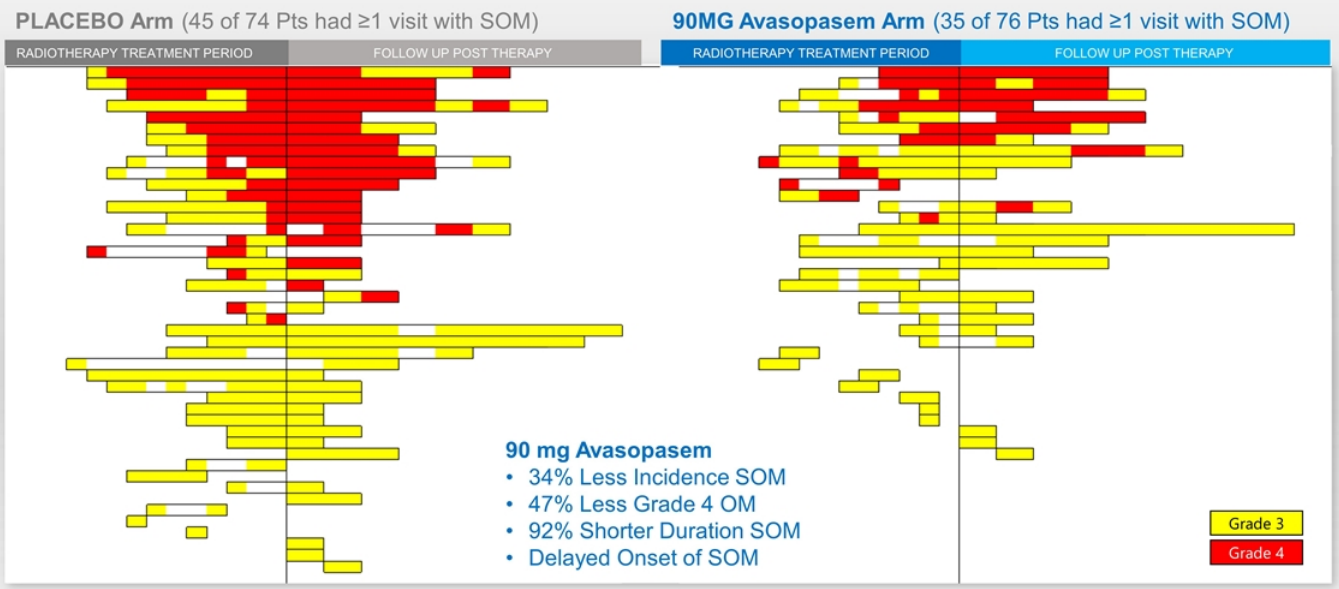

### Severity

**47%** Reduction in incidence of Grade 4 OM



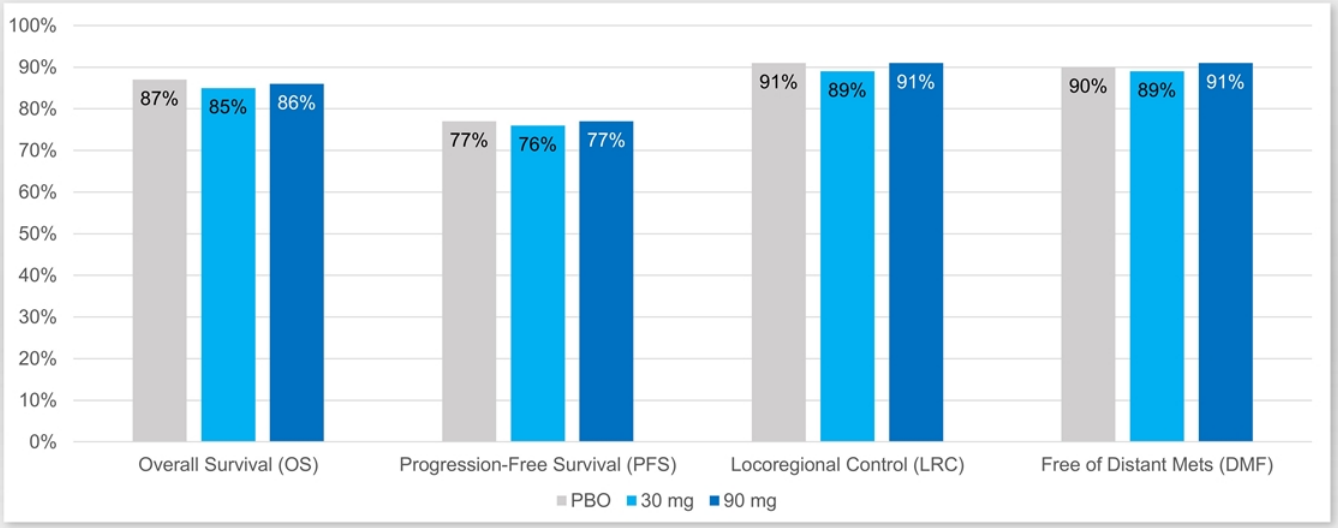

Anderson CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265
*Secondary endpoints (incidence and severity) have nominal p values compared to placebo
Intent-To-Treat (ITT) Population

# Avasopasem Efficacy Significantly Better than Placebo




Anderson CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265

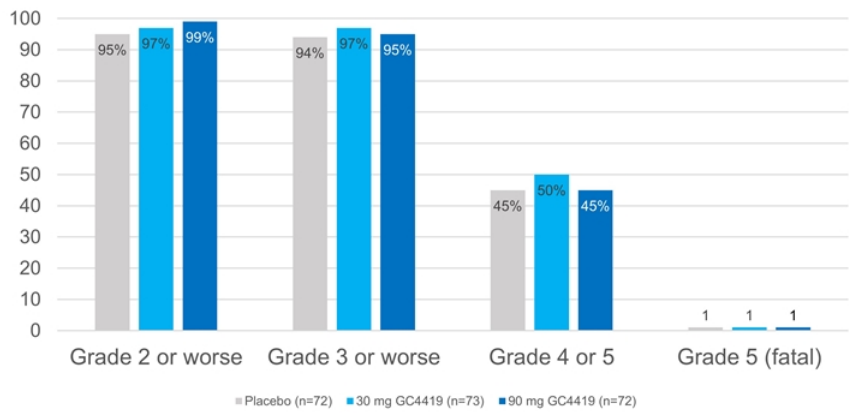
# Radiotherapy Efficacy Maintained Over Two Years




Final ITT Analysis

# Safety Results Comparable to Placebo

## Avasopasem Generally Well Tolerated




| Most Frequent AEs (any grade) | Placebo (n=72) | 30 mg Avasopasem (n=73) | 90 mg Avasopasem (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 CM et al. Journal of Clinical Oncology 2019 37:34, 3256-3265

# SOM Market Opportunity

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# Head and Neck Cancer – Large Market Opportunity

Severe Oral Mucositis is most burdensome side effect – 70% get SOM

**650,000**
Global Head & Neck Cancer Incidence

**65,630**
US Patients Diagnosed each year

**42,000**
US Patients at Risk for RT-related SOM


Locally advanced HNC is curable with the standard-of-care IMRT and cisplatin regimen

# Head and Neck Cancer Can Affect Anyone

Babe Ruth, Lana Turner, Jamie Dimon, Ulysses S. Grant, Sigmund Freud, Humphrey Bogart, Grover Cleveland, Eddie Van Halen
Sammy Davis Jr., George Harrison, Michael Douglas, Ann Richards, Tony Gwynn

# Concentrated Physician Population

SOM is most burdensome side effect of curative IMRT + cisplatin regimen

**5,000**
Radiation Oncologists in U.S

**2,500**
Radiotherapy Treatment Sites

**700**
Top centers where >80% HNC patients are treated


**72%**
Sites with Existing Infusion Capability[1]

**64%**
Market Patient Share

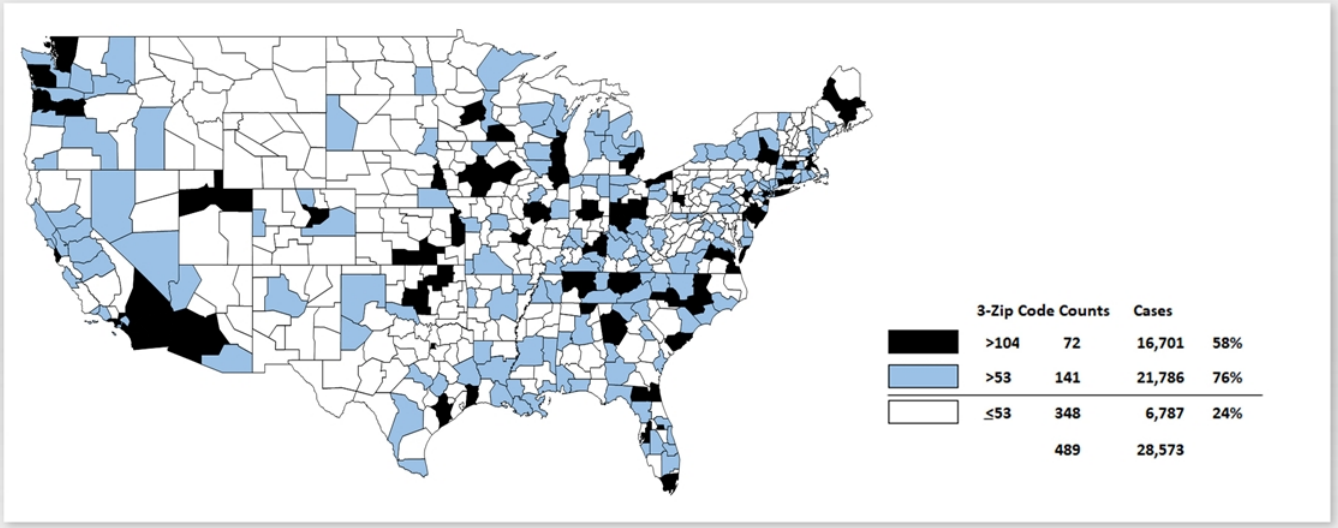
38% IMRT centers currently infuse drugs[1]
34% more coordinate with medical oncology to infuse patients
Additional 17% can add capabilities to infuse patients



[1]Primary market research with 125 IMRT centers in the US

# Where Patients with Head & Neck Cancer are Treated

## 76% Treated in only 29% Zip Code areas




Galera Market Research (122 Zip Codes are 0)

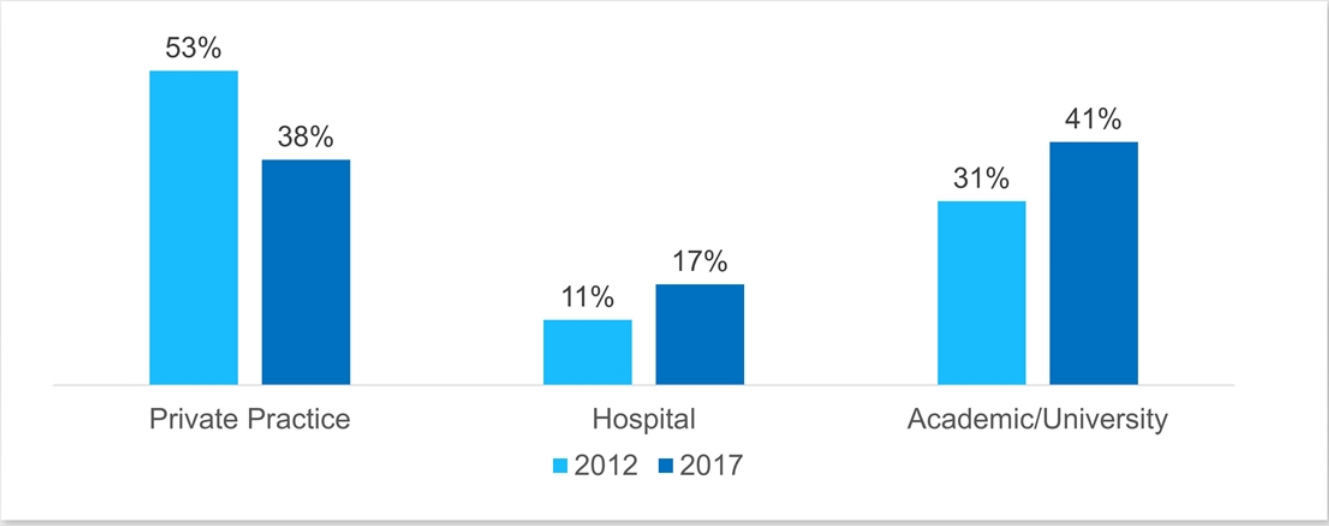
# Most Centers Have Ability to Infuse Today

## 72% Radiotherapy Sites Have Existing Infusion Capability

| Adoption Archetype Determinants | A<br>Rad Oncs Have Current Capabilities | B<br>Med Oncs Administer Infusions for Rad Onc | C<br>Rad Oncs Need to Add Capabilities | D<br>Rad Oncs Unlikely to Add Capabilities |
|---|---|---|---|---|
| Total % Sample Distribution | **38%** | **34%** | 17% | 11% |
| Avasopasem Infusion Owner | Rad Onc | Med Onc | Rad Onc | - |
| Ease of Coordination Today | **High** | **High** | Low | Low |
| Likelihood of Prescribing Avasopasem | **High** | **High** | **High** | Low |

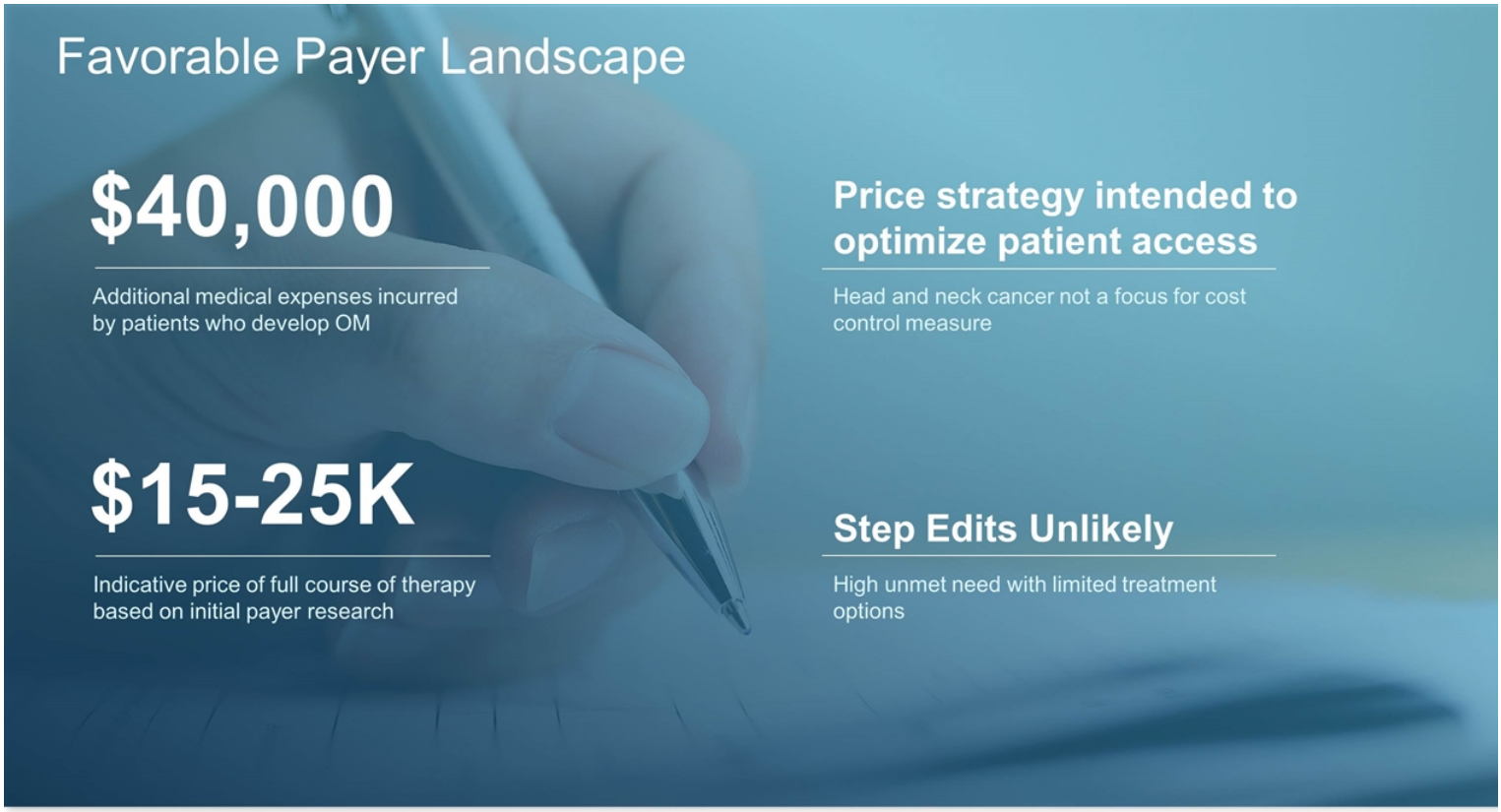
Data in above table based on primary research with 125 IMRT centers in the US

# US Radiation Oncologists Trending Away from Private Practice




[1]Data from ASTRO

# Favorable Payer Landscape



**$40,000**

Additional medical expenses incurred by patients who develop OM

**$15-25K**

Indicative price of full course of therapy based on initial payer research

## Price strategy intended to optimize patient access

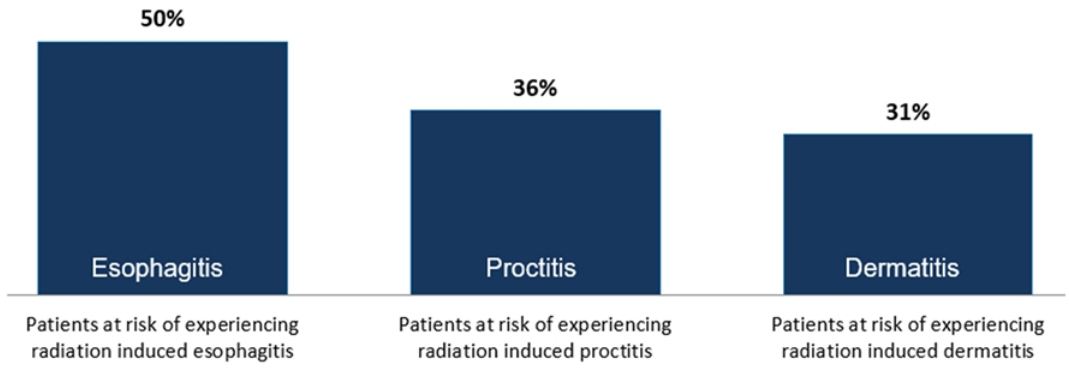
Head and neck cancer not a focus for cost control measure

## Step Edits Unlikely

High unmet need with limited treatment options

# Beyond Oral Mucositis: Other RT-Related Toxicities

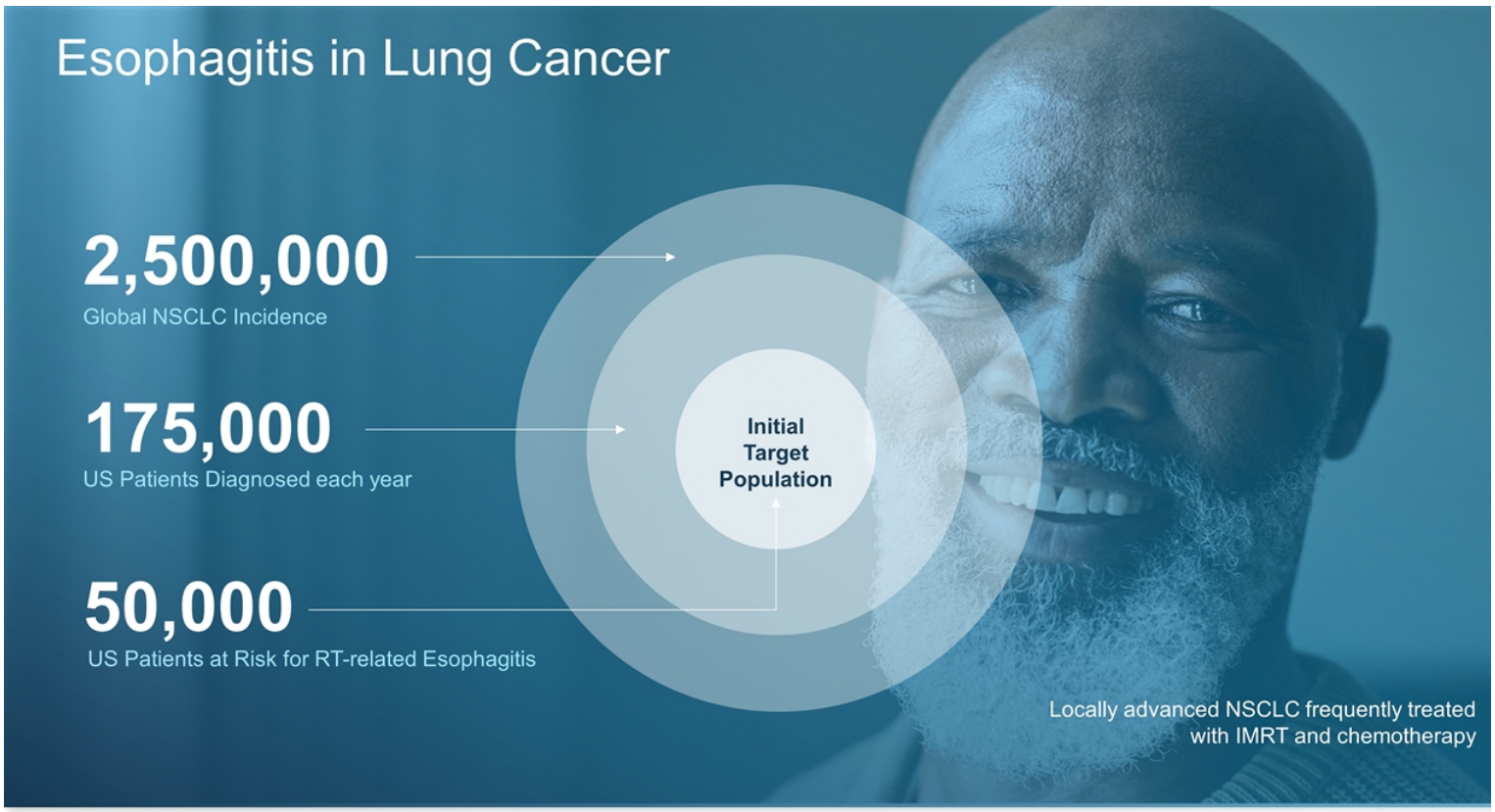
## Physicians view oral mucositis data as potentially applicable to other radiation-related toxicities




150 Rad Oncs were asked the following: *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?*

Galera primary research with 150 Radiation Oncologists

# Esophagitis in Lung Cancer



# Esophagitis: Major Unmet Need in Lung Cancer

## Common Side Effect of Chemoradiotherapy (IMRT x 6 weeks)

### 50% Patients Get Grade 2+ Esophagitis

RTOG Grading System

1. Asymptomatic
2. Symptoms & altered eating/swallowing
3. Severely altered eating or swallowing
4. Required urgent operative intervention
5. Results in death

### Current Approaches Lack Efficacy

No established drug therapy

Supportive care measures:

- Soft bland diet
- Prophylactic antifungals
- Dilation if stricture develops

### AESOP Trial Design

Phase 2 Trial (n=60)

- 6 weeks of standard IMRT to ≥ 5 cm of esophagus

- Will compare esophagitis rate with historical data

# Increasing
# SBRT Efficacy

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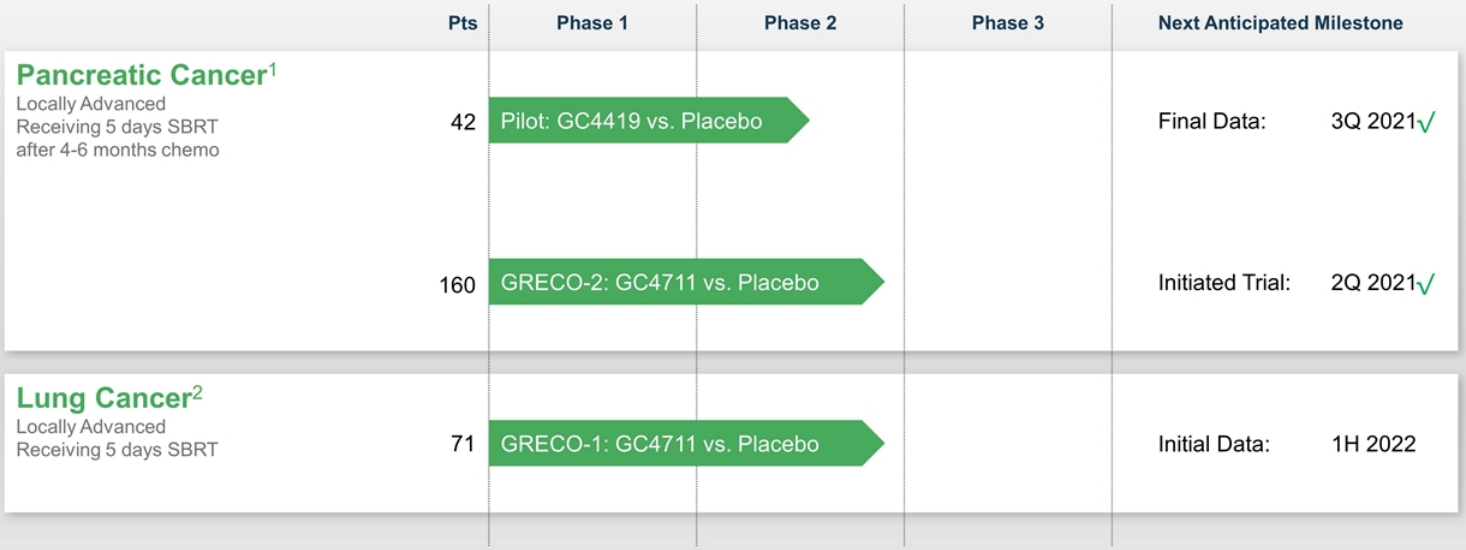
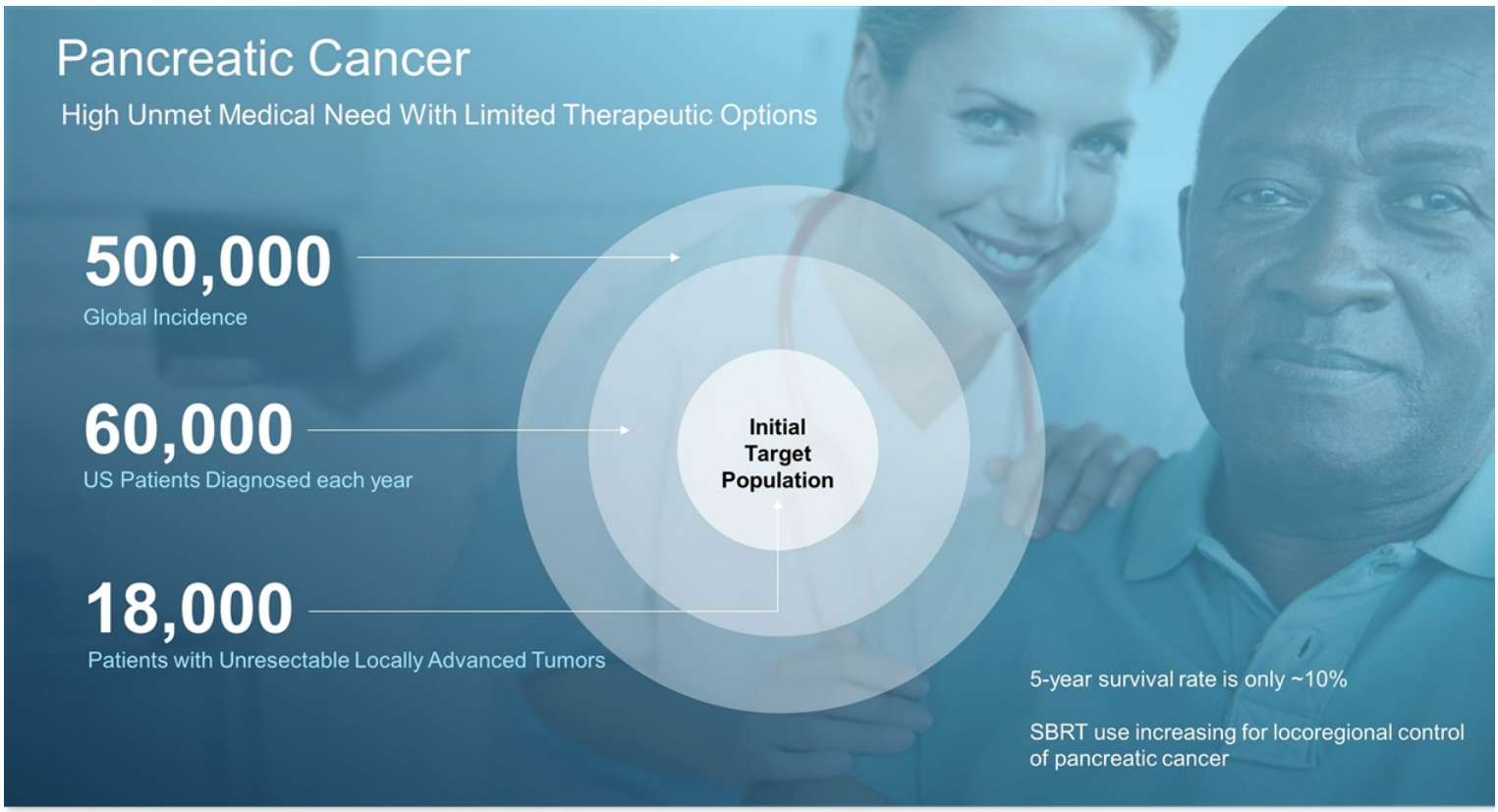
# Radiosensitizer Programs




[1]First SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT
[2]Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711

# Pancreatic Cancer

## High Unmet Medical Need With Limited Therapeutic Options




5-year survival rate is only ~10%

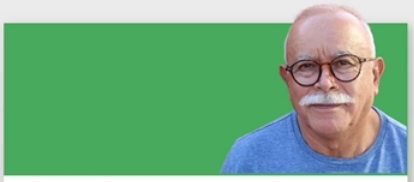
SBRT use increasing for locoregional control of pancreatic cancer

# People We Have Lost to Pancreatic Cancer

Pavarotti, Donna Reed, Dizzy Gillespie, Cardinal Bernardin, Eiko Ishioka, Bonanza's Pernell Roberts, Joan Crawford
Ben Gazzara, Alex Trebek, Alan Bates, Jack Benny, Dr. Sydney Salmon, Billy Paul, Rand Pausch (last lecture)
Ruth Bader Ginsburg, John Lewis, Henry Mancini, Sally Ride, Munsters' Fred Gwynne, Columnist William Safire, Michal Landon

# Proof of Concept Trial in Pancreatic Cancer

## 42-Patient Double-blind, Placebo-controlled, Randomized Trial



### Population

- Patients with Locally-advanced Pancreatic Cancer (LAPC)
- Screened after 4-6 months of chemotherapy

### Treatment

R

- SBRT + GC4419 90mg x 5 doses
- SBRT+ Placebo x 5 doses

- 60-minute IV infusion before SBRT
- 4 Centers: MDA, Moffitt, Duke, UTSW

### Endpoints

- Primary: Safety and feasibility of dismutase mimetic with SBRT
- Secondary: Survival (OS, PFS), Tumor Control (LRC, DMC), Response Rate

# Proof of Concept Trial in Pancreatic Cancer – Final Analysis

42-Patient Double-blind, Placebo-controlled, Randomized Trial

- SBRT and SBRT+GC combination generally well tolerated
- Improvements observed across all evaluated efficacy endpoints
  - HR < 0.5 for Overall & Progression-Free Survival
  - HR < 0.4 for Local & Distant Tumor Control
- Results reinforce the rationale for ongoing GRECO-2 trial

# Final Analysis of Safety & Efficacy

## Minimum of One Year Follow-up on All Patients

| Baseline Characteristics | Placebo (n=18) | GC4419 (n=24) |
|---|---|---|
| Median age (range), yrs | 68 (48–82) | 72 (41–83) |
| Male / Female | 39% / 61% | 67% / 33% |
| Borderline resectable / Unresectable | 11% / 89% | 29% / 71% |
| ECOG Performance status 0/1/2 | 50% / 50% / 0% | 50% / 46% / 4% |
| Prior chemo, duration median (range), wks | 22 (12.0–36.3) | 18 (9.1–67.1) |
| CA19-9 at randomization, median (range) | 71 (0.5–5505) | 31 (0.3–719) |
| Smokers/Nonsmokers | 17% / 83% | 8% / 92% |

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

# Final Safety Analysis - Regimen Generally Well Tolerated

12-Month Safety Follow-up (% of Patients)

## Similar SBRT Toxicity Across Arms

| AEs Considered related by Investigator to SBRT | | SBRT + PBO | SBRT + GC |
|---|---|---|---|
| ≤90 days after SBRT | Any AE | 67% | 46% |
| | GI AE | 44% | 42% |
| | Severe AE | 0% | 0% |
| >90 days after SBRT | Any AE | 22% | 25% |
| | GI AE | 17% | 21% |
| | Severe AE | 11% | 8% |

- *No bleeding ulcers by 12-week endoscopy*

## No Early or Late Toxicity Signal for GC

| AEs Considered related by Investigator to GC/PBO | | SBRT + PBO | SBRT + GC |
|---|---|---|---|
| ≤90 days after SBRT | Any AE | 67% | 46% |
| | GI AE | 44% | 42% |
| | Severe AE | 0% | 0% |
| >90 days after SBRT | Any AE | 17% | 21% |
| | GI AE | 17% | 17% |
| | Severe AE | 11% | 4% |

*AE = Adverse Event, GI AE = Gastrointestinal AE*

# Final Efficacy Analysis – Improvements Across All Parameters

Encouraging hazard ratios across all endpoints

**Hazard Ratios Below 0.5 Overall & Progression-Free Survival**

## Survival

| Median | OS | PFS (mos) |
|---|---|---|
| GC | **17.0** | **11.2** |
| PBO | **13.3** | **7.1** |

| **Survival** | OS | PFS |
|---|---|---|
| **Hazard Ratio** | 0.48 | 0.46 |

**Hazard Ratios Below 0.4 Local & Distant Tumor Control**

## Tumor Control

| Median | LRC | DMC (mos) |
|---|---|---|
| GC | **NR** | **13.9** |
| PBO | **9.6** | **7.0** |

| **Tumor Control** | LRC | DMC |
|---|---|---|
| **Hazard Ratio** | 0.30 | 0.39 |

**2.5-fold Increase in Response Rate**

## Response

| Partial Response Rate | |
|---|---|
| GC | **29%** |
| PBO | **11%** |

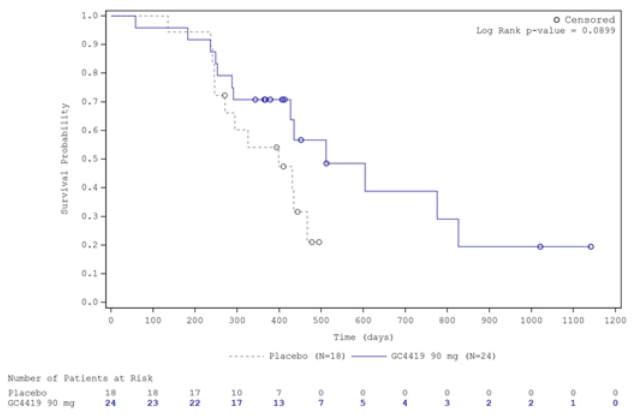
| **Surgery** | GC | PBO |
|---|---|---|
| **R0*** | 5 | 1 |

*R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)
LRC = Locoregional Control; DMC = Control of Distant Metastases; PFS = Progression-Free Survival; OS = Overall Survival; NR = Not Reached

# Improved Overall and Progression-Free Survival

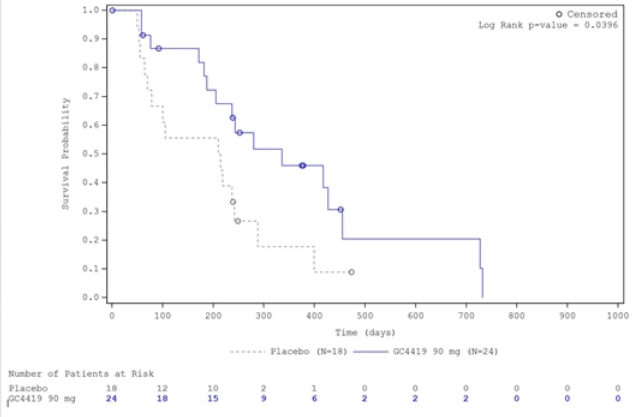
46% (11/24) alive on GC arm at last follow up compared to 33% (6/18) on placebo

## Overall Survival (OS)




P-value = 0.0899 Hazard Ratio = 0.48

## Progression-Free Survival (PFS)




P-value = 0.0396 Hazard Ratio = 0.46

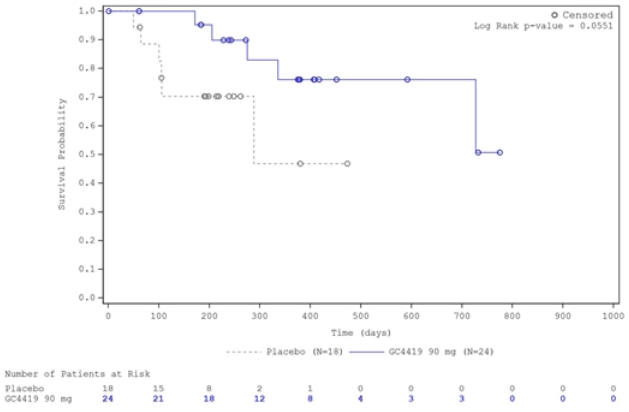
*Minimum 12-month follow-up on all patients,*
*PFS defined as local progression or distant metastasis, not censored for treatment post SBRT*

# Improved Control of Both Local and Distant Disease

Median LRC on GC arm not yet reached at data cut-off; Increased median DMC by 100%

## Locoregional Control (LRC)

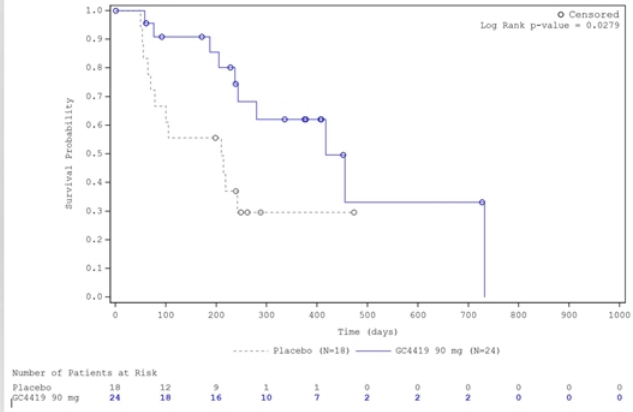
– within RT Field




P-value = 0.0551 Hazard Ratio = 0.30

## Distant Metastases Control

– outside RT Field



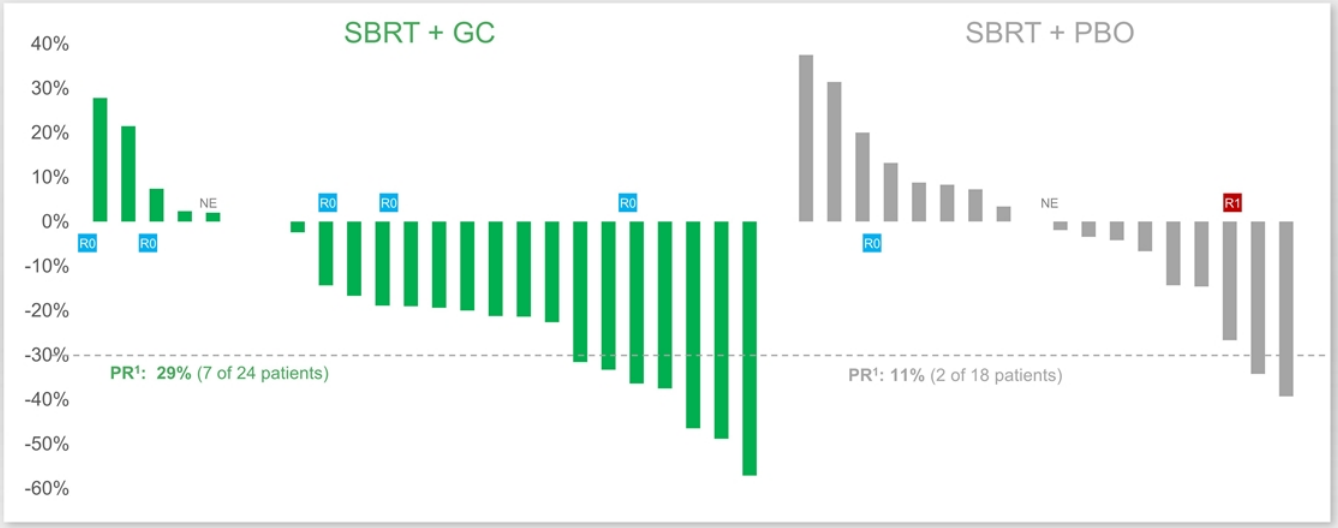

P-value = 0.0279 Hazard Ratio = 0.39

*Minimum 12-month follow-up on all patients, HR = Hazard Ratio*

*DMC and LRC defined as distant metastasis or local regional progression, not censored for treatment post SBRT*

# Partial Response Rate Increased 2.5-fold

## Best Local Response with follow-up of at least 12 months on all patients (ITT, n=42)




[1]Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)
NE = not evaluable (scans not performed post SBRT)
R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)
R1 = positive tumor margins at surgery

# Galera's Radiosensitization Trials

## Galera Radiotherapy Efficacy Cancer Optimization

### GRECO-1 in Lung Cancer


- 71 Patients
- Placebo-controlled multicenter trial
- Locally Advanced NSC Lung Cancer
- Large & central tumors
- Status: Open & recruiting patients

### GRECO-2 in Pancreatic Cancer


- 160 Patients
- Placebo-controlled multicenter trial
- Locally Advanced Pancreatic Cancer
- Following 4 months chemotherapy
- Status: Open & recruiting patients

# SBRT for Non-Small Cell Lung Cancer

SBRT is an established treatment for central and large peripheral NSCLC tumors

**2,500,000**
Global NSCLC Incidence

**175,000**
US Patients Diagnosed each year

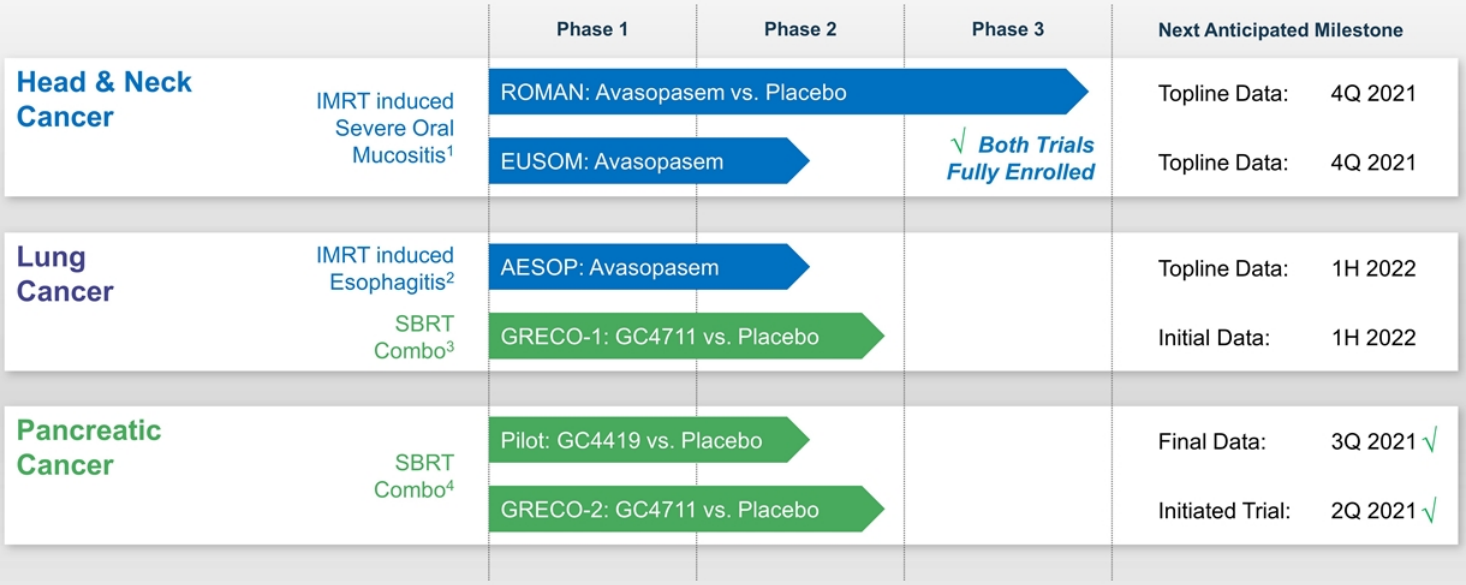
**55,100**
Node-Negative NSCLC


| All SBRT | 14,600 | 12,120 | 15,430 |
|---|---|---|---|
| Node-Negative NSCLC | Peripheral Tumor >3cm | Central Tumor <3cm | Central Tumor >3cm |
| Surgery ONLY | 16% | 30% | 12% |
| SBRT (+/- other modalities) | 81% | 67% | 85% |
| Other | 3% | 2% | 4% |

# Corporate Highlights

Galera Therapeutics, Inc

# Robust Pipeline




[1]EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe
[2]Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
[3]Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711
[4]The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of GC4711 in combination with SBRT

# Thank you.

Galera Therapeutics, Inc

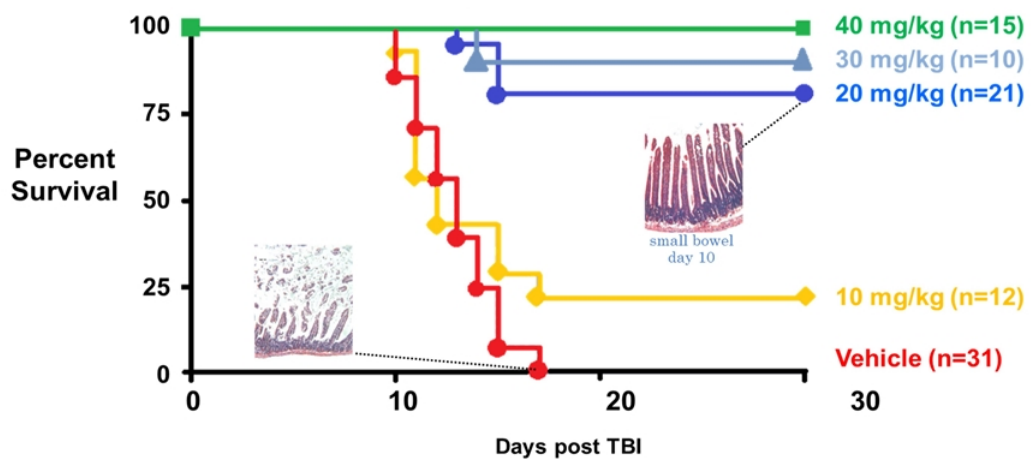
# Back-up Slides

## Mechanistic and Preclinical Data

Galera Therapeutics, Inc

# Protection from Lethal Radiation Exposure

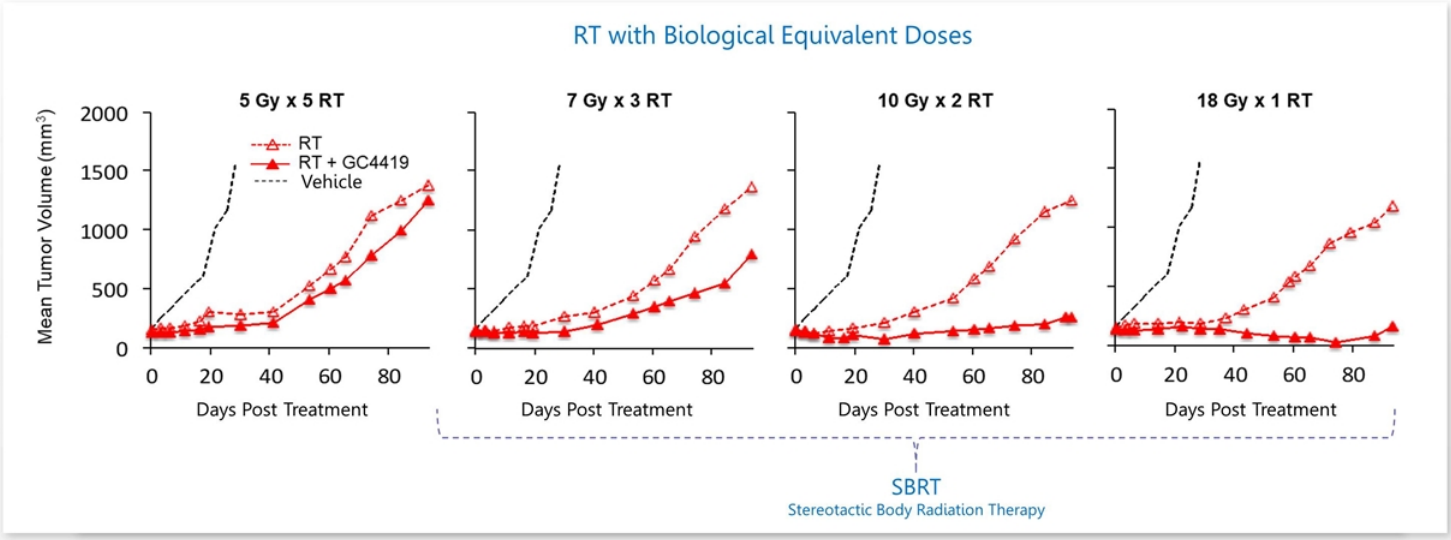
## Observed in Preclinical Studies – Total Body Irradiation (8.5 Gy) to Mice




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

# Synergy with High-Dose RT (SBRT)

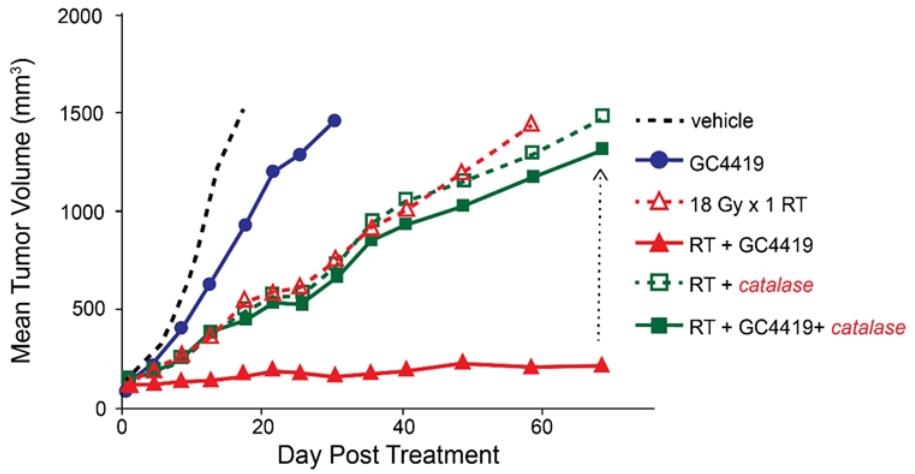
## High-fraction focal irradiation of human tumor xenografts (H1299 NSCLC) in mice




Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

# $H_2O_2$ build-up in Cancer Cell → Synergy with SBRT

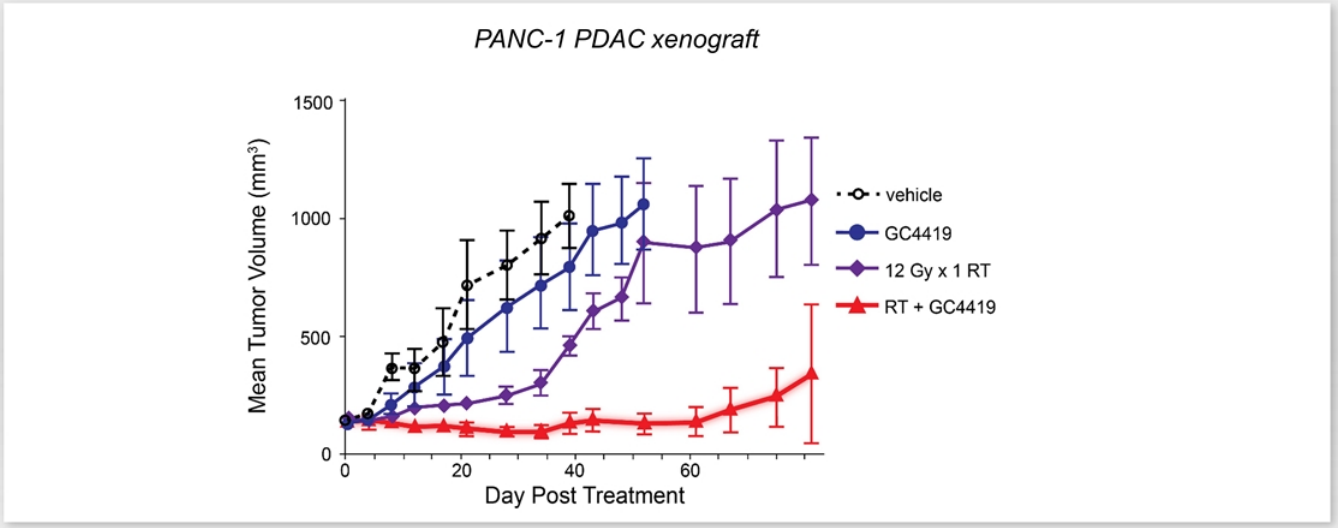
## Synergy abrogated with doxycycline-induced catalase in genetically modified $H1299^{CAT}$ cells




Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

# Pancreatic Tumor Model → Synergy with SBRT

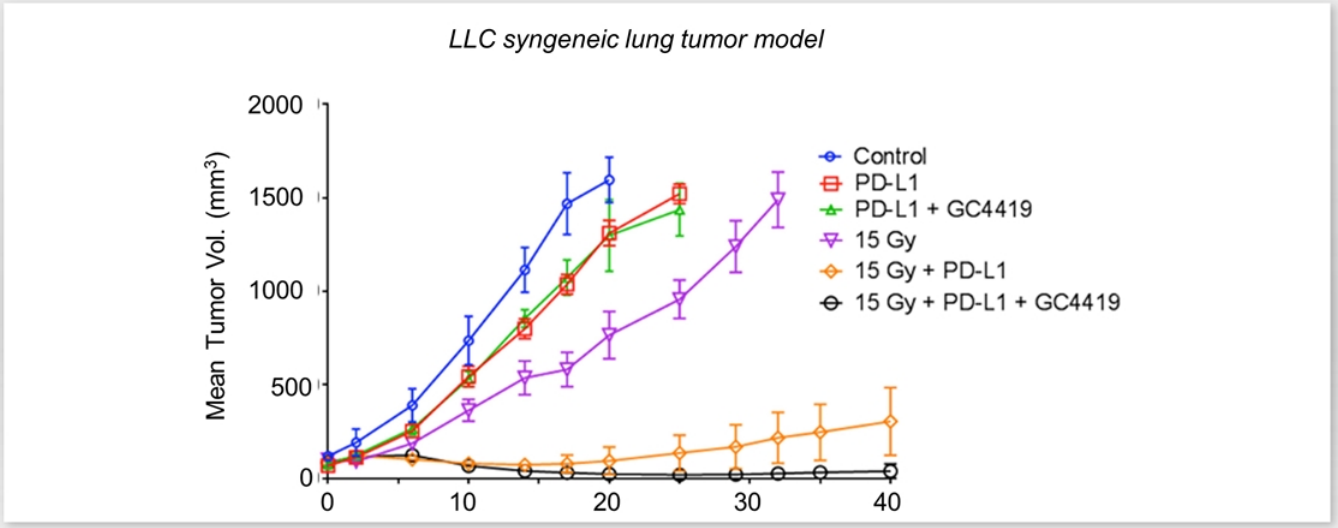
## Marked synergy of Dismutase Mimetic with 12 Gray Radiotherapy




Sishc, et al., Science Translational Medicine 12 May 2021:Vol. 13, Issue 593

# Enhanced Checkpoint Inhibitor Activity in Vivo

GC4419 enhances tumor response to SBRT + anti-PD-L1, PD-1 or CTLA-4 – within and outside RT field




Galera data on file