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): October 26, 2022

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.

On October 26, 2022, Galera Therapeutics, Inc. (the "Company") issued a press release announcing the presentation of one-year tumor and renal function outcomes data from its Phase 3 ROMAN trial of avasopasem manganese 90 mg for radiotherapy-induced severe oral mucositis (SOM), as well as topline results from a recently completed meta-analysis of the ROMAN and GT-201 SOM trial results, at the 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting. The press release also announces that final data from the Company's Phase 2 AESOP trial of avasopasem for radiotherapy-induced esophagitis were also presented in a separate session and that, in addition, poster presentations during ASTRO highlighted the completed Phase 2 EUSOM trial of avasopasem for SOM in Europe and the ongoing GRECO-1 trial of rucosopasem for non-small cell lung cancer. A copy of the press release is attached to this Current Report on Form 8-K ("Form 8-K") as Exhibit 99.1.

On October 26, 2022, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at www.galeratx.com. A copy of that corporate slide presentation is attached to this 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 Item 7.01 of this Form 8-K (including Exhibit 99.1 and Exhibit 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 8.01 Other Events.

On October 26, 2022, the Company announced the presentation of the one-year tumor and renal function outcomes data from its Phase 3 ROMAN trial of avasopasem manganese 90 mg for radiotherapy-induced severe oral mucositis (SOM), as well as topline results from a recently completed meta-analysis of the ROMAN and GT-201 SOM trial results at the 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting.

Highlights from the Phase 3 ROMAN data presented at ASTRO:

- After one-year follow-up, patients with locally advanced head and neck cancer treated with avasopasem in combination with the standard-of-care regimen (intensity-modulated radiation therapy (IMRT) + cisplatin) demonstrated comparable tumor outcomes and overall survival to patients in the placebo arm.
- Patients treated with avasopasem in combination with IMRT + cisplatin had a 10 percent incidence of chronic kidney disease (CKD) after one year of post treatment follow-up, compared to 20 percent of patients in the placebo arm ($p=0.0043$). CKD (eGFR <60) is a known toxicity risk with cisplatin for these patients and the results highlight success on a predefined exploratory endpoint of renal function. The prospective exploration of this potential benefit of avasopasem was driven by published preclinical data and a post hoc assessment of patients from the GT-201 trial presented at the 2020 American Society of Clinical Oncology (ASCO) annual meeting.

In addition to the ROMAN long-term endpoints, a meta-analysis of the Company's two randomized placebo-controlled trials (ROMAN and GT-201; n=551) was included in the ASTRO presentation; these results reinforced that avasopasem therapy resulted in clinically meaningful reductions in radiotherapy-induced SOM, including a significant reduction in the incidence (19% reduction; $p=0.0053$), duration (58% reduction in the median number of days of SOM; $p=0.0002$), onset (28% delay in the median number of days to first SOM; $p=0.0005$) and severity (32% reduction in the incidence of Grade 4 oral mucositis; $p=0.0102$) of SOM compared to placebo.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibits 99.1 and 99.2 relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release of Galera Therapeutics, Inc. issued October 26, 2022
99.2	Corporate Presentation of Galera Therapeutics, Inc. dated October 26, 2022
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: October 26, 2022

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

Galera Announces Presentation of Phase 3 ROMAN Long-term Follow-up Data at 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting

Tumor outcomes and overall survival maintained in patients with HNC at one-year

Cisplatin-related chronic kidney disease reduced by 50% in avasopasem patients compared to placebo at one-year

Meta-analysis of ROMAN and GT-201 (Phase 2b) supports efficacy across trials and key SOM endpoints

Company remains on track to submit NDA to the U.S. FDA for avasopasem for radiotherapy-induced severe oral mucositis by end of 2022

MALVERN, Pa. – October 26, 2022 – 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 the presentation of one-year tumor and renal function outcomes data from its Phase 3 ROMAN trial of avasopasem manganese 90 mg for radiotherapy-induced severe oral mucositis (SOM), as well as topline results from a recently completed meta-analysis of the ROMAN and GT-201 SOM trial results, at the 2022 American Society for Radiation Oncology (ASTRO) Annual Meeting. Final data from its Phase 2 AESOP trial of avasopasem for radiotherapy-induced esophagitis were also presented today in a separate session. In addition, poster presentations during ASTRO highlighted the completed Phase 2 EUSOM trial of avasopasem for SOM in Europe and the ongoing GRECO-1 trial of rucosopasem for non-small cell lung cancer. The presentations and posters are currently available in the ASTRO digital program.

Highlights from the Phase 3 ROMAN data presented at ASTRO:

- After one-year follow-up, patients with locally advanced head and neck cancer treated with avasopasem in combination with the standard-of-care regimen (intensity-modulated radiation therapy (IMRT) + cisplatin) demonstrated comparable tumor outcomes and overall survival to patients in the placebo arm.
- Patients treated with avasopasem in combination with IMRT + cisplatin had a 10 percent incidence of chronic kidney disease (CKD) after one year of post treatment follow-up, compared to 20 percent of patients in the placebo arm (p=0.0043). CKD (eGFR <60) is a known toxicity risk with cisplatin for these patients and the results highlight success on a predefined exploratory endpoint of renal function. The prospective exploration of this potential benefit of avasopasem was driven by published preclinical data and a post hoc assessment of patients from the GT-201 trial presented at the 2020 American Society of Clinical Oncology (ASCO) annual meeting.

“The ROMAN one-year follow-up data show that avasopasem can protect head and neck cancer patients from severe oral mucositis without affecting the treatment benefit of standard-of-care chemoradiotherapy,” said Dr. Carryn Anderson, Clinical Associate Professor of Radiation Oncology at the University of Iowa. “Treatment with avasopasem also significantly reduced the likelihood of patients developing cisplatin-related chronic kidney disease compared to placebo at one-year follow-up, suggesting avasopasem can reduce cisplatin renal toxicities and greatly improve patient quality of life.”

In addition to the ROMAN long-term endpoints, a meta-analysis of Galera’s two randomized placebo-controlled trials (ROMAN and GT-201; n=551) was included in Dr. Anderson’s ASTRO presentation; these results reinforced that avasopasem therapy resulted in clinically meaningful reductions in radiotherapy-induced SOM, including a significant reduction in the incidence, duration, onset and severity of SOM compared to placebo.

“The data presented today affirm our belief that avasopasem is providing real benefit for patients with head and neck cancer undergoing the current standard of care,” said Mel Sorensen, M.D., Galera’s President and CEO. “We look forward to submitting the NDA to the FDA by the end of 2022 with the intention of bringing avasopasem to patients as the first FDA-approved drug for radiotherapy-induced SOM.”

About Severe Oral Mucositis (SOM)

Approximately 42,000 patients with head and neck cancer undergo standard-of-care radiotherapy every year in the U.S. and are at risk of experiencing SOM. In patients with head and neck cancer, radiotherapy is a mainstay of treatment. Approximately 70 percent of patients receiving radiotherapy for head and neck cancer develop SOM, defined by the inability to eat solid food or drink liquids. The impact on patients who develop SOM is substantial, particularly when hospitalization and/or surgical placement of PEG tubes to maintain nutrition and hydration are required. SOM can adversely affect cancer treatment outcomes by causing interruptions in radiotherapy, which may compromise the otherwise good prognosis for tumor control in many of these patients. There is currently no drug approved to prevent or treat SOM for these patients.

About Avasopasem

Avasopasem manganese (avasopasem, or GC4419) is a selective small molecule dismutase mimetic in development for the reduction of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and for the reduction of radiotherapy-induced esophagitis in patients with lung cancer. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy, with or without systemic therapy.

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutic candidates that have the potential to transform radiotherapy in cancer. Galera’s selective dismutase mimetic product candidate avasopasem manganese (avasopasem, or GC4419) is being evaluated for radiotherapy-induced toxicities. The

Company's second product candidate, rucosopasem manganese (rucosopasem, or GC4711), is in clinical-stage development to augment the anti-cancer efficacy of stereotactic body radiation therapy in patients with non-small cell lung cancer and locally advanced pancreatic cancer. Galera is headquartered in Malvern, PA. For more information, please visit www.galeratx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding: the expectations surrounding the continued advancement of Galera's product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; the timing of the submission of an NDA for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer with the FDA; the ability of avasopasem to protect head and neck cancer patients from SOM without affecting the treatment benefit of standard-of-care chemoradiotherapy; the ability of avasopasem to reduce cisplatin renal toxicities and improve patient quality of life; and the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics. 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 or maintain 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; the possibility of Galera's common stock being delisted from The Nasdaq Global Market; 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission (SEC) 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.

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Exhibit 99.2

Transforming **radiotherapy** for patients with cancer

October 2022

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 been 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 timing thereof, and therapeutic potential of current and prospective product candidates, plans and timing for the commencement of, and the release of data from, clinical trials, plans and timing for the submission of applications for marketing approval to regulatory authorities, our plans to prepare for commercialization and a U.S. 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, 2021 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

1.9 million new cancers annually[1] in US; over 50% of patients receive radiation therapy as part of their treatment

IMRT

Intensity Modulated Radiation Therapy

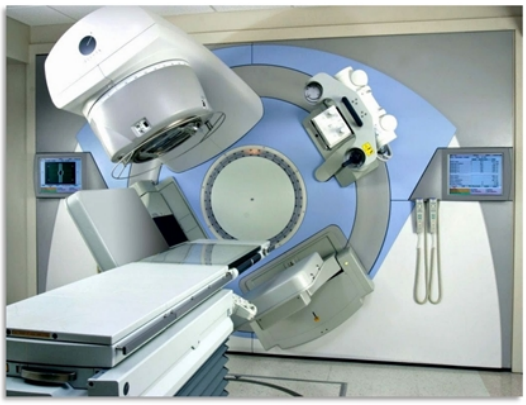
Low doses for weeks
(~2 Gy/day)

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

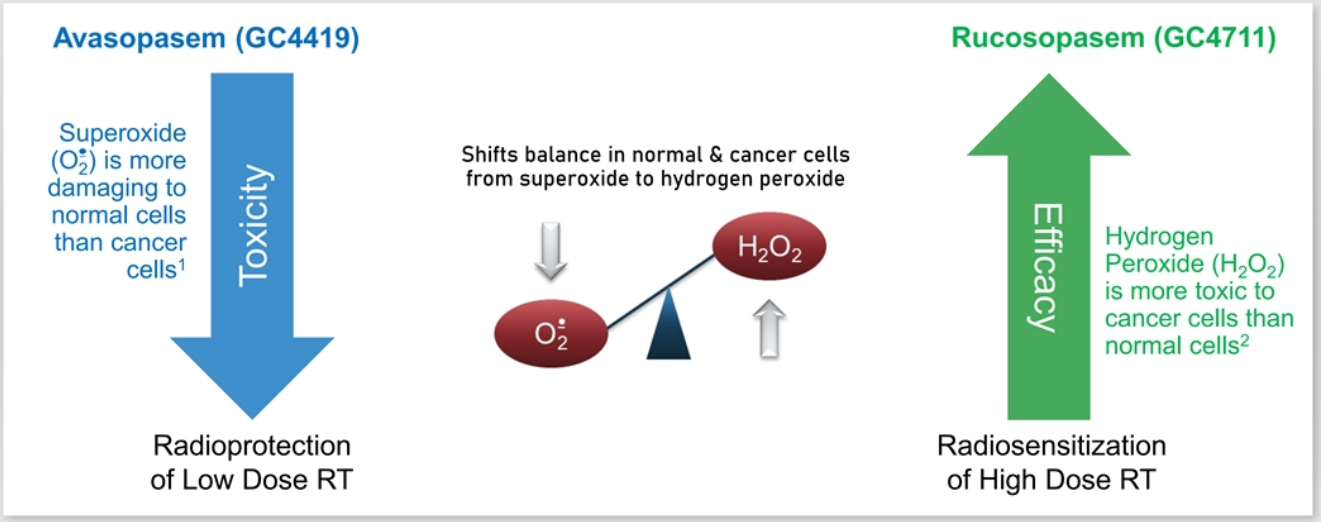
Radiosensitization

Efficacy

[1]SEER data for 2020

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

Potential to improve both sides of the therapeutic index

Avasopasem
Reducing IMRT Toxicity

- **Severe Oral Mucositis in Head & Neck Cancer (HNC)**
- **Esophagitis in Lung Cancer**

2 positive randomized placebo-controlled trials in HNC
- GT-201 Phase 2b (n=223)
- ROMAN Phase 3 (n=455)

NDA submission planned by end of 2022
- FDA Breakthrough Therapy Designation (BTD)

Rucosopasem
Increasing SBRT Efficacy

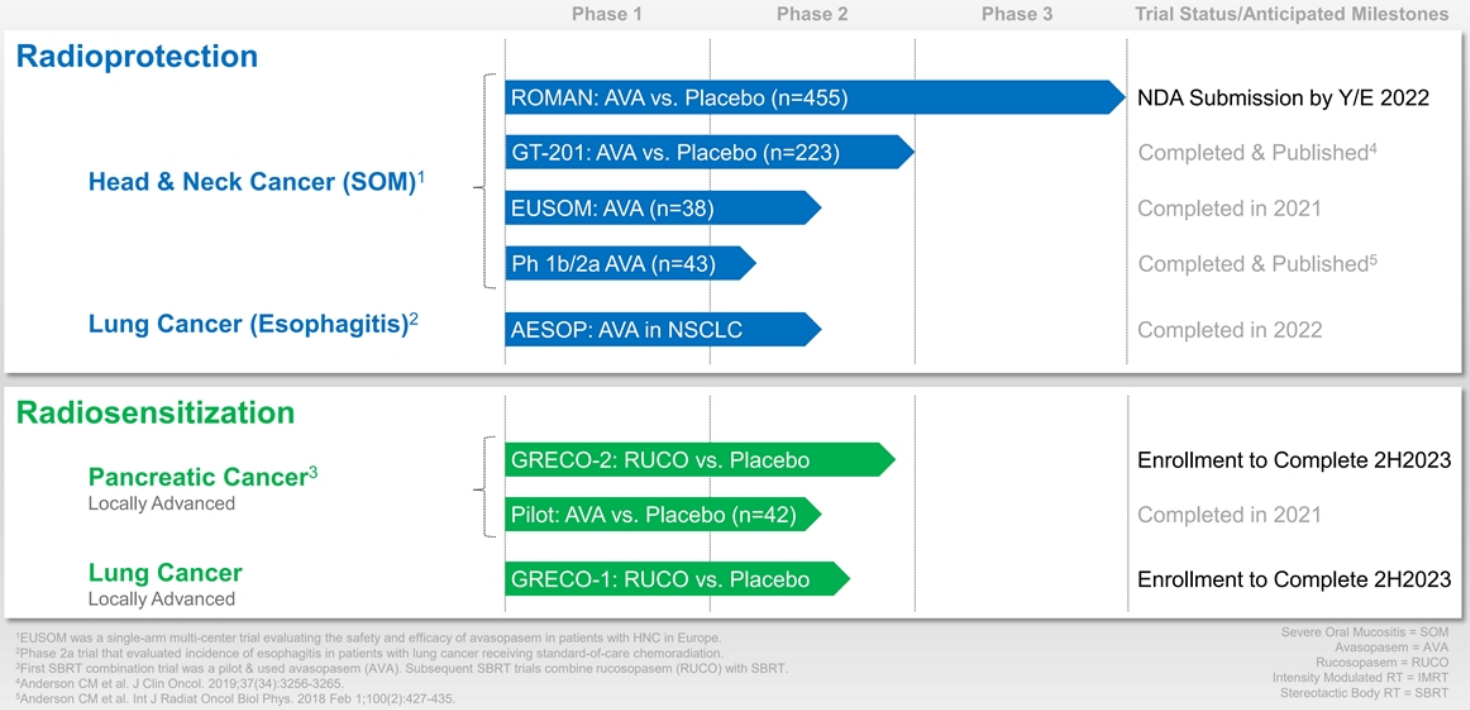
- **Locally Advanced Pancreatic Cancer (LAPC)**
- **Non-Small Cell Lung Cancer (NSCLC)**

Encouraging survival data in pancreatic cancer trial[1]

GRECO trials evaluating SBRT + rucosopasem – Enrollment expected to complete 2H 2023
- GRECO-1 in NSCLC
- GRECO-2 in LAPC

[1]The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial used to guide development of rucosopasem in combination with SBRT.

Clinical Stage Pipeline



[1]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[2]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[3]First SBRT combination trial was a pilot & used avasopasem (AVA). Subsequent SBRT trials combine rucosopasem (RUCO) with SBRT.
[4]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[5]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Severe Oral Mucositis = SOM
Avasopasem = AVA
Rucosopasem = RUCO
Intensity Modulated RT = IMRT
Stereotactic Body RT = SBRT

Reducing
IMRT Toxicity

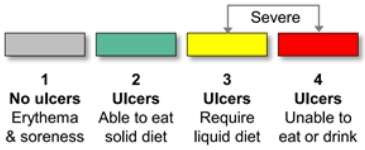
Galera® Therapeutics, Inc

Severe Oral Mucositis in Head & Neck Cancer

The most burdensome toxicity of standard-of-care chemoradiotherapy (radiotherapy & cisplatin)[1]

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

WHO Scale Criteria for Oral Mucositis



Current Approaches Lack Efficacy

MASCC Guidelines focus principally on symptoms[2]

- Basic Oral care
- Opioids, anesthetics
- Coating agents
- Benzydamine
- Anti-inflammatories
- Laser and other light therapy

Physicians Consider Topicals Ineffective

Market Research with 150 Radiation Oncologists[1]

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

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

Avasopasem: First-to-Market Potential for Severe Oral Mucositis

Achieved statistical significance in two randomized trials in patients with head and neck cancer

Avasopasem has FDA Breakthrough Therapy Designation based on GT-201 results

[1]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[2]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[3]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[4]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Comparison of Galera's Two Placebo-Controlled Trials

Both GT-201 and ROMAN were double-blind placebo-controlled randomized trials

GT-201 Phase 2b

N=223

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

Endpoints

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

Similarities

- SoC IMRT + Cisplatin
- 60-minute IV infusion just before IMRT
- WHO Grading
- Multicenter in North America (~90% US)

- Patients with Head & Neck Cancer (locally advanced)
- Same inclusion / exclusion criteria

ROMAN Phase 3

N=455

R
- Avasopasem 90mg x 7 weeks

Randomized 3:2

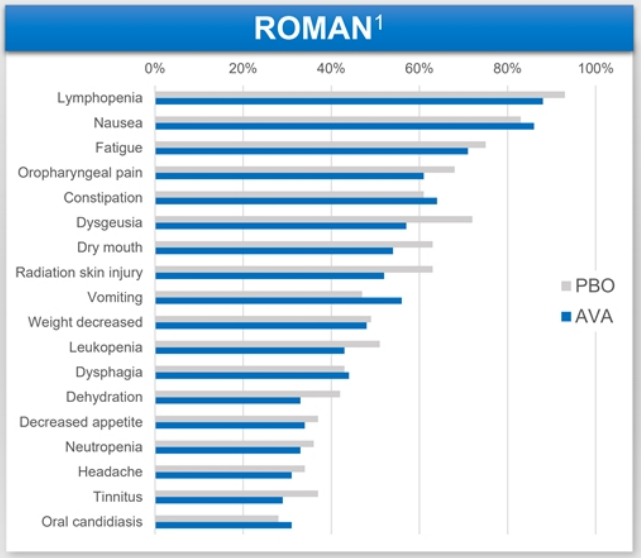
- Placebo x 7 weeks

Endpoints

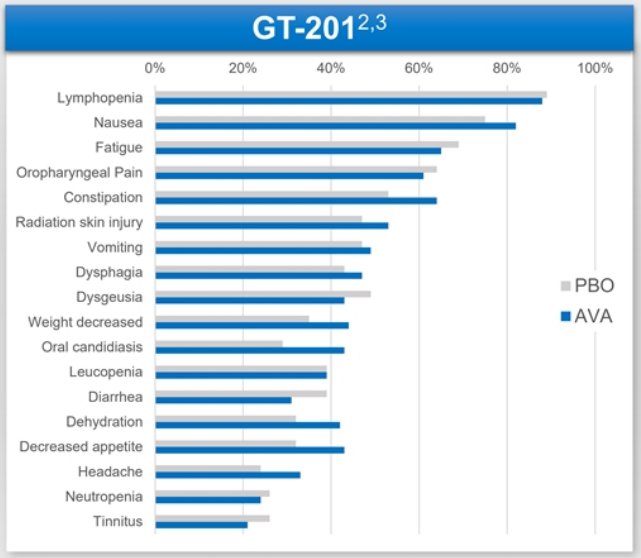
- Primary: Reduction in the incidence of SOM
- Secondary: Reduction in SOM duration & severity

Most Frequent Adverse Events on the Two Randomized Trials

Avasopasem 90mg appears generally well tolerated (all grades and causes)



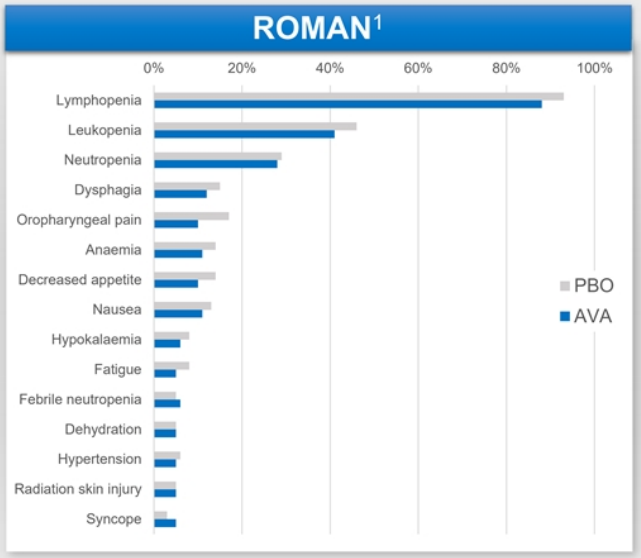
[1]ITT population: 166 patients on placebo; 241 on 90mg avasopasem



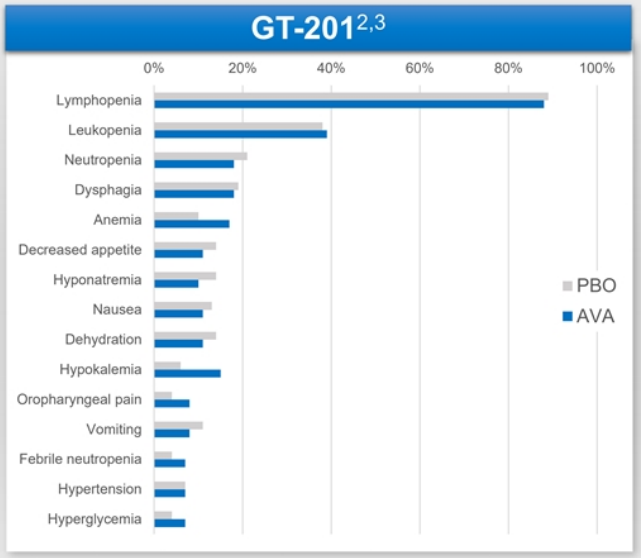
[2]Intent-to-Treat (ITT) population: 72 patients on placebo; 72 patients on 90mg avasopasem
[3]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Most Frequent ≥ Grade 3 AEs on the Two Randomized Trials

Avasopasem 90mg appears generally well tolerated



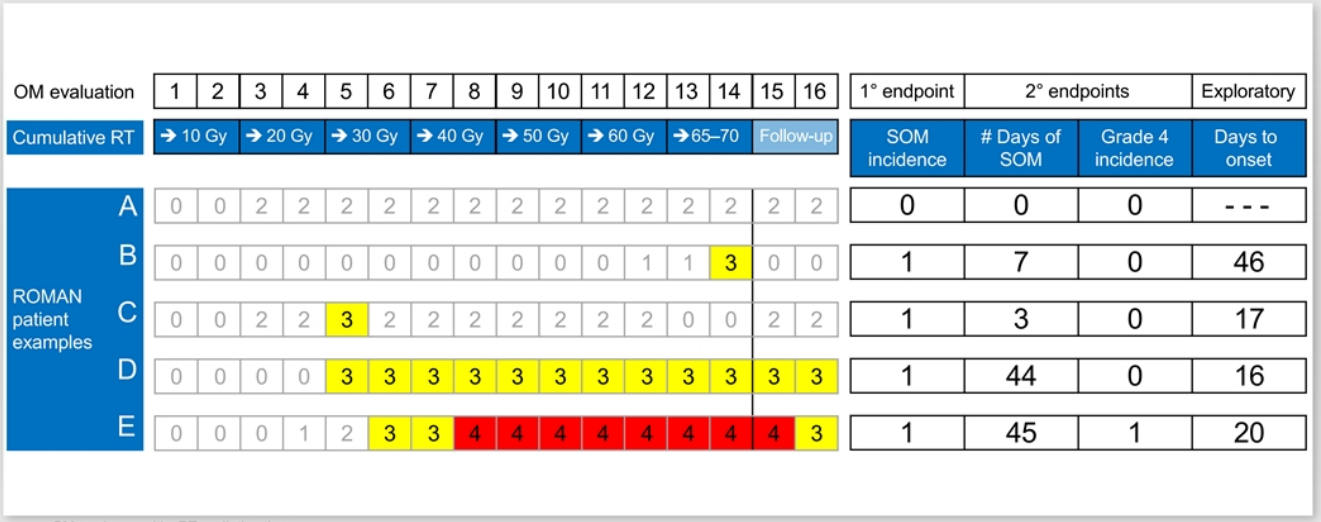
[1]ITT population: 166 patients on placebo; 241 on 90mg avasopasem
AE = Adverse Event



[2]Intent-to-Treat (ITT) population: 72 patients on placebo; 72 patients on 90mg avasopasem
[3]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Multiple Efficacy Parameters Define the Patient Burden of SOM

Incidence doesn't tell full story; real patient examples from ROMAN



	OM evaluation	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	1° endpoint	2° endpoints		Exploratory
	Cumulative RT	→ 10 Gy		→ 20 Gy		→ 30 Gy		→ 40 Gy		→ 50 Gy		→ 60 Gy		→65–70		Follow-up		SOM incidence	# Days of SOM	Grade 4 incidence	Days to onset
ROMAN patient examples	A	0	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	- - -
	B	0	0	0	0	0	0	0	0	0	0	0	1	1	3	0	0	1	7	0	46
	C	0	0	2	2	3	2	2	2	2	2	2	2	0	0	2	2	1	3	0	17
	D	0	0	0	0	3	3	3	3	3	3	3	3	3	3	3	3	1	44	0	16
	E	0	0	0	1	2	3	3	4	4	4	4	4	4	4	4	3	1	45	1	20

OM=oral mucositis; RT=radiation therapy

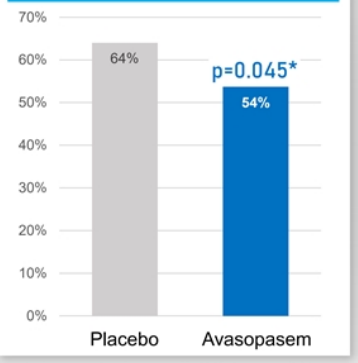
Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

ROMAN Results (ITT n=407)

Reductions across SOM endpoints; statistical significance on the primary & median days SOM secondary endpoint

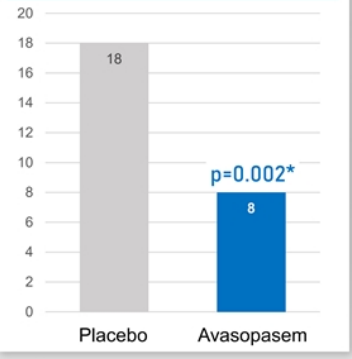
SOM Incidence

16% ↓ **Reduction** in SOM incidence



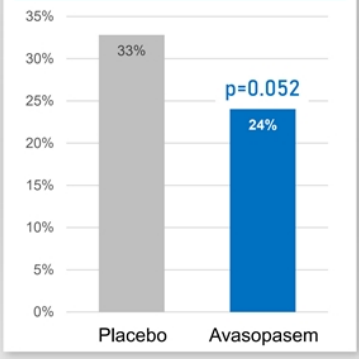
SOM Days

56% ↓ **Reduction** in median days of SOM



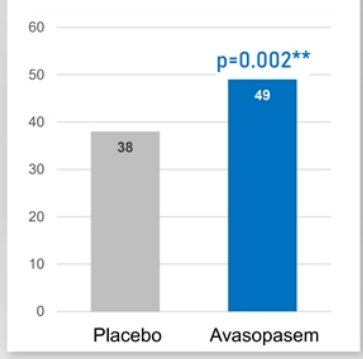
Grade 4 OM Incidence

27% ↓ **Reduction** in incidence of Grade 4 OM



SOM Onset

29% ↓ **Delay** in median days to 1st SOM

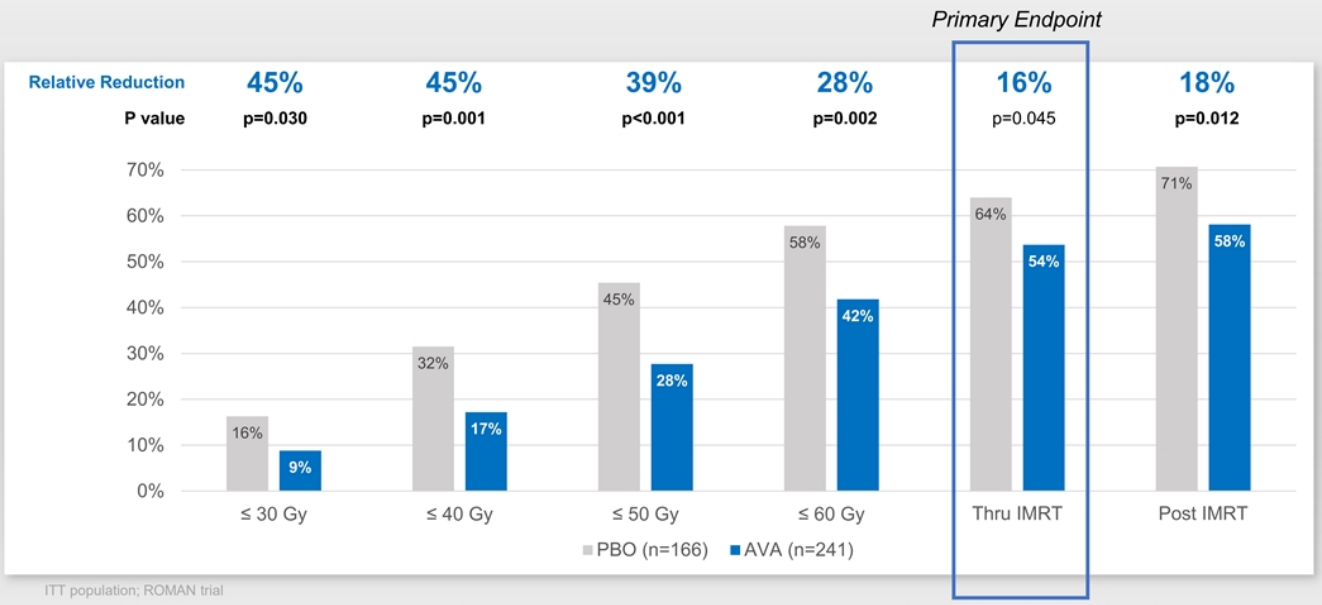


*Statistical significance per statistical analysis plan for this Phase 3 trial
**Time to Onset was an exploratory endpoint

Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

Incidence Reduced at All Landmarks of Radiation Therapy

Both before and after primary endpoint at end of IMRT – all patients



ITT population; ROMAN trial

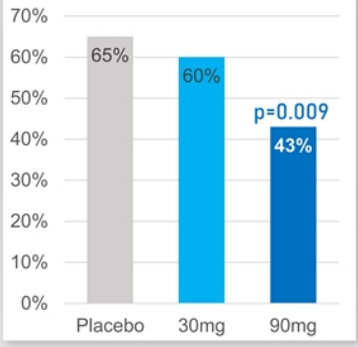
Anderson CM, Lee C, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem manganese (GC4419) for severe oral mucositis (SOM) in patients receiving chemoradiotherapy (CRT) for locally advanced, nonmetastatic head and neck cancer (LAHNC). Presented at ASCO Annual Meeting, June 3, 2022.

GT-201 Results (n=223)

Consistent and encouraging results across SOM endpoints – ITT Population

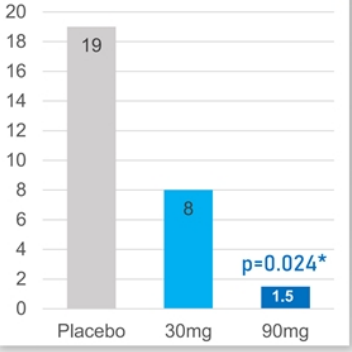
SOM Incidence

34% ↓ **Reduction** in SOM incidence



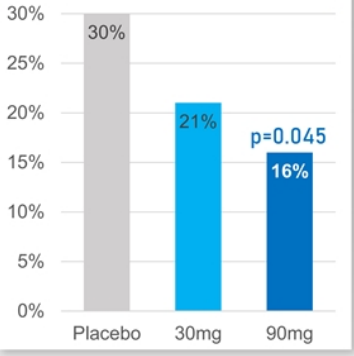
SOM Days

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



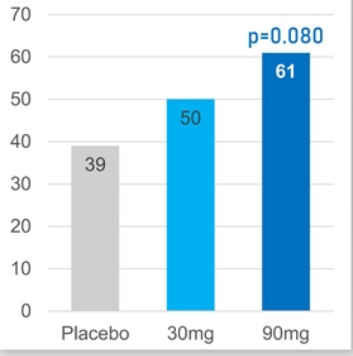
Grade 4 OM Incidence

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



SOM Onset

56% ↓ **Delay** in median days to 1st SOM



*Statistical significance per statistical analysis plan for this trial

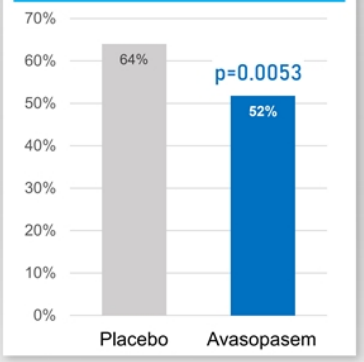
Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Combined Meta-analysis of the Two Randomized Trials (n=551)

Avasopasem SOM improvement consistent across trials and key parameters

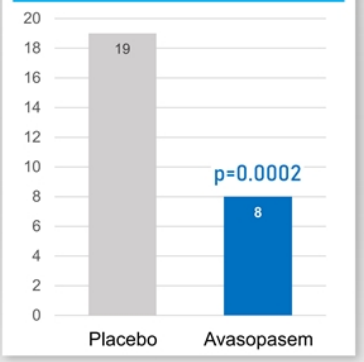
SOM Incidence

19% ↓ **Reduction** in SOM incidence



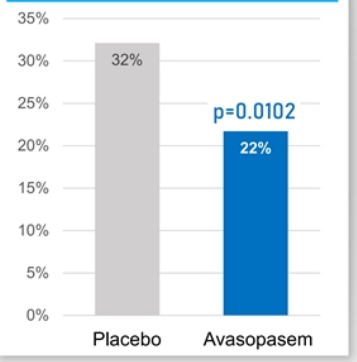
SOM Days

58% ↓ **Reduction** in median days of SOM



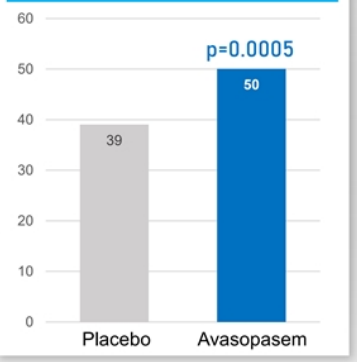
Grade 4 OM Incidence

32% ↓ **Reduction** in incidence of Grade 4 OM



SOM Onset

28% ↓ **Delay** in median days to 1st SOM



Note: Nominal p values for all endpoints, calculated according to prespecified statistical analysis plan (SAP) for the meta-analysis; 238 patients on placebo; 313 patients on 90mg avasopasem

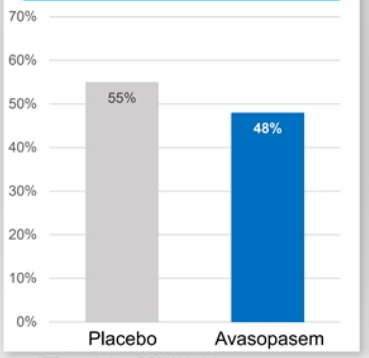
Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

Avasopasem Reduced Narcotic and Feeding Tube Usage

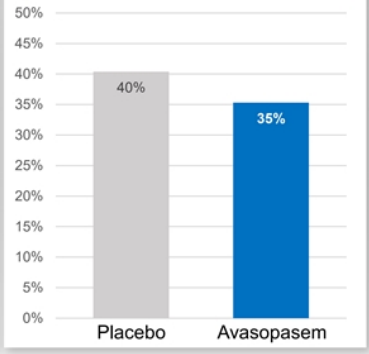
Reductions in SOM with avasopasem appeared to decrease utilization in ROMAN trial

Narcotics

13% ↓ **Reduction** in usage after RT start

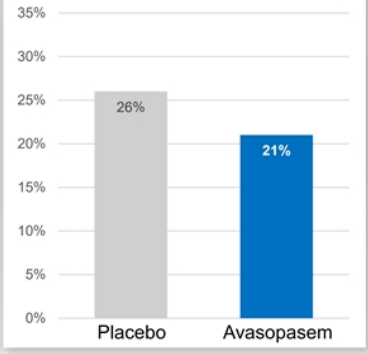


13% ↓ **Reduction** in usage for OM pain

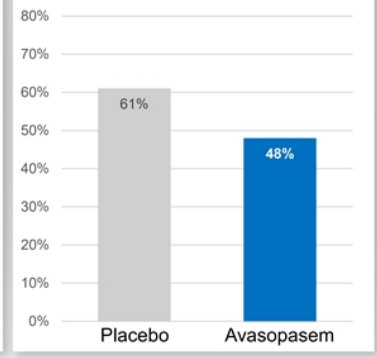


Gastrostomy (Feeding) Tubes

19% ↓ **Reduction** in placements after RT start



21% ↓ **Reduction** in overall utilization

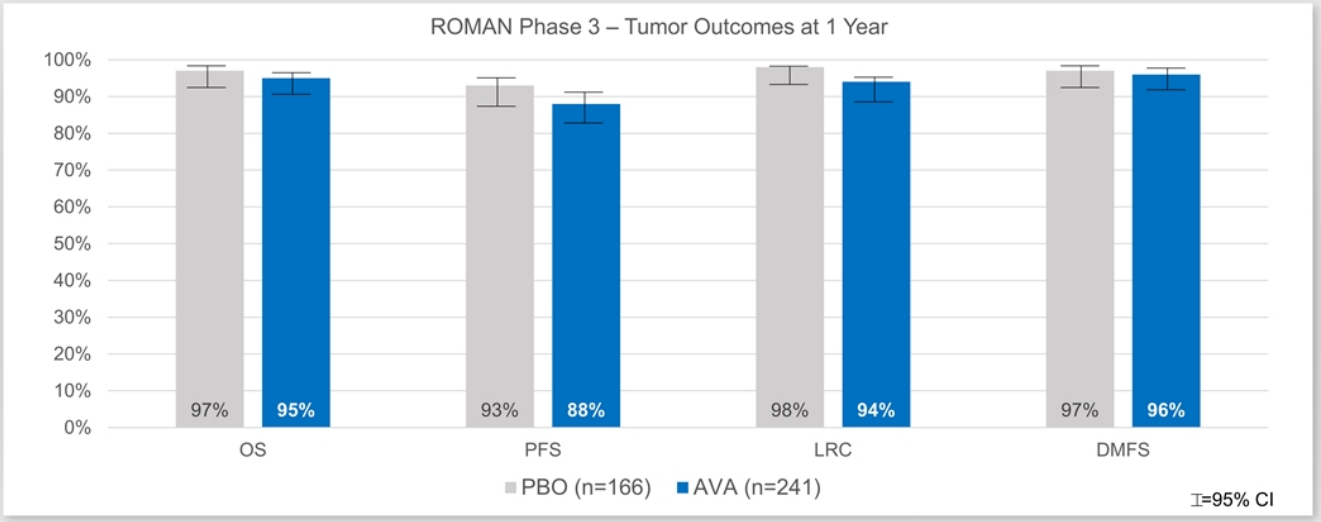


ITT population; ROMAN trial

Saunders D, Lee CM, Kelley JR, et al. ROMAN: Phase 3 trial of avasopasem to reduce chemoradiotherapy (CRT)-related severe oral mucositis (SOM) in patients with head and neck cancer (HNC). Presented at Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology Annual Meeting, June 23-25, 2022.

ROMAN Long-term Outcomes: Tumor Control & Survival

Overlapping 95% confidence intervals at 1 year; consistent with GT-201 tumor outcomes[1]



OS = overall survival, PFS = progression-free survival, LRC = locoregional control, DMFS = distant metastasis-free survival. 95% Confidence Intervals for each endpoint.

Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

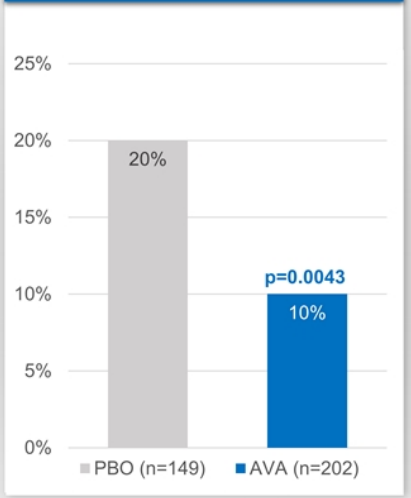
ROMAN Long-Term Outcomes: Cisplatin Renal Endpoints

Avasopasem halved Chronic Kidney Disease (CKD) at 1 year; a predefined endpoint (CKD <60 mL/min/1.73m^2)

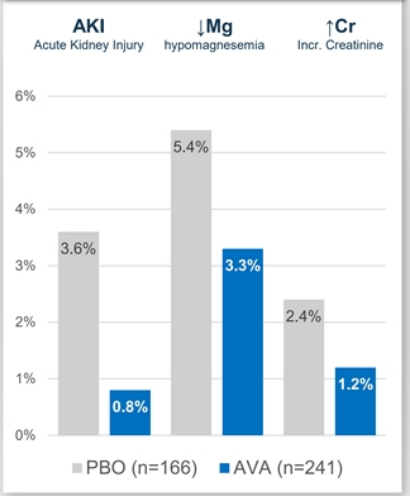
Previous Scientific Data

- Superoxide drives cisplatin nephrotoxicity
  - Mapuskar, *Redox Biol* 2021
- Avasopasem preclinically prevented cisplatin acute kidney injury
  - Mapuskar, *Antioxid* 2018
- Retrospective analysis of Phase 2b patient subset suggested CKD prevention
  - Steinbach, *ASCO* 2020

CKD @ 1 Year on ROMAN



Cisplatin Renal Gr. 3+ AEs



ITT population; CKD defined by Nat. Kidney Foundation as eGFR (estimated Glomerular Filtration Rate) < 60 mL/min/1.73 m2 (approx. the % of normal kidney function that is working)

Anderson CM, Lee C, Kelley JR, et al.. Tumor Outcomes for ROMAN: Phase 3 Trial of Avasopasem Manganese (GC4419) for Severe Oral Mucositis (SOM) in Patients Receiving Chemoradiotherapy (CRT) for Locally Advanced Head and Neck Cancer (LAHNC). Presented at ASTRO Annual Meeting, October 26, 2022.

Plan to Submit Avasopasem NDA by End of 2022

- No FDA-approved treatments for radiotherapy-induced SOM
- Avasopasem has Breakthrough Therapy and Fast Track Designations
- Productive interactions with FDA
- NDA will be based on statistically significant, clinically meaningful data from two placebo-controlled randomized trials: ROMAN and GT-201
- ROMAN results presented in oral presentations at 2022 ASCO (June), MASCC (June), and ASTRO (October) annual meetings
- NDA submission planned by end of 2022

NDA=New Drug Application; FDA=U.S. Food and Drug Administration; ASCO=American Society of Clinical Oncology; MASCC=Multinational Association of Supportive Care in Cancer; ASTRO=American Society for Radiation Oncology

SOM Market Opportunity

Galera® Therapeutics, Inc

Head and Neck Cancer – Large Market Opportunity

Severe Oral Mucositis is >$1B total market opportunity in the US[1]

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

Source: Globocan & US SEER Data in CA Cancer J Clin 2021

[1] Based on 42,000 US patients and branded supportive care price analogs

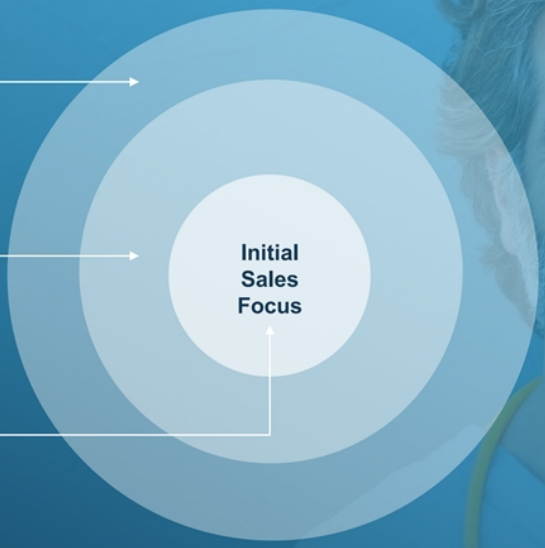
Concentrated Physician Population

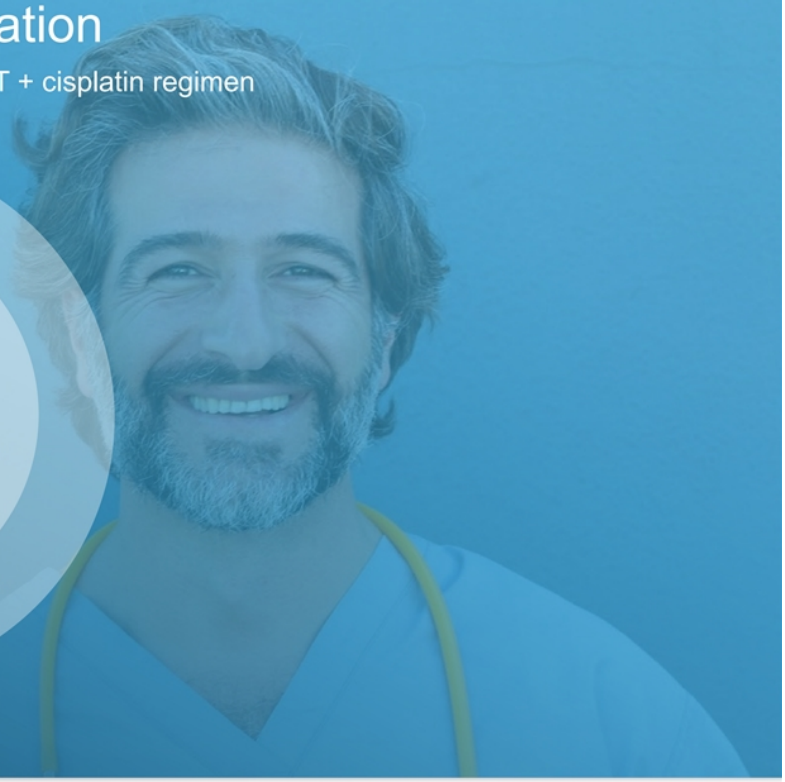
SOM is most burdensome side effect of curative IMRT + cisplatin regimen

5,000
Radiation Oncologists in US

2,500
Radiotherapy Treatment Sites

700
Top centers where >80% HNC patients are treated





Most Centers Have Ability to Infuse Avasopasem Today

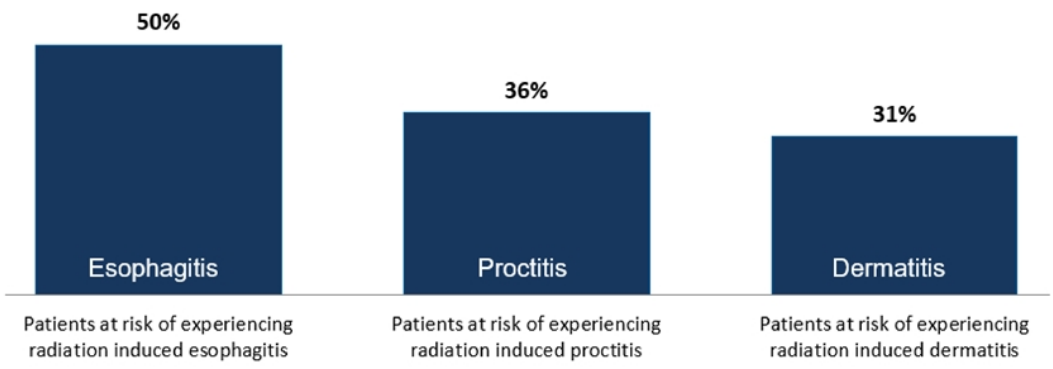
72% Radiotherapy Sites Have Existing Infusion Capability

Adoption Archetype Determinants	A Rad Oncs Have Current Capabilities	B Med Oncs Administer Infusions for Rad Onc	C Rad Oncs Need to Add Capabilities	D 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

Beyond Oral Mucositis: Other RT-Related Toxicities

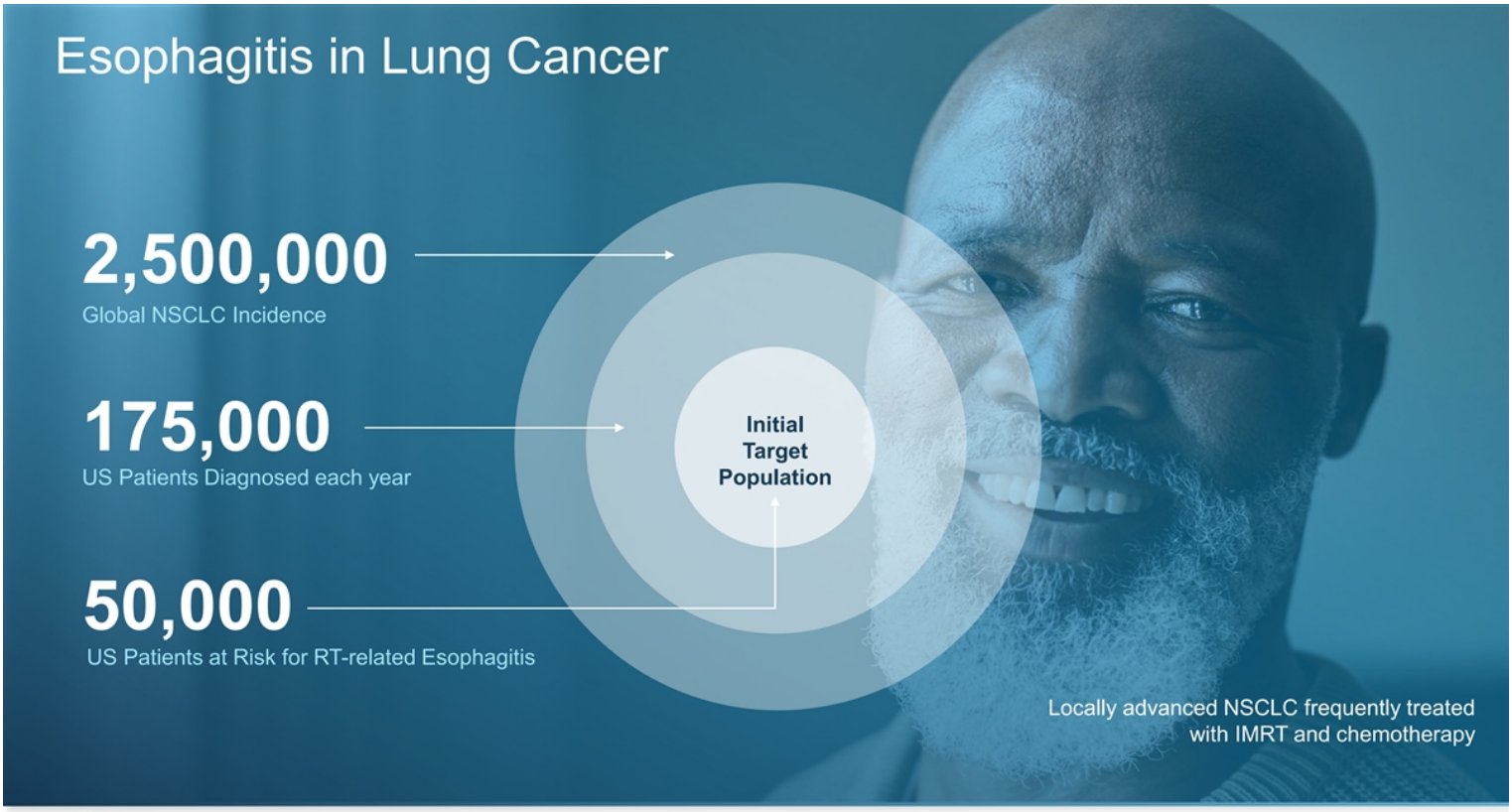
Physicians view SOM data as potentially applicable to other radiation-related toxicities



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)

50-60% Get Grade 2+[1]
20-30% Get Grade 3+[2,3]

NCI Grading for esophagitis[4]

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 in Lung Cancer

Single-arm Phase 2 Trial

- 6 weeks of standard IMRT to ≥ 5 cm of esophagus
- Will compare esophagitis rate with historical data

[1]Palma, DA. (2013). Int J Radiation Oncol Biol Phys, Vol. 87 (4), 690-696.
[2]LAMP Study. Belani, CP et al. (2005). J Clin Oncol, 23:5883-5891 (carboplatin + paclitaxel chemo).
[3]RTOG 9410. Curran, WJ et al. (2011). J Natl Cancer Inst, 103:1452–1460 (cisplatin + vinblastine).
[4]NCI Common Toxicity Criteria 5.0.

Esophagitis Trial (AESOP)

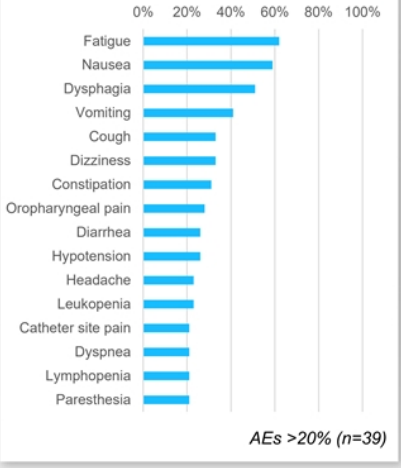
Low incidence of Grade 3+ esophagitis with avasopasem compared to literature

Trial Design
Patients and Treatment

- Single-arm Phase 2a open-label trial
- Patients with lung cancer (NSCLC or SCLC)
- Standard-of-care chemoradiotherapy over 6 weeks (60 Gy IMRT) + avasopasem 90mg
- Eligibility criteria required ≥5 cm (≥20%) of the esophagus in the radiotherapy field
  - Patients who get ≥60 Gy to ≥17% of their esophagus are considered at highest risk: 59% risk of grade ≥2 and 22% of grade ≥3 esophagitis[1]

Pt #	Disposition
39	Enrolled (Safety)
35	Full Chemoradiation (6 weeks)
29	Per Protocol AVA (≥5 weeks)

Safety
AE profile consistent with chemoradiotherapy



AEs >20% (n=39)

AESOP Results
(Per Protocol n=29)

Esophagitis Incidence by Grade[2]

	Weeks of IMRT					
	1	2	3	4	5	6
Gr. 2	-	10%	17%	38%	48%	45%
Gr. 3	-	-	3%	-	-	3%
Gr. 4-5	-	-	-	-	-	-

- Grade 3 esophagitis was much less than in comparable trial results
- Most patients free of Grade 3 for most weeks of treatment—no Grade 4 or 5

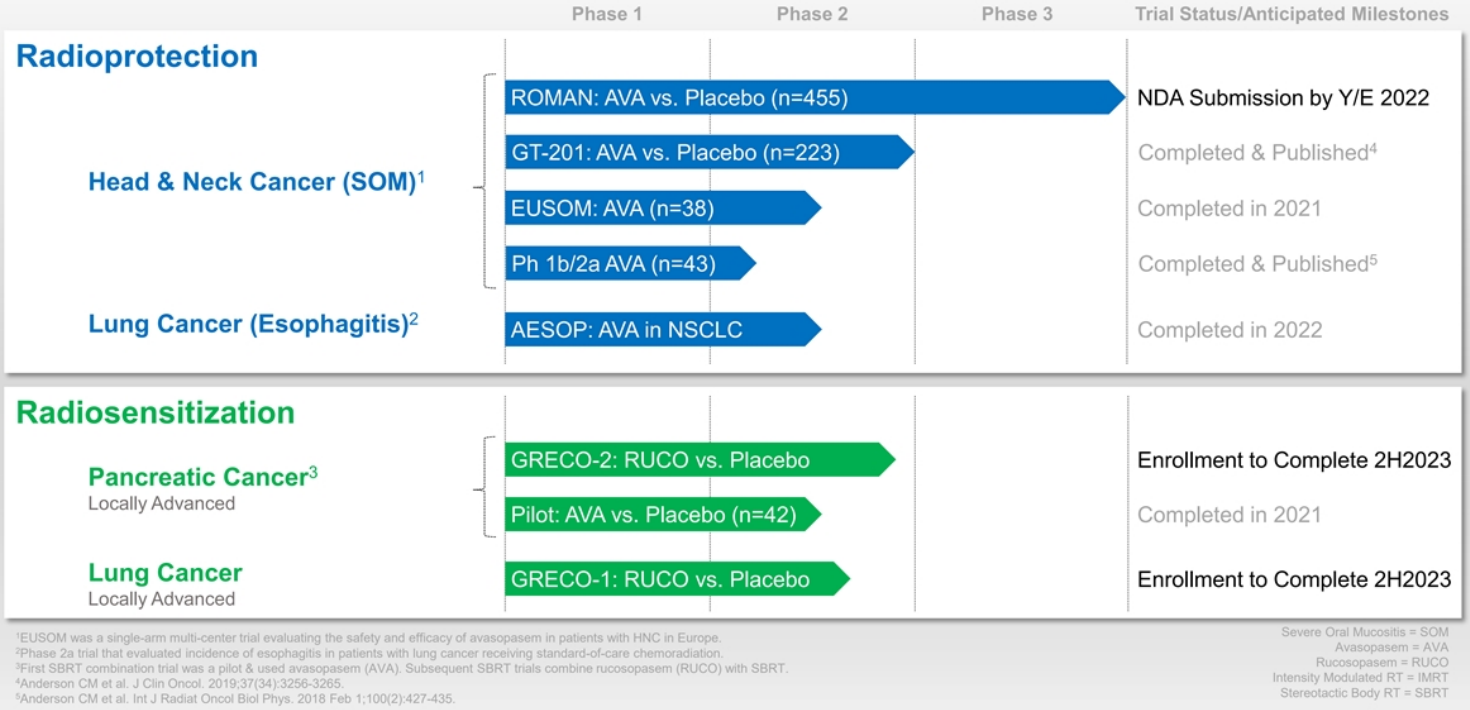
Trial	Pt #	CXRT Arms	Grade 3+4
AESOP	**29**	**CT+RT**	**7%**
LAMP Study[3]	74	CT → CT+RT	19%
	92	RT+CT → CT	28%
RTOG 9410[4]	193	CT+RT	22%

[1]Palma, DA. (2013). Int J Radiation Oncol Biol Phys, Vol. 87 (4), 690-696.
[2]NCI Common Toxicity Criteria 5.0.
[3]LAMP Study. Belani, CP et al. (2005). J Clin Oncol, 23:5883-5891 (carboplatin + paclitaxel chemo).
[4]RTOG 9410. Curran, WJ et al. (2011). J Natl Cancer Inst, 103:1452–1460 (cisplatin + vinblastine).

Increasing
SBRT Efficacy

Galera® Therapeutics, Inc

Clinical Stage Pipeline

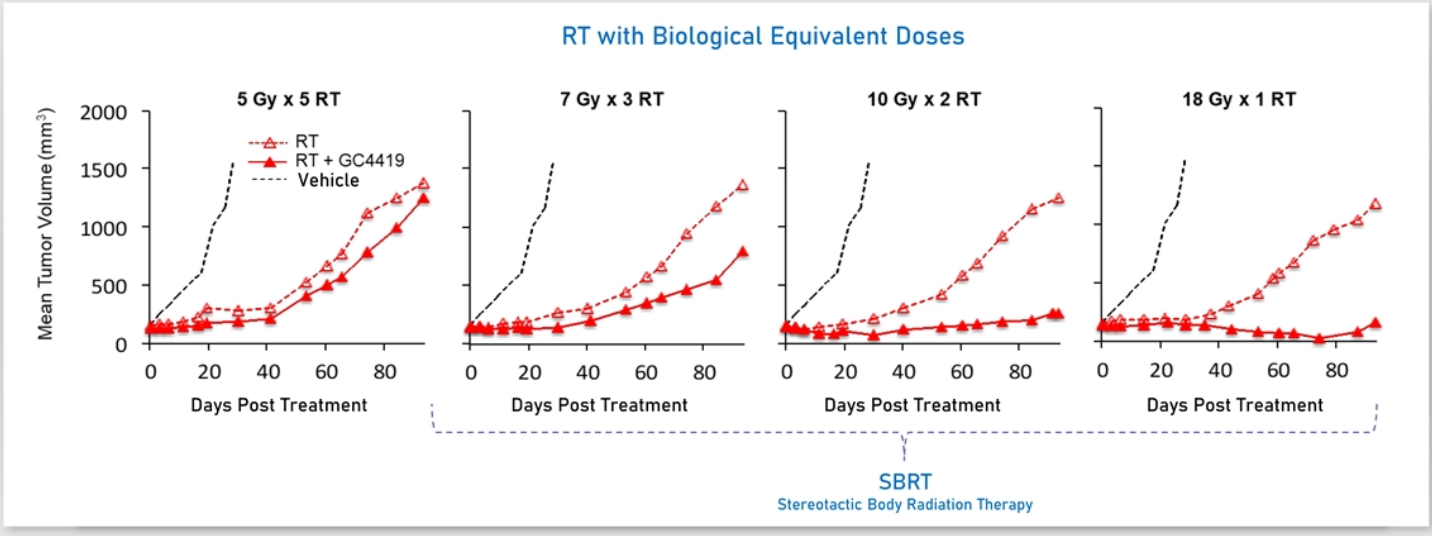


[1]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[2]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[3]First SBRT combination trial was a pilot & used avasopasem (AVA). Subsequent SBRT trials combine rucosopasem (RUCO) with SBRT.
[4]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[5]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Severe Oral Mucositis = SOM
Avasopasem = AVA
Rucosopasem = RUCO
Intensity Modulated RT = IMRT
Stereotactic Body RT = SBRT

Synergy with High-Dose RT (SBRT)

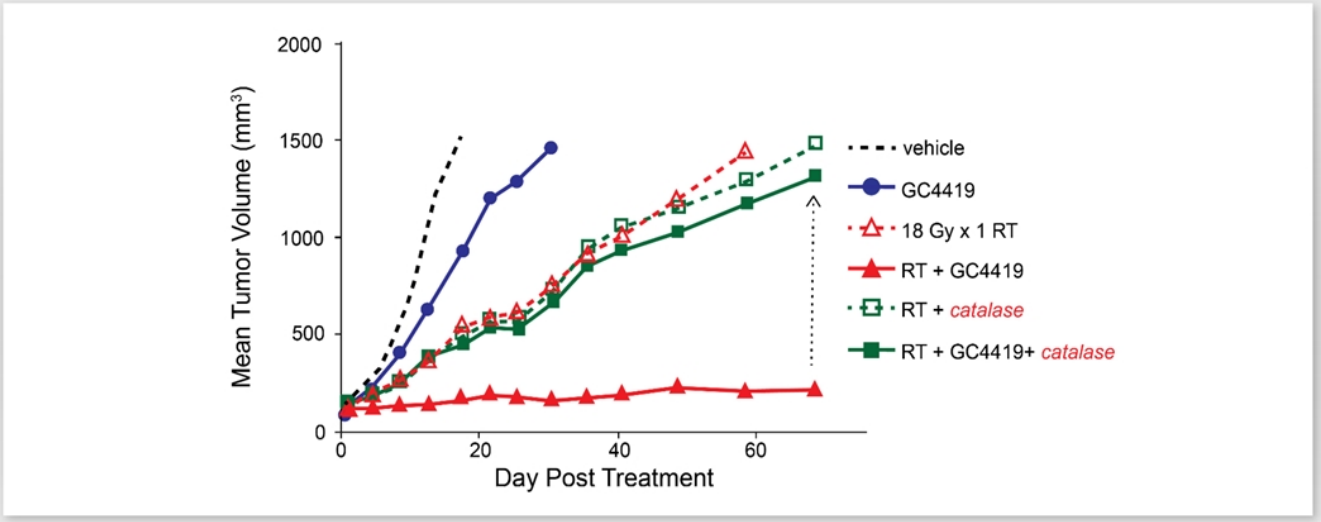
High-fraction focal irradiation of human tumor xenografts (H1299 NSCLC) in mice



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

H_2O_2 build-up in Cancer Cell → Synergy with SBRT

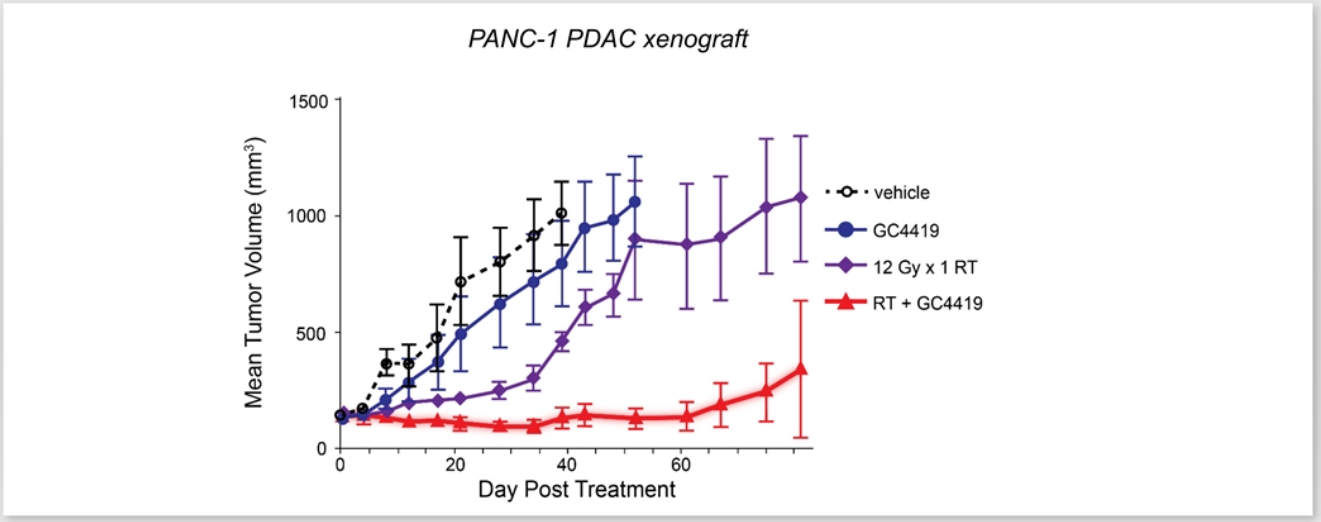
Synergy eliminated with doxycycline-induced catalase in genetically modified $H1299^{CAT}$ cells



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

Pancreatic Tumor Model → Synergy with SBRT

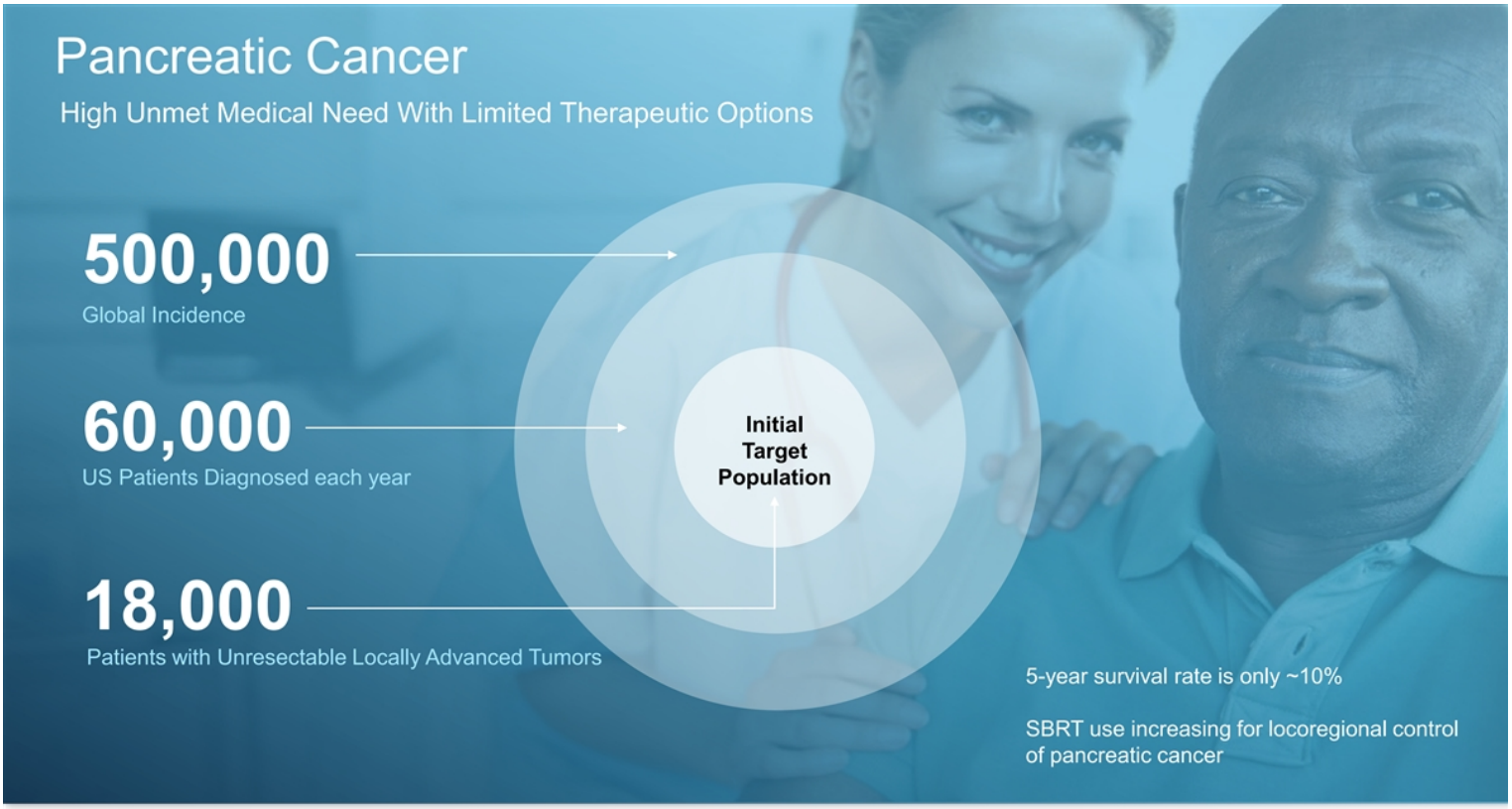
Marked synergy of Dismutase Mimetic with 12 Gray Radiotherapy



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

Pancreatic Cancer

High Unmet Medical Need With Limited Therapeutic Options

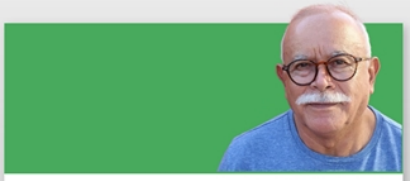


5-year survival rate is only ~10%

SBRT use increasing for locoregional control of pancreatic cancer

Proof of Concept Trial in Pancreatic Cancer

Completed 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

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*

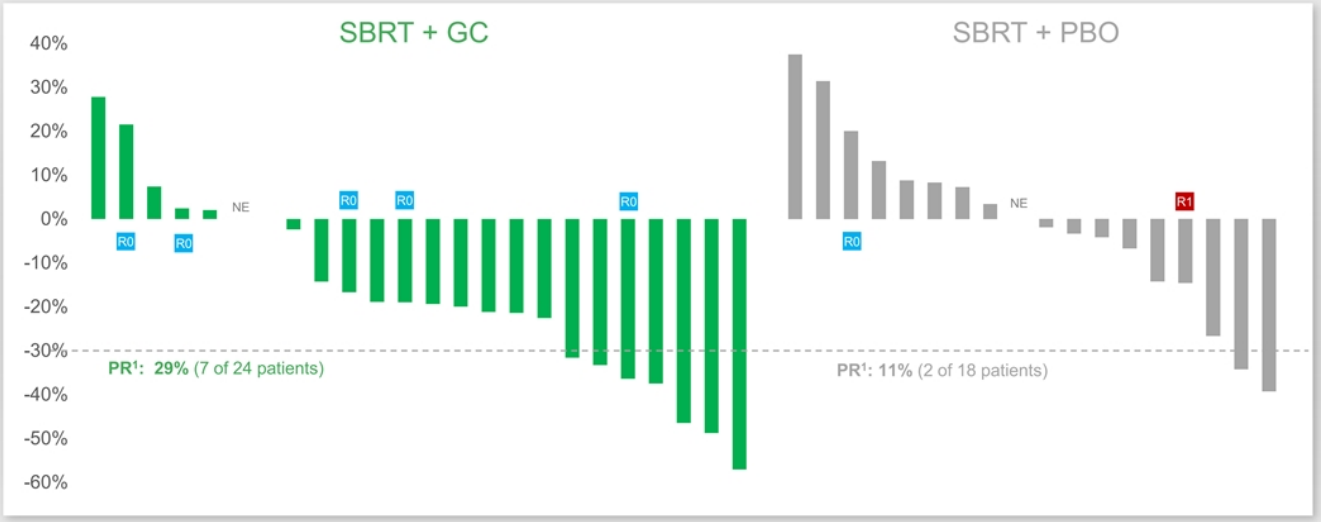
No Early or Late Toxicity Signal for GC

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

Partial Response Rate Increased 2.5-fold

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

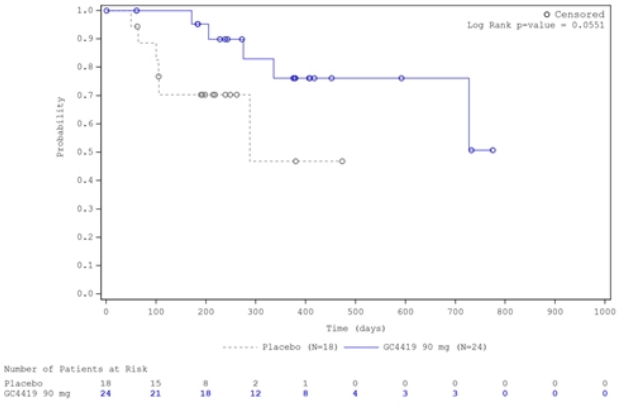


[1]Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)
NE = not evaluable (scans not performed post SBRT)
R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)
R1 = positive tumor margins at surgery

Improved Control of Both Local and Distant Disease

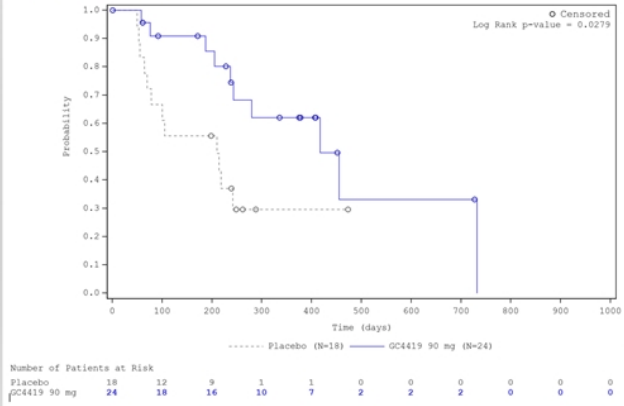
Median LRC on GC arm not yet reached at data cut-off; Increased median DMC by 100%

Locoregional Control (LRC)
– within RT Field



P-value = 0.0551 Hazard Ratio = 0.30

Distant Metastases Control
– outside RT Field



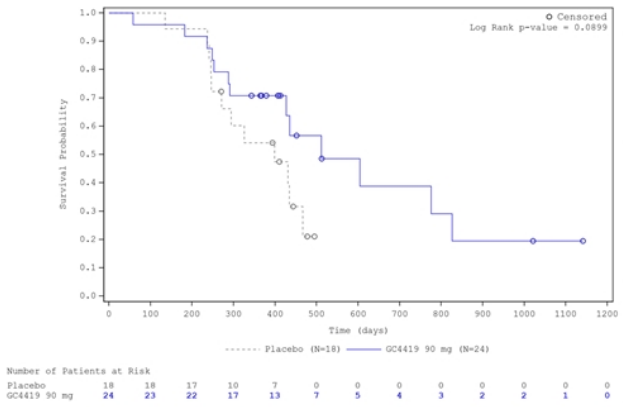
P-value = 0.0279 Hazard Ratio = 0.39

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

Improved Overall and Progression-Free Survival

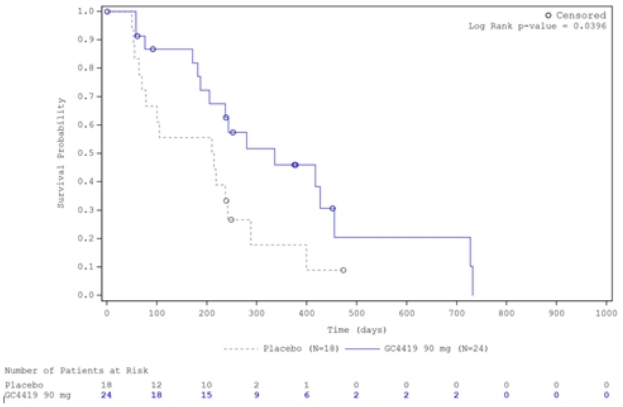
46% (11/24) alive on GC arm at last follow up compared to 33% (6/18) on placebo

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

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

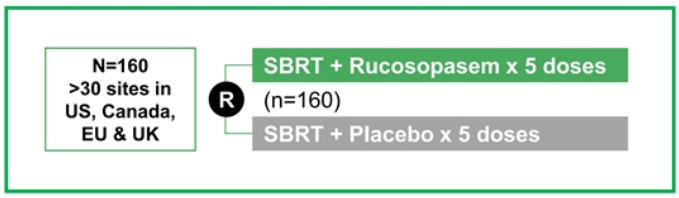
*R0 = margins free of microscopic tumor (5/5 patients on GC and 1/2 patients on placebo had clear margins at surgery)
LRC = Locoregional Control; DMC = Control of Distant Metastases; PFS = Progression-Free Survival; OS = Overall Survival; NR = Not Reached

GRECO-2 Trial of Rucosopasem + SBRT in LAPC

Galera Radiotherapy Efficacy Cancer Optimization

- Multicenter, double-blinded, placebo-controlled trial
- 160 patients, 1:1 randomization
- Locally Advanced Pancreatic Cancer (LAPC) – unresectable or borderline resectable, non-metastatic
- ECOG Performance 0-2
- Must have 6 weeks or more of chemotherapy (FOLFIRINOX or Gemcitabine doublet regimen)
- Stratified for borderline resectable vs. unresectable

Rucosopasem 100mg IV or placebo administered over 15 mins <3 hrs before SBRT (5 fractions of 10 Gy each)



- Primary Endpoint: Overall Survival
- Secondary Endpoints: PFS, LRC, TDM, surgical resection, in-field response rate, acute & late toxicity

PFS = Progression-Free Survival; LRC = Locoregional Control; TDM = Time to Distant Metastasis

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

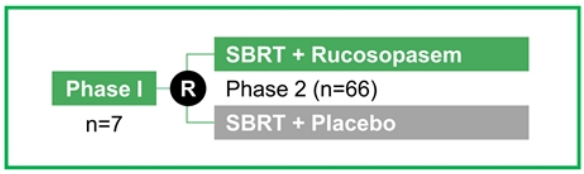
All SBRT	14,600	12,120	15,430
Node-Negative NSCLC	Peripheral Tumor >3cm	Central Tumor <3cm	Central Tumor >3cm
Surgery ONLY	16%	30%	12%
SBRT (+/- other modalities)	81%	67%	85%
Other	3%	2%	4%

GRECO-1 Trial of Rucosopasem + SBRT in NSCLC

Galera Radiotherapy Efficacy Cancer Optimization

GRECO-1 Trial

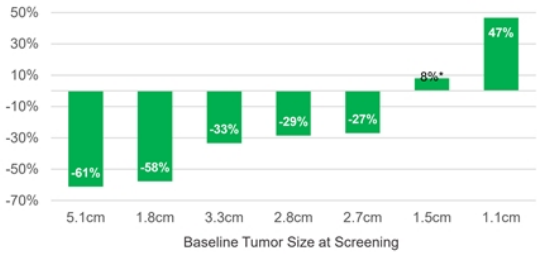
Rucosopasem 100mg IV or placebo over 15 mins before each SBRT fraction



- Patients with central and/or large NSCLC tumors
- Single-arm open label Phase 1 stage complete
- Multicenter, double-blinded, placebo-controlled Phase 2 stage actively enrolling; anticipate completion of enrollment in 2H2023
- SBRT Dose Schedule:
  - Phase 1: 5 fractions x 10 Gy
  - Phase 2: 5 x 10 Gy or 3 x 18 Gy

Phase 1 Results

- Rucosopasem + SBRT was well tolerated in Phase 1 with fatigue, cough & nausea most frequent adverse events (common in patients receiving RT)
- Pulmonary function preserved:
  - No Grade 2-4 declines in DLCO[1] (RTOG scale) with rucosopasem
  - Historical expectation 7-12% in prospective trial[2] evaluating effect of lung SBRT on pulmonary function (4-5 fractions, n=127)
- Target tumor volume at 6 months post SBRT + Rucosopasem, as follows:



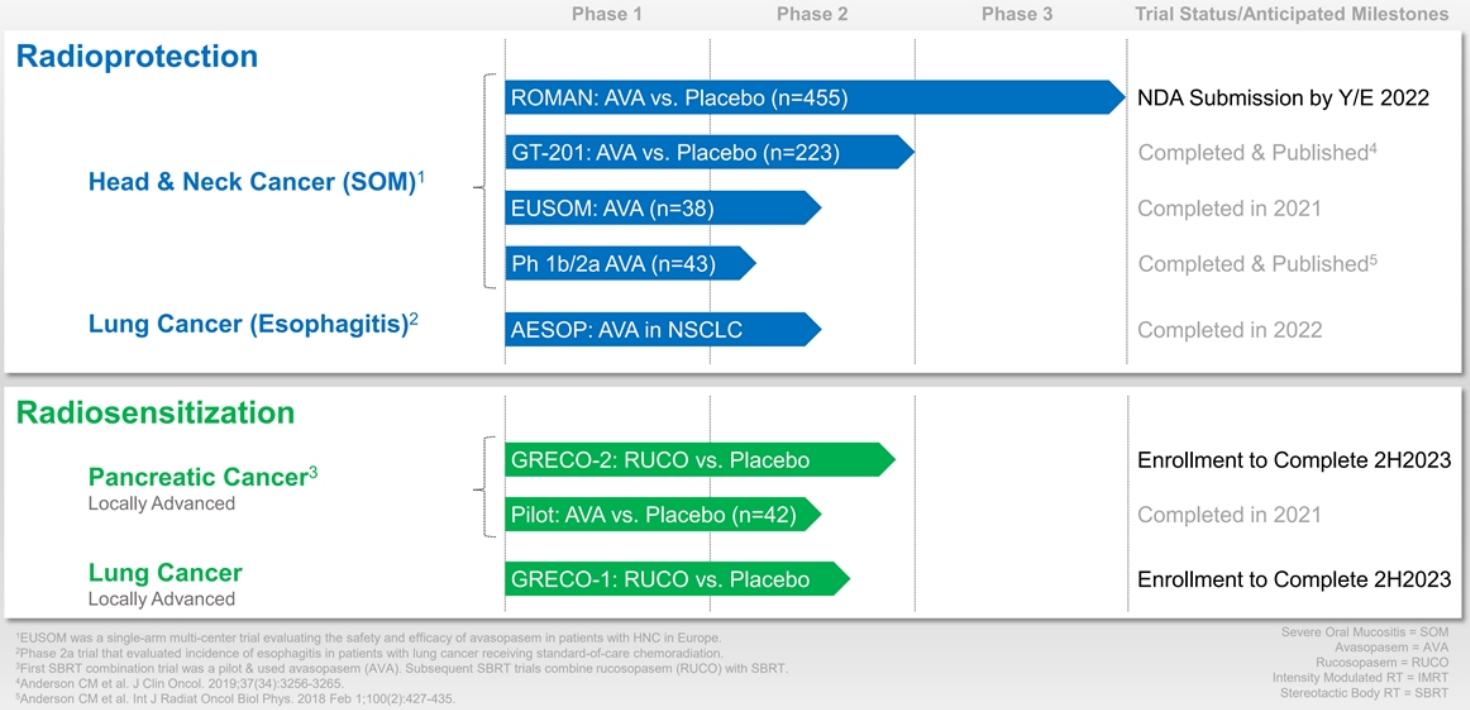
* Measurement at 3 months, target lesion unevaluable at 6 months; progressed out of RT field at 6 months; only patient with prior chemotherapy

[1]DLCO is the diffusing capacity of the lung for carbon monoxide, a measurement of the lung's ability to transfer gas from inspired air to the bloodstream.
[2]Stone B, Mangona VS, Johnson MD et.al. Changes in pulmonary function following image-guided stereotactic lung radiotherapy. J Thorac Oncol. 2015;10: 1762–1769

Corporate Highlights

Galera® Therapeutics, Inc

Clinical Stage Pipeline



[1]EUSOM was a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe.
[2]Phase 2a trial that evaluated incidence of esophagitis in patients with lung cancer receiving standard-of-care chemoradiation.
[3]First SBRT combination trial was a pilot & used avasopasem (AVA). Subsequent SBRT trials combine rucosopasem (RUCO) with SBRT.
[4]Anderson CM et al. J Clin Oncol. 2019;37(34):3256-3265.
[5]Anderson CM et al. Int J Radiat Oncol Biol Phys. 2018 Feb 1;100(2):427-435.

Severe Oral Mucositis = SOM
Avasopasem = AVA
Rucosopasem = RUCO
Intensity Modulated RT = IMRT
Stereotactic Body RT = SBRT

Thank you.

Galera® Therapeutics, Inc