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): December 14, 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.

On December 14, 2021, Galera Therapeutics, Inc. (the "Company" or "Galera") issued a press release announcing corrected topline results from the Phase 3 ROMAN trial of avasopasem manganese for severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy (the "ROMAN trial"), topline results from a single-arm Phase 2a trial of avasopasem in Europe, and certain other regulatory developments. A copy of the press release is furnished as Exhibit 99.1 hereto.

On December 14, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at www.galeratx.com to accompany the conference call the Company will hold at 8:30 a.m. ET on December 14, 2021. A copy of that corporate slide presentation is attached to this Current Report on Form 8-K ("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 December 14, 2021, the Company announced that corrected results from the ROMAN trial achieved statistical significance on the primary endpoint of reduction in the incidence of SOM. An error by the contract research organization was identified in the statistical program. Correction of this error resulted in improved p-values for the primary and secondary endpoints.

The corrected p-values are as follows:

- 16% relative reduction in the incidence of SOM in the avasopasem treatment group (54%) vs. placebo group (64%) **(p=0.045*)** (previously reported as p=0.113) (primary endpoint)
- 56% relative reduction in the number of days of SOM in the avasopasem treatment group (8 days) vs. placebo group (18 days) **(p=0.002*)** (previously reported as p=0.011) (secondary endpoint)
- 27% relative reduction in the severity (incidence of Grade 4 OM) of SOM in the avasopasem treatment group (24%) vs. placebo group (33%) **(p=0.052)** (previously reported as p=0.167) (secondary endpoint)

* Statistical significance per statistical analysis plan for the Phase 3 ROMAN trial

The Company also announced topline results from its single-arm Phase 2a EUSOM trial of avasopasem in Europe for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care radiotherapy + cisplatin. This trial was conducted in 12 centers across six countries in Europe and enrolled 38 patients, of which 33 completed full treatment. Avasopasem appeared to be generally well tolerated. In EUSOM, the incidence of SOM was 54.5% and the median number of days of SOM was nine days.

The Company continues to analyze the full data set and evaluate its resources and expects to meet with the FDA in 2022 to discuss whether the results from the single Phase 3 ROMAN trial together with the randomized Phase 2b trial could support an NDA submission.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding: expectations surrounding the continued advancement of our product pipeline, including timing of a meeting with the U.S. Food and Drug Administration to discuss avasopasem data; whether the results from the Phase 3 ROMAN trial together with the randomized Phase 2b trial could support an NDA submission; and participation in upcoming events and presentations. 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) and rucosopasem manganese (GC4711); 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; Galera's reliance on third parties; and the impact of the COVID-19 pandemic on Galera's business and operations, including preclinical studies and clinical trials, and general economic conditions. 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, 2020 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 Form 8-K. Any forward-looking statements speak only as of the date of this Form 8-K and are based on information available to Galera as of the date of this Form 8-K, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 and Exhibit 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 December 14, 2021
99.2	Corporate Presentation of Galera Therapeutics, Inc. dated December 14, 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: December 14, 2021

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

Galera Announces Primary Endpoint Met Statistical Significance in Corrected Topline Efficacy Data of Phase 3 ROMAN Trial of Avasopasem

Corrected topline Phase 3 ROMAN data demonstrate primary endpoint achieved statistical significance in reducing the incidence of radiotherapy-induced severe oral mucositis (p=0.045)

Topline results from single-arm Phase 2a trial of avasopasem in Europe in line with the ROMAN trial results

Company plans to discuss avasopasem data with the FDA in 2022

Company to host conference call and live audio webcast on Tuesday, December 14 at 8:30 a.m. ET

MALVERN, Pa. – December 14, 2021 – 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 (RT) in cancer, today announced that corrected results from its Phase 3 ROMAN trial of avasopasem for the treatment of RT-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) achieved statistical significance on the primary endpoint of reduction in the incidence of SOM. Avasopasem has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the reduction of SOM induced by RT.

The Company previously announced the Phase 3 ROMAN trial of avasopasem in SOM did not achieve statistical significance on the primary endpoint. Upon further analysis, an error by the contract research organization (CRO) was identified in the statistical program. Correction of this error resulted in improved p-values for the primary and secondary endpoints.

The corrected p-values are as follows:

- 16% relative reduction in the incidence of SOM in the avasopasem treatment group (54%) vs. placebo group (64%) (**p=0.045***) (previously reported as p=0.113) (primary endpoint)
- 56% relative reduction in the number of days of SOM in the avasopasem treatment group (8 days) vs. placebo group (18 days) (**p=0.002***) (previously reported as p=0.011) (secondary endpoint)
- 27% relative reduction in the severity (incidence of Grade 4 OM) of SOM in the avasopasem treatment group (24%) vs. placebo group (33%) (**p=0.052**) (previously reported as p=0.167) (secondary endpoint)

* Statistical significance per statistical analysis plan for the Phase 3 ROMAN trial

The Company also announced topline results from its single-arm Phase 2a EUSOM trial of avasopasem in Europe for RT-induced SOM in patients with HNC undergoing standard-of-care RT + cisplatin. This trial was conducted in 12 centers across six countries in Europe and enrolled 38 patients, of which 33 completed full treatment. Avasopasem appeared to be generally well tolerated. In EUSOM, the incidence of SOM was 54.5% and the median number of days of SOM was 9 days, in line with the ROMAN trial in which the incidence was 54% and the median duration was 8 days.

“Given the high unmet medical need for patients with head and neck cancer who develop radiotherapy-induced severe oral mucositis, we are gratified that the Phase 3 ROMAN trial achieved statistical significance on the primary endpoint after the correction of the statistical programming error,” said Mel Sorensen, M.D., President and CEO of Galera. “ROMAN is our second randomized trial conducted in patients with head and neck cancer to achieve statistical significance and demonstrate improved clinical benefit. As we continue to analyze the full data set and evaluate our resources, we look forward to meeting with the FDA in 2022 to discuss whether the results from this single Phase 3 trial together with the randomized Phase 2b trial could support an NDA submission.”

Approximately 42,000 HNC patients undergo standard-of-care RT every year in the U.S. and are at risk of experiencing SOM, painful mouth sores that impact the ability to eat and drink. In market research, both radiation oncologists and patients cite SOM as the most burdensome RT toxicity in HNC treatment. Currently, there are no FDA approved drugs to reduce the incidence or duration of SOM in solid tumors.

Continued Dr. Sorensen, “In parallel, our anti-cancer therapeutic trials in lung and pancreatic cancer, which we refer to as the GRECO-1 and GRECO-2 trials, respectively, are currently enrolling, and we look forward to reporting initial data from our GRECO-1 trial in the first half of 2022. Both trials combine our second dismutase mimetic candidate, rucosopasem, with stereotactic body radiation therapy (SBRT) with the goal of augmenting the anti-cancer efficacy of SBRT.”

Conference Call

Galera will host a conference call and live audio webcast on Tuesday, December 14 at 8:30 a.m. ET to discuss the ROMAN Phase 3 data, including additional analyses from the full data set, and provide a general business update. The webcast will be accessible from the Investors page of Galera’s website, investors.galeratx.com, and an archived version of the webcast will be available in the News & Events section of the Investors page of Galera’s website for 30 days following the event.

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 (GC4419, also referred to as avasopasem) is being evaluated for radiotherapy-induced toxicities. The Company’s second product candidate, rucosopasem manganese (GC4711, also referred to as rucosopasem), 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: expectations surrounding the continued advancement of our product pipeline,

including timing of a meeting with the U.S. Food and Drug Administration to discuss avasopasem data; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development, including the interpretation of the safety and efficacy results from the Phase 3 ROMAN trial and the EUSOM trial; whether the results from the Phase 3 ROMAN trial together with the randomized Phase 2b trial could support an NDA submission; timing of enrollment in the Company's anti-cancer therapeutic trials in lung and pancreatic cancer, which the Company refers to as GRECO-1 and GRECO-2, respectively; timing of reporting initial data from the Company's GRECO-1 trial; 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) and rucosopasem manganese (GC4711); 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; 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, 2020 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.

###

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

William Windham
Solebury Trout
646-378-2946
wwindham@soleburytrout.com

Media Contact:
Zara Lockshin
Solebury Trout
330-417-6250
zlockshin@soleburytrout.com

Exhibit 99.2

ROMAN Phase 3 Trial Update

December 14, 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 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, 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, 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.

Executive Summary

Corrected ROMAN Phase 3 topline results: achieved statistical significance on primary endpoint

- Corrected topline Phase 3 ROMAN data demonstrate primary endpoint achieved statistical significance in reducing the incidence of severe oral mucositis (p=0.045)
- Additional analyses from ROMAN full data set further suggest efficacy of avasopasem in patients with head and neck cancer
- Announced results from single-arm Phase 2a trial of avasopasem in Europe; in line with ROMAN results
- Company plans to discuss avasopasem data with the FDA in 2022

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

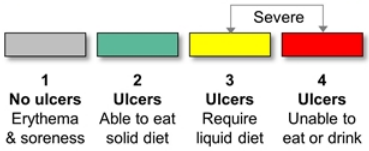
Source: Globocan & US SEER Data in CA Cancer J Clin 2021

Severe Oral Mucositis in Head & Neck Cancer

The most burdensome toxicity of standard-of-care chemoradiotherapy (radiotherapy & cisplatin)[2]

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

WHO Grading System



Current Approaches Lack Efficacy

MASCC Guidelines focus principally on symptoms[1]

- 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[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

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

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

Avasopasem Prevents RT Injury

Patients get avasopasem before each RT dose

Blocks initiating injury in normal cells from RT burst of superoxide[1]

Does not interfere with RT anti-cancer efficacy[1]

Breakthrough Therapy Designation (FDA)

3-arm placebo-controlled randomized Phase 2b (n=223)

34% reduction in SOM incidence (p=0.009)[2]

92% reduction in median days of SOM (p=0.024)[2]

Successful Phase 3 ROMAN Trial

2-arm placebo-controlled randomized Phase 3 (n=455)

16% reduction in SOM incidence (p=0.045)[3]

56% reduction in median days of SOM (p=0.002)[3]

[1]Anderson CM et al. Multidisciplinary Head & Neck Cancer symposium, 2020 Feb 28 LBA 2
[2]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265
[3]Data on file - ROMAN Phase 3 Trial

Comparison of Galera's Rand. Phase 2b & ROMAN Phase 3

Two Double-blinded Placebo-controlled Randomized Trials

Rand. 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)
- Receiving standard IMRT and cisplatin over 7 weeks
- 70% expected to get SOM

ROMAN Phase 3

N=455

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

Endpoints

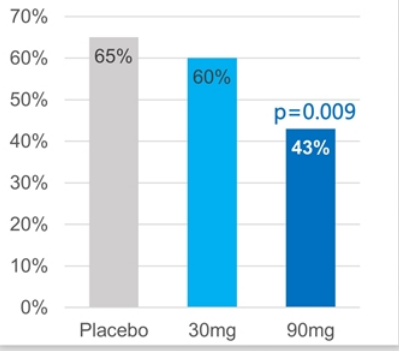
- Primary: Reduction in the incidence of SOM
- Secondary: Reduction in SOM duration & severity

Results from Rand. Phase 2b (n=223)

Consistent and encouraging results across SOM endpoints – ITT Population

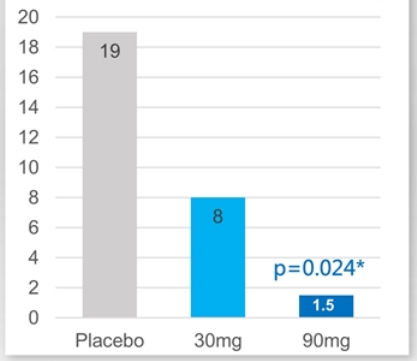
Incidence

34% Reduction in SOM incidence



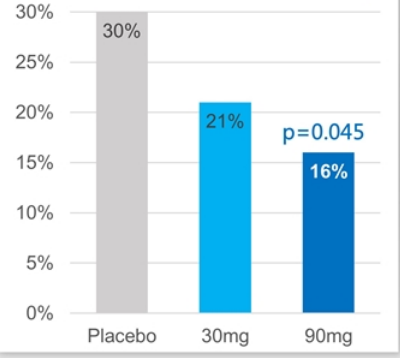
Duration

92% Reduction in median days of SOM



Severity

47% Reduction in incidence of Grade 4 OM

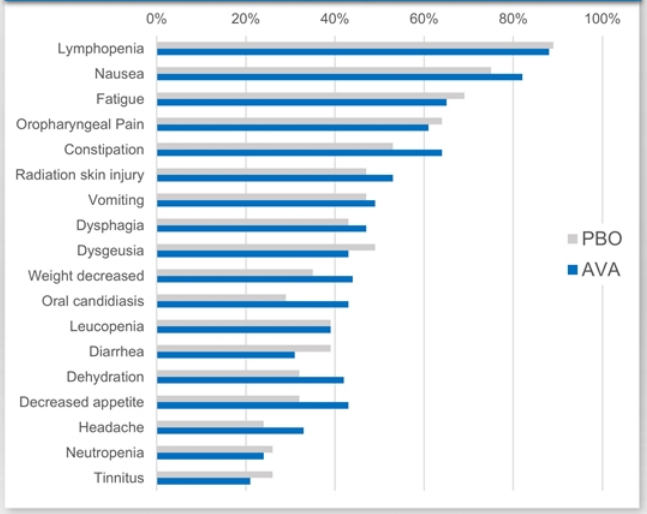


Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265
*Statistical significance per statistical analysis plan for this trial

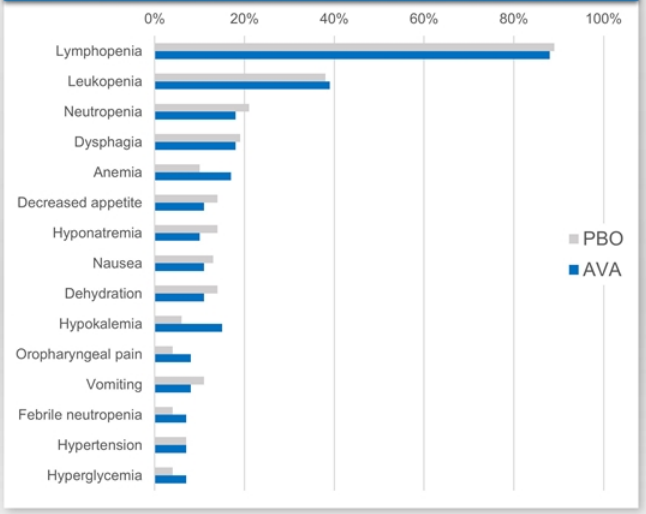
Randomized Phase 2b: Most Frequent Adverse Events

Avasopasem 90mg appears generally well-tolerated

Adverse Events[1,2] (all grades & causes)



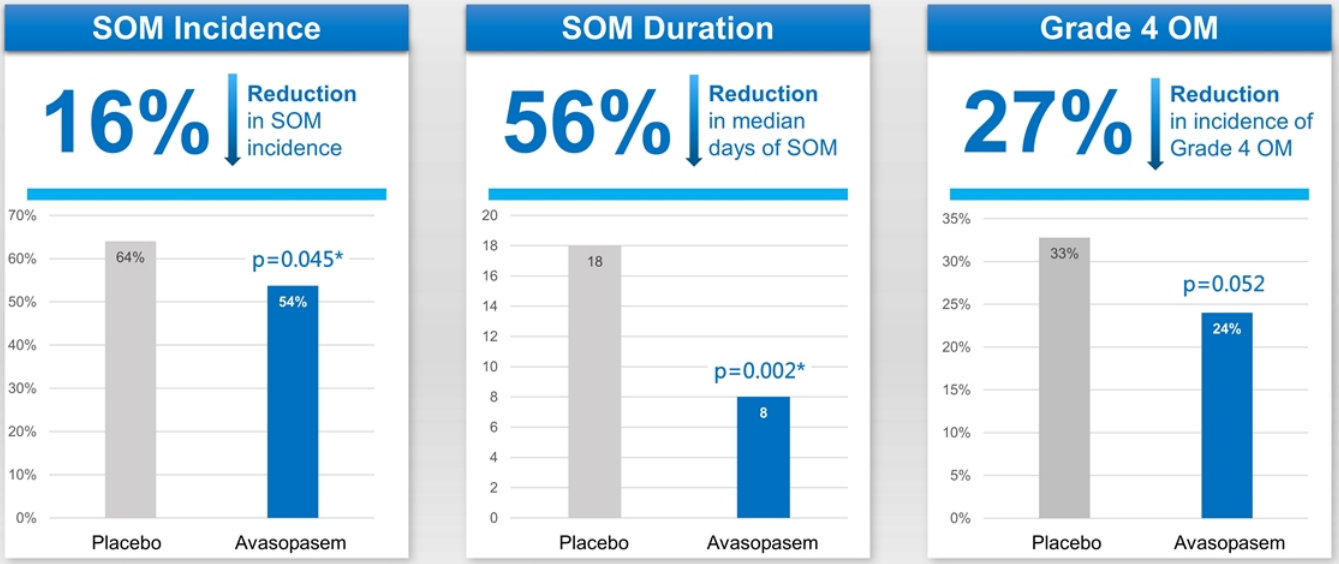
Adverse Events[1,2] ≥ Grade 3



[1]Intent-to-Treat (ITT) population: 73 patients on placebo; 72 patients on 90mg avasopasem
[2]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

Results from ROMAN Phase 3 (n=455)

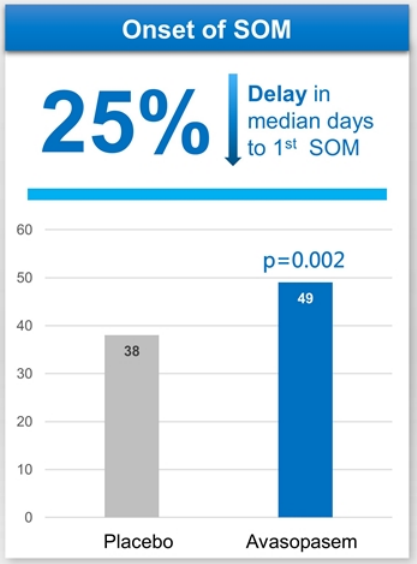
Reductions across SOM endpoints; statistical significance on the primary & SOM duration secondary endpoint



*Statistical significance per statistical analysis plan for this Phase 3 trial

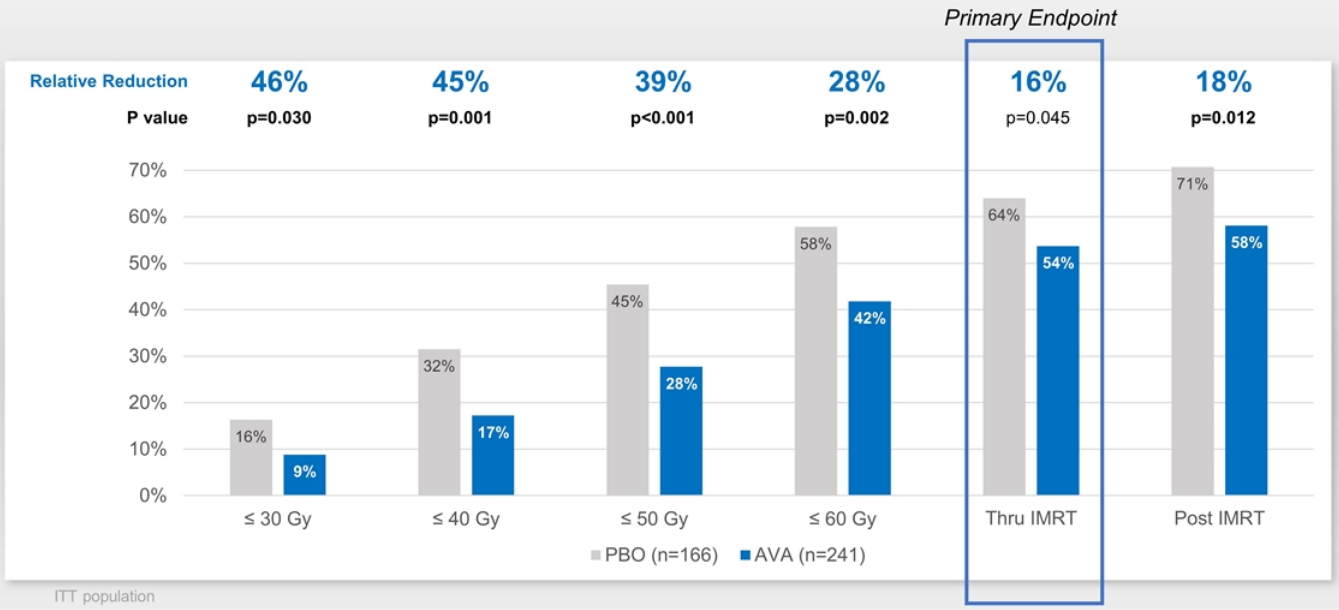
Avasopasem also appears to delay the onset of SOM

Time to onset of SOM was an exploratory endpoint



Incidence Reduced at All Landmarks of Radiation Therapy

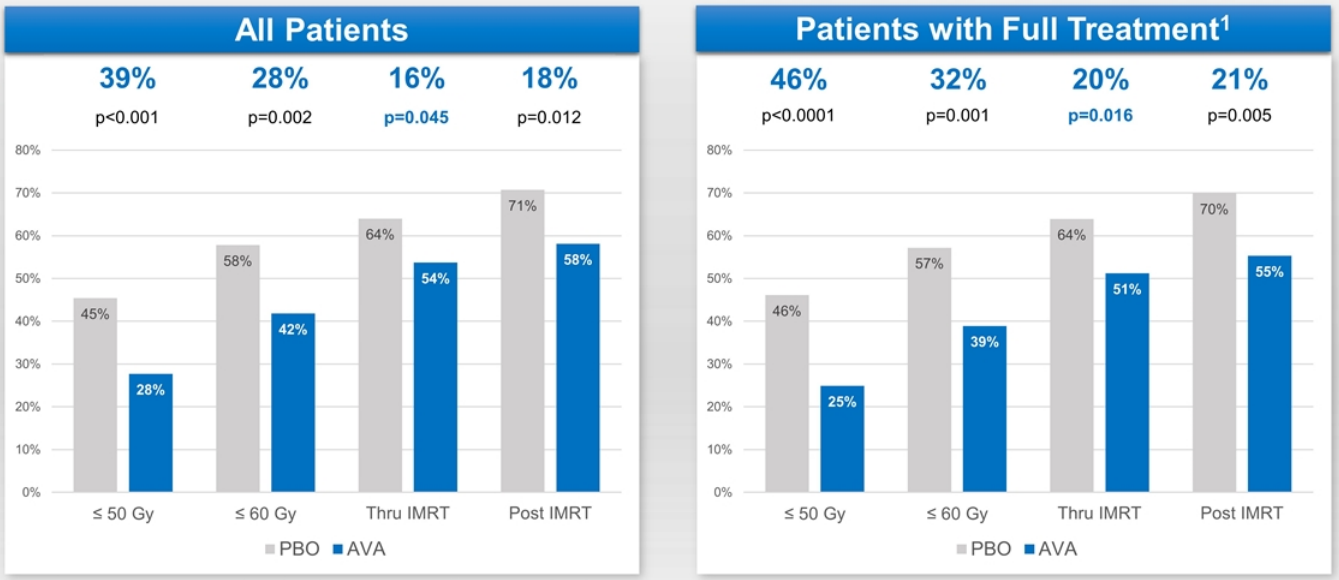
Both before and after primary endpoint at end of IMRT – all patients



ITT population

Greater Reductions with Full Treatment

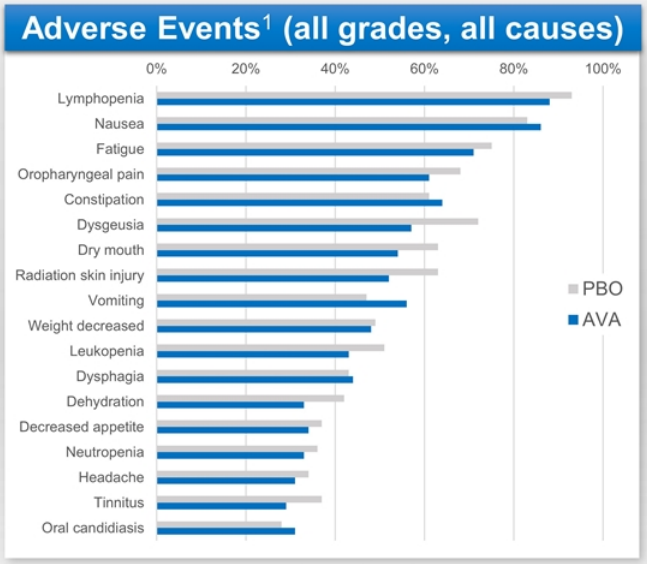
Patients with full courses of IMRT & avasopasem demonstrated a greater relative reduction in SOM incidence

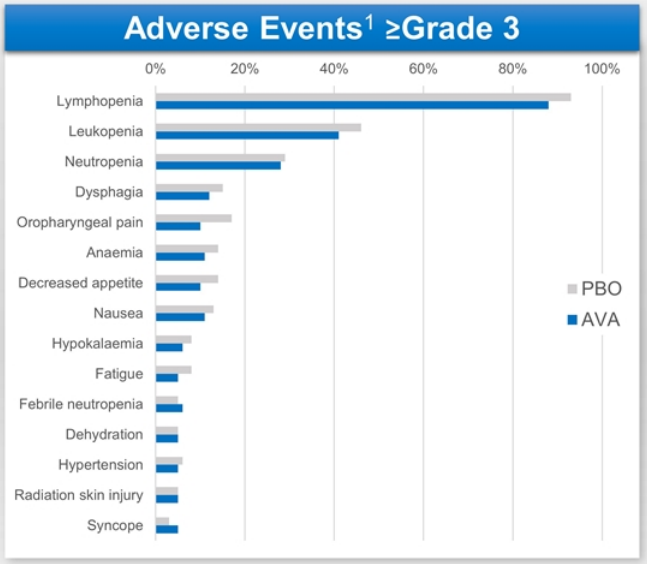


[1]Patients who received ≥ 60 Gy of radiotherapy and ≥ 25 infusions of placebo or avasopasem

ROMAN Phase 3: Most Frequent Adverse Events

Avasopasem 90mg appears generally well-tolerated, consistent with Phase 2b





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

European Safety Trial (EUSOM) – Similar results to ROMAN P3

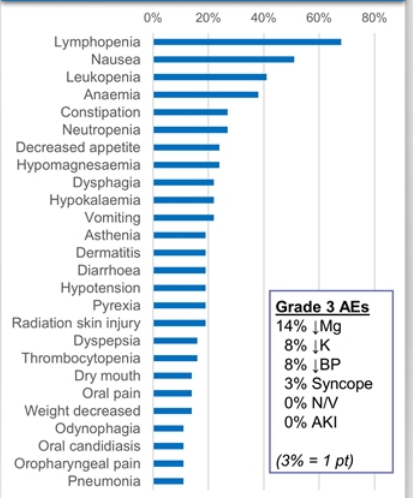
Safety was primary endpoint; efficacy was secondary (n=38)

Sites & Subjects

- Head & Neck Cancer
- 7 weeks of IMRT and cisplatin
- 35 doses of avasopasem
- 41% oral cavity (vs. 16% in P3)
- 54% oropharyngeal (vs. 80% in P3)
- 81% male, Median age 61

6 Countries in Europe
Germany, Spain, Poland, Czech, Switzerland & Belgium

Safety Profile (AEs>10%)



SOM Efficacy Data

Subjects treated with ≥60Gy IMRT (n=33) – full treatment[1]

Full Treatment	n=33
SOM Incidence Thru end IMRT	54.5%
SOM Duration (Median days thru end IMRT)	9 days

[1] Full treatment = Patients who received ≥ 60 Gy of radiotherapy and ≥ 25 infusions of avasopasem
AE = Adverse Event, Mg = Magnesium, K = Potassium, BP = Blood pressure, N/V = Nausea & Vomiting, AKI = Acute kidney Injury

Key Conclusions: ROMAN Phase 3 Data

SOM Efficacy

- Achieved statistical significance on primary endpoint of reduction in SOM incidence (p=0.045)
- Achieved statistical significance (p=0.002) on secondary endpoint of SOM duration – 56% relative reduction
- Greater reductions in SOM incidence at earlier landmarks & in fully treated patients
- 25% delay in SOM onset (p=0.002)

Patients and Safety

- Patient characteristics well-balanced
- Stratification factors well-balanced
  - Cisplatin regimen and surgery
- Avasopasem appears generally well-tolerated
- Long-term follow-up ongoing
  - Tumor outcomes
  - Chronic kidney disease

Executive Summary

Corrected ROMAN Phase 3 topline results: achieved statistical significance on primary endpoint

- Corrected topline Phase 3 ROMAN data demonstrate primary endpoint achieved statistical significance in reducing the incidence of severe oral mucositis (p=0.045)
- Additional analyses from ROMAN full data set further suggest efficacy of avasopasem in patients with head and neck cancer
- Announced results from single-arm Phase 2a trial of avasopasem in Europe; in line with ROMAN results
- Company plans to discuss avasopasem data with the FDA in 2022

Q&A

Galera Therapeutics, Inc