# ROMAN Phase 3 Trial Update

December 14, 2021

Galera Therapeutics, Inc

# Forward-Looking Statements

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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

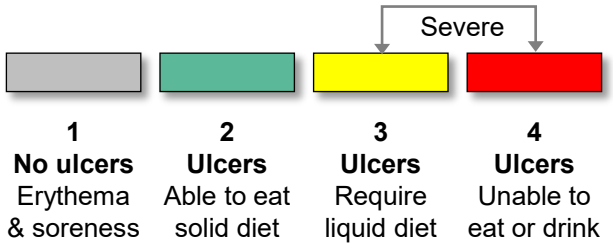
Source: Globocan & US SEER Data in CA Cancer J Clin 2021

# 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

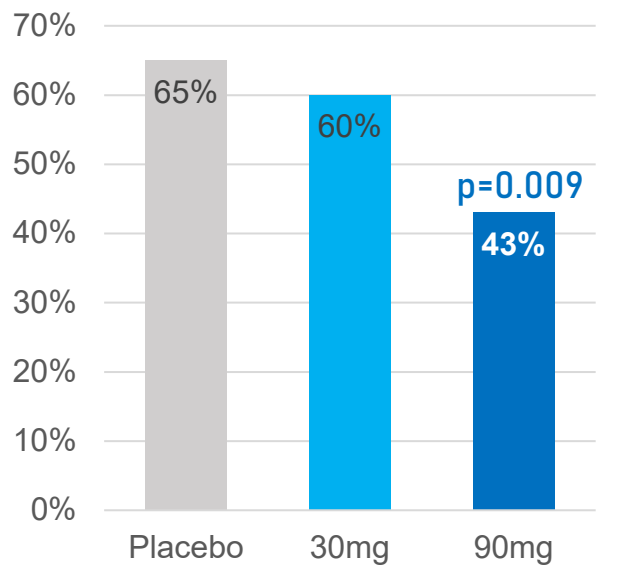
- Primary: Reduction in the incidence of SOM
- Secondary: Reduction in SOM duration & severity

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

## Consistent and encouraging results across SOM endpoints – ITT Population

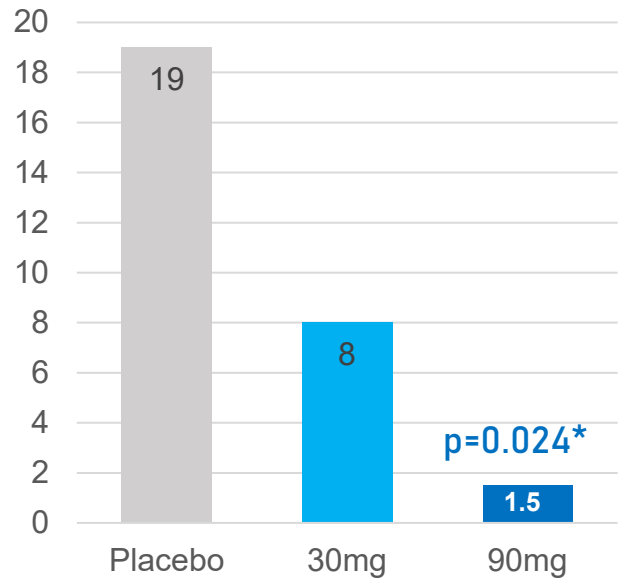
### Incidence

**34%** **Reduction** in SOM incidence



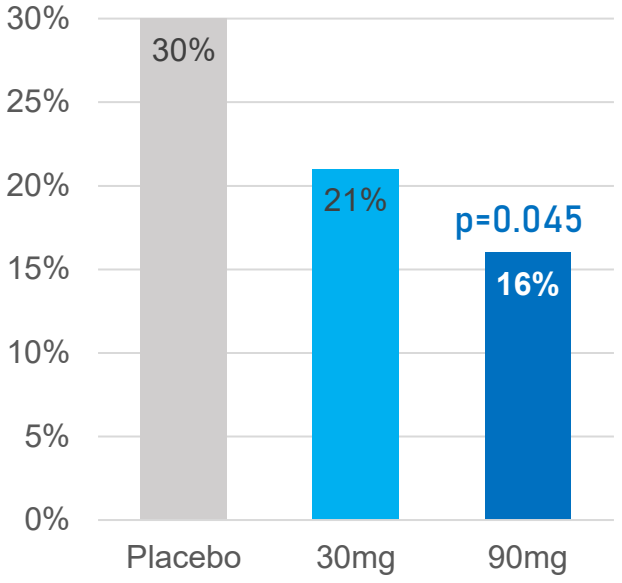

### Duration

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




### Severity

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



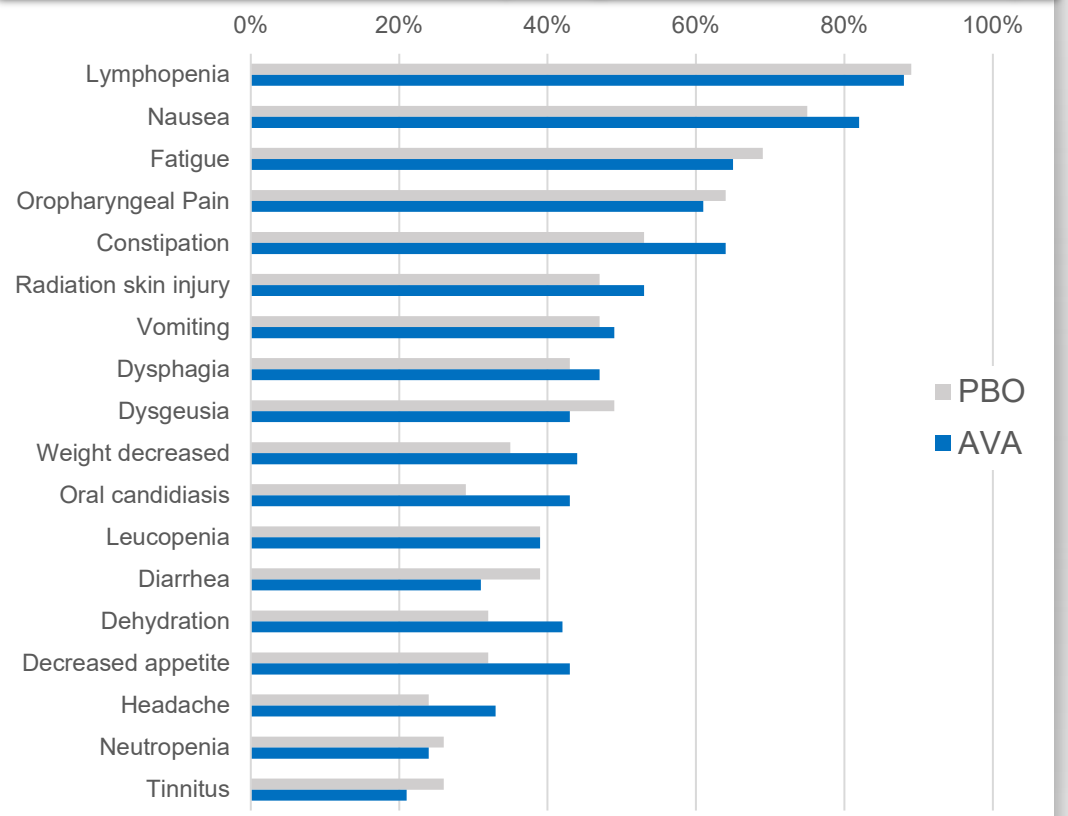

Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

*Statistical significance per statistical analysis plan for this trial

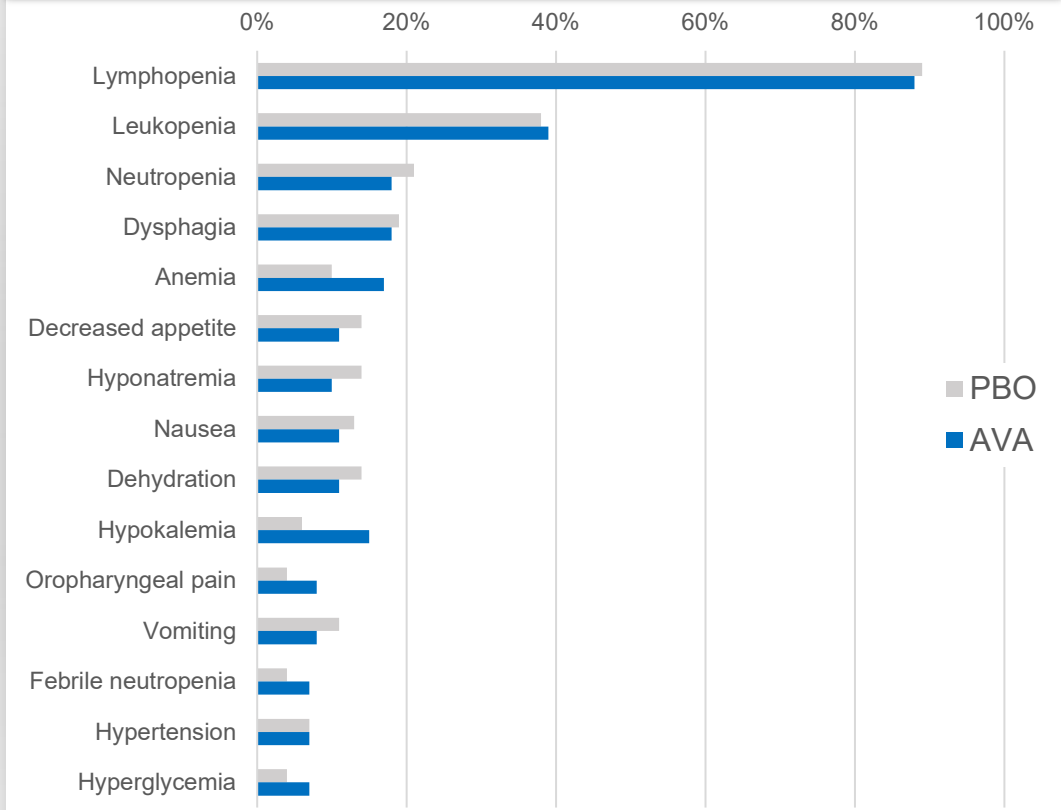
# Randomized Phase 2b: Most Frequent Adverse Events

## Avasopasem 90mg appears generally well-tolerated

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




### Adverse Events[1,2] ≥ Grade 3



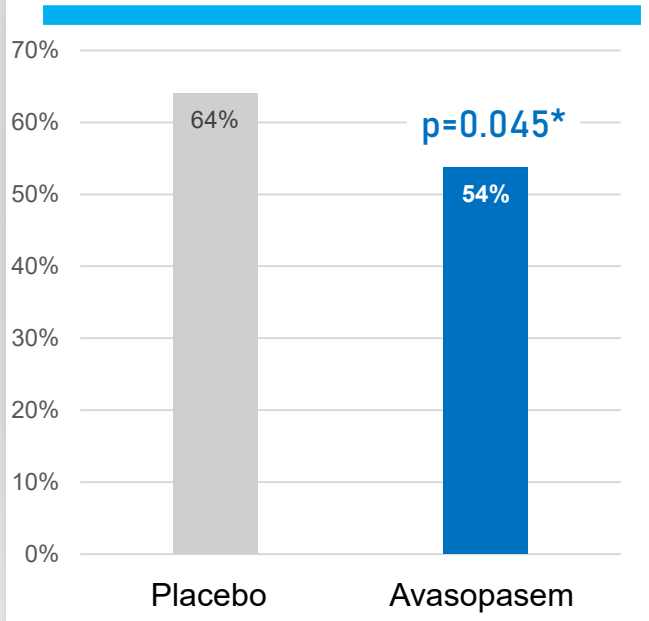

[1]Intent-to-Treat (ITT) population: 73 patients on placebo; 72 patients on 90mg avasopasem
[2]Anderson CM et al. Journal of Clinical Oncology 2019 Dec 1; 37(34): 3256-3265

# Results from ROMAN Phase 3 (n=455)

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

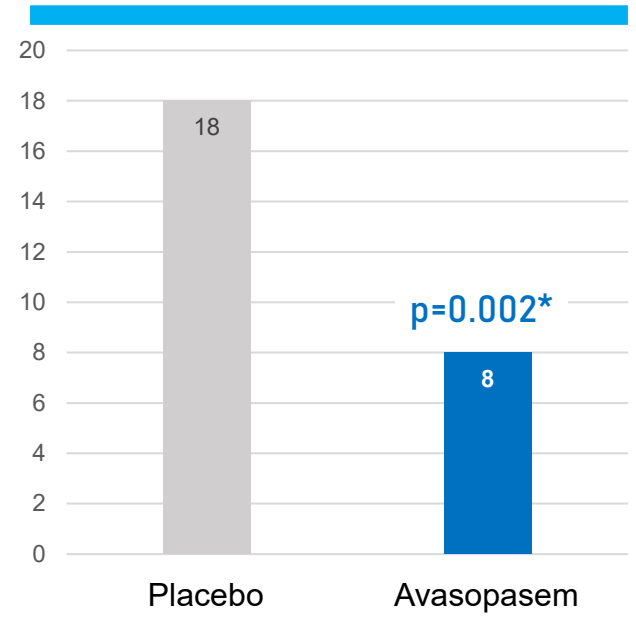
### SOM Incidence

**16%** **Reduction** in SOM incidence



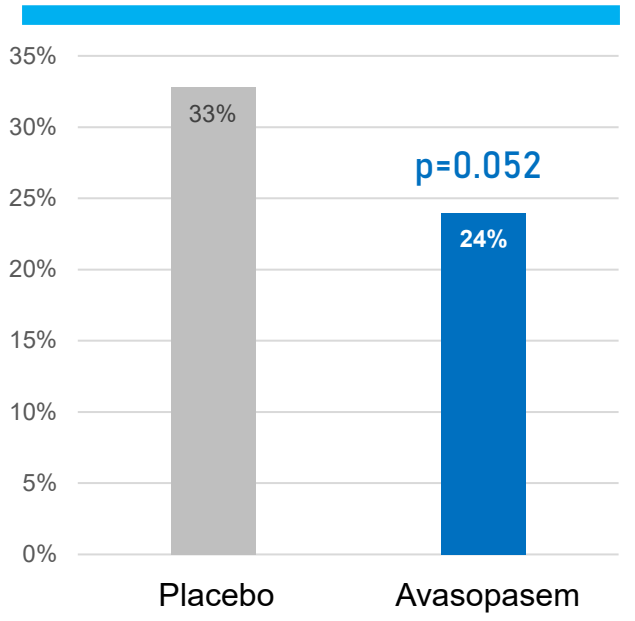

### SOM Duration

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




### Grade 4 OM

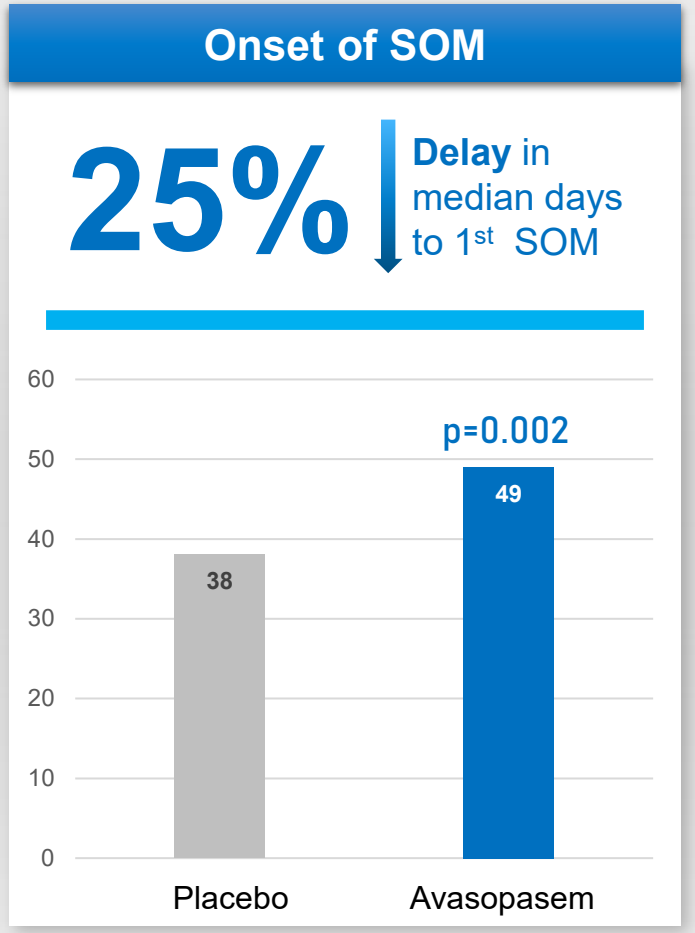
**27%** **Reduction** in incidence of Grade 4 OM




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

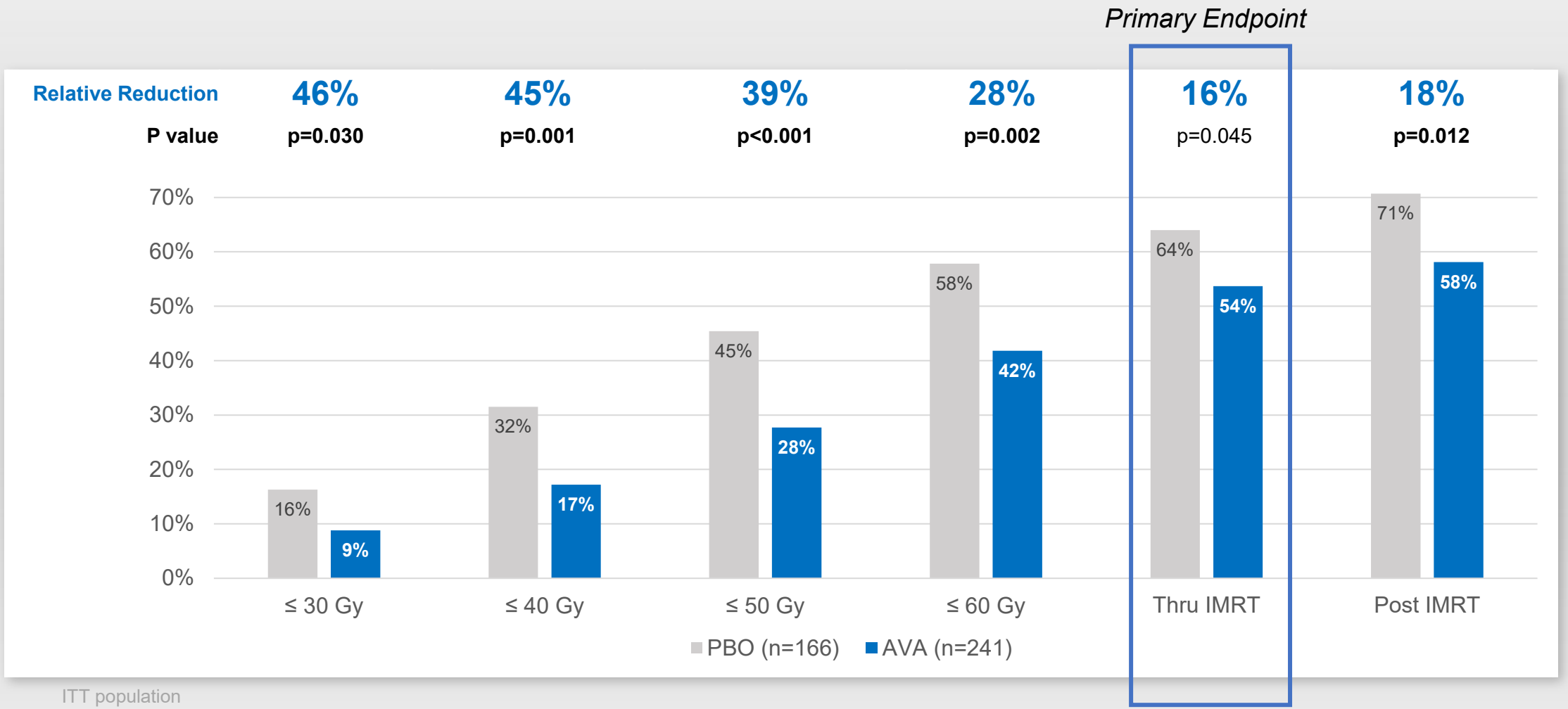
# Avasopasem also appears to delay the onset of SOM

## Time to onset of SOM was an exploratory endpoint



# Incidence Reduced at All Landmarks of Radiation Therapy

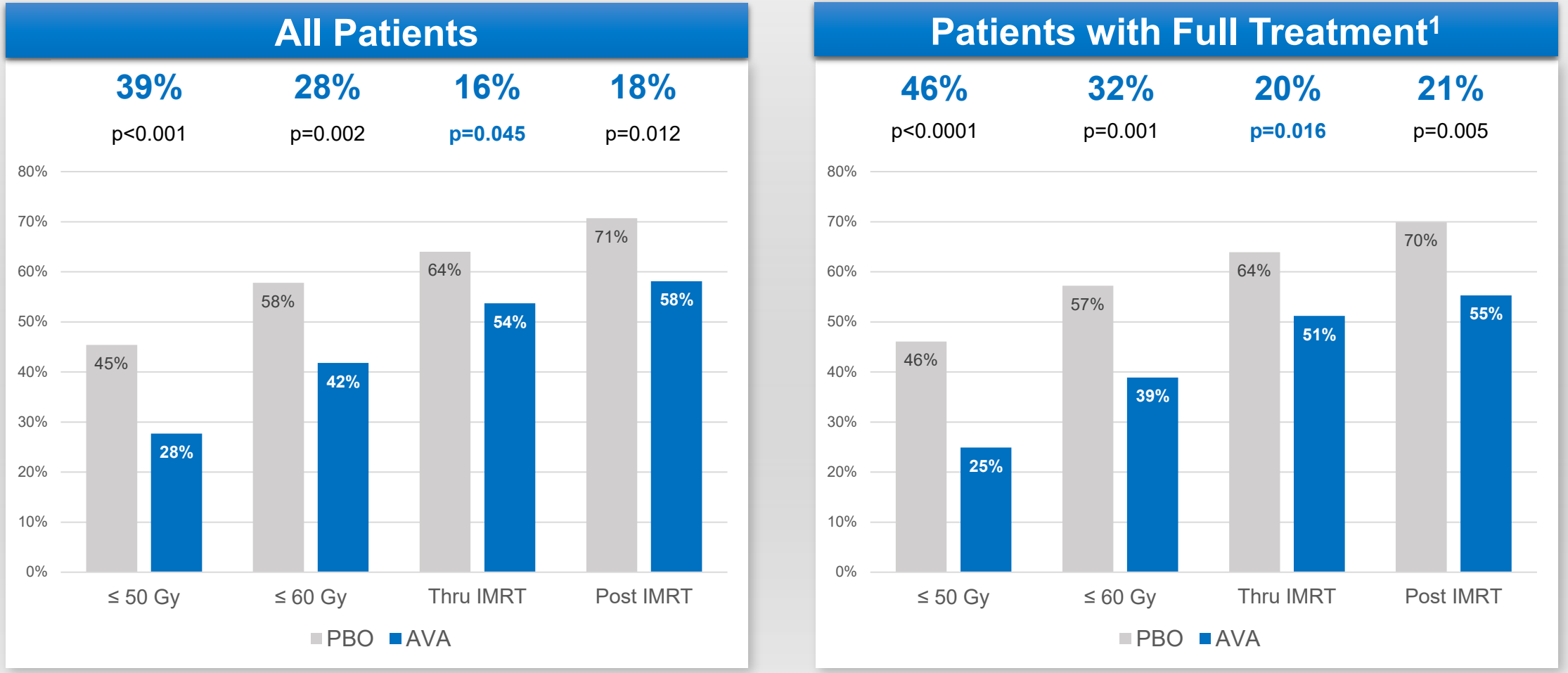
## Both before and after primary endpoint at end of IMRT – all patients




ITT population

# Greater Reductions with Full Treatment

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

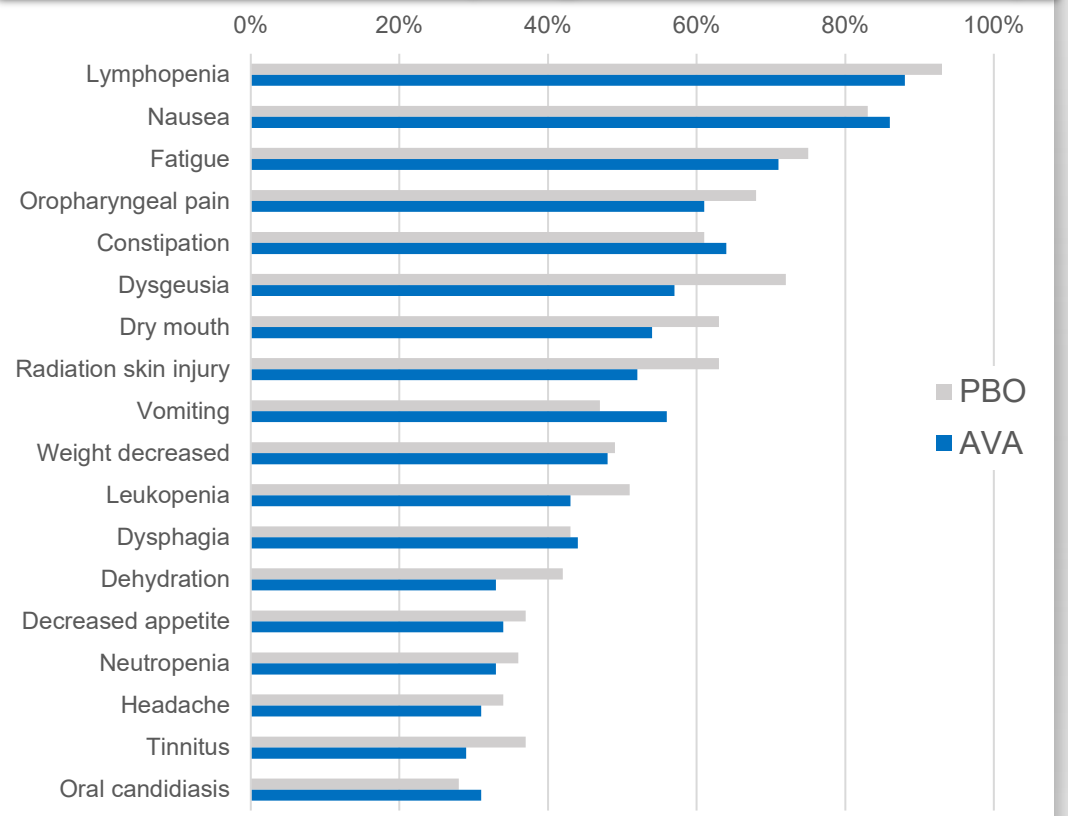



[1]Patients who received ≥ 60 Gy of radiotherapy and ≥ 25 infusions of placebo or avasopasem

# ROMAN Phase 3: Most Frequent Adverse Events

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

### Adverse Events[1] (all grades, all causes)

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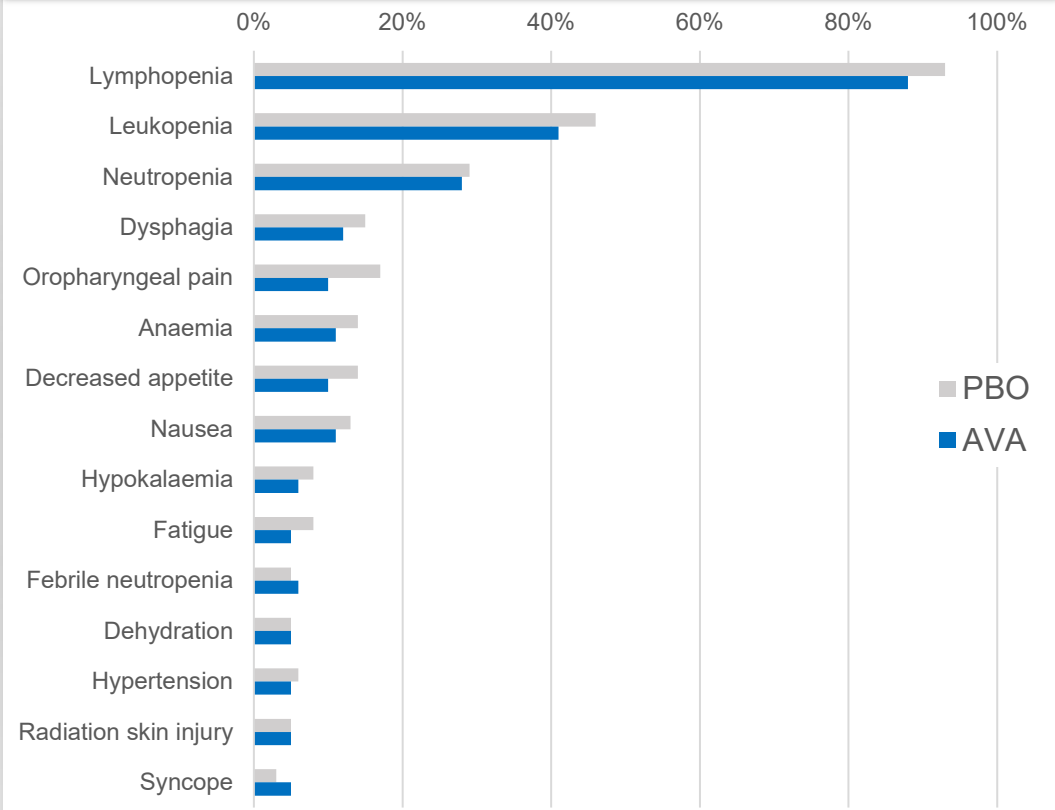



[1]ITT population: 166 patients on placebo; 241 on 90mg avasopasem

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

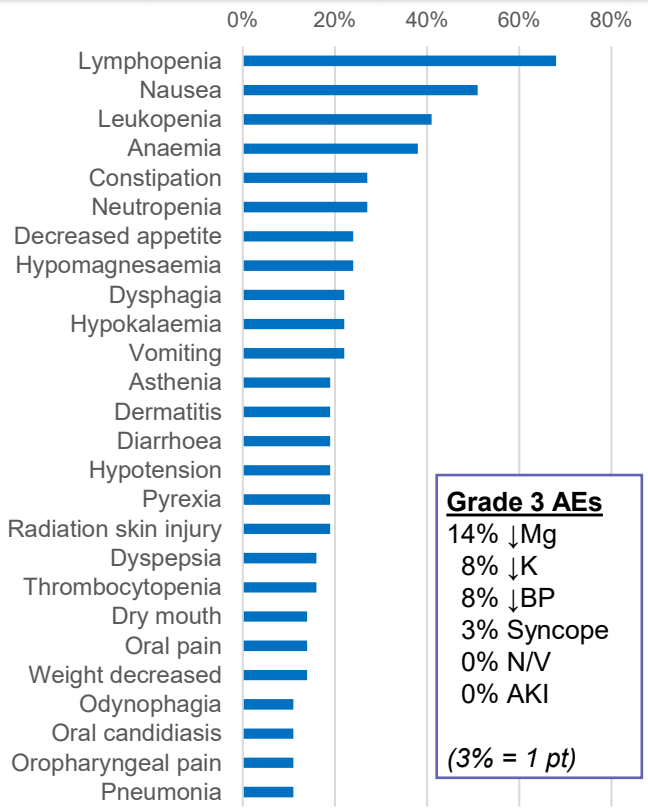
## Safety was primary endpoint; efficacy was secondary (n=38)

### 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<br>Thru end IMRT | 54.5% |
| SOM Duration<br>(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

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# Q&A

Galera Therapeutics, Inc