GC4419, small molecule superoxide (SO) dismutase (SOD) mimetic: Randomized trial to reduce chemoradiotherapy (CRT)-induced mucositis (OM) in oral cavity (OC)/oropharyngeal (OP) carcinoma (OCC) patients (pts)

_Carryn M. Anderson_, Christopher M. Lee, Deborah Saunders, Amarinthia Curtis, Neal Dunlap, Chaitali Nangia, Arielle S. Lee, Jon Holmlund, Jeffrey M. Brill, Stephen T. Sonis, Matt Downs, John M. Buatti
Faculty Disclosure

x  No, nothing financial to disclose

Yes, please specify:

- Will discuss an investigational use of a drug
- Research funding provided by Galera Therapeutics, Inc
- Safety and efficacy results presented at ASCO Annual Meeting in Chicago, IL, June 3, 2018
Background

- IMRT + cisplatin is SOC for locally advanced oral cavity/oropharyngeal cancer
- Approx 70% of patients develop severe OM (SOM), defined as WHO Grade 3 or 4
  - ~20-25% Grade 4
  - ~40 Gy median onset
  - 3-4 weeks median duration

WHO OM Score

1. No ulcers
   - Erythema and Soreness
   - WHO OM Score 1

2. Ulcers
   - Able to eat a solid diet
   - WHO OM Score 2

3. Ulcers
   - Requires a liquid diet
   - WHO OM Score 3

4. Ulcers
   - Unable to tolerate a solid or liquid diet. Requires IV or tube feeding
   - WHO OM Score 4

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GC4419 Mechanistic Rationale:
Differential effect on cancer & normal cells
Superoxide is a key initiator of radiation-induced mucosal injury

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GC4419 Enhances Tumor Response via H$_2$O$_2$

- Catalase is a disposal enzyme for Hydrogen Peroxide (H$_2$O$_2$)
- H1299$^{\text{CAT}}$ – WT engineered for doxycycline-induced Catalase overexpression
- Overexpressing catalase blocks RT synergy by removing GC4419-generated H$_2$O$_2$

Definitive Proof of H$_2$O$_2$ MOA in Tumors

![Graph showing tumor response over days post treatment with different treatments including Vehicle, GC4419, 18 Gy x 1 RT, 18 Gy + GC4419, 18 Gy + dox, 18 Gy + GC4419 + dox.](image)

Sishc et al AACR 2018
GC4419 Phase 1b/2a Clinical Data
Anderson, et al. IJROBP, 2018 Feb 1;100(2):427-435

- Established doses (30, 90 mg) throughout IMRT for further study
  - 2.5 days median SOM duration
  - 29% SOM thru 60 Gy
- Acceptable safety profile
- 1 yr. tumor outcomes not impaired
GC4419 Phase 2b Study Outline

**Patient Population**
- Locally advanced OC/OP SCCa
- Standard-of-care IMRT + cisplatin (weekly or Q3wk)
- $\geq 50$ Gy to 2+ oral sites

**GC4419 Treatment**
- 60-minute IV, Mon-Fri
- Ending <60 minutes pre RT

**Endpoints**
- Grade 3 or 4 OM – duration, incidence, onset
- Safety per NCI-CTCAE v4.03

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GC4419 Phase 2b Study Schema

Randomize (1:1:1)

Arm A: GC4419 90mg x 7 weeks
Arm B: GC4419 30mg x 7 weeks
Arm C: Placebo x 7 weeks

POST-RT FOLLOW UP for OM: up to 8 weeks post RT OR until the OM score is 0 or 1
COMPLETE

2-yr POST-RT TUMOR FOLLOW UP (OS, PFS, LRC, DM-free)
ONGOING

STRATIFICATION
Tumor HPV Status
Cisplatin dosing

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Statistical Methods

- Efficacy on ITT population
- Each GC4419 arm compared separately vs placebo
- SOM duration: Van Elteren test on all pts/arm
  - First WHO of 3-4 to last WHO of 3-4 with no subsequent 3-4
  - NO WHO of 3-4: zero days’ SOM duration
- Incidence: Cochran-Mantel-Haenszel test
- 2-sided $\alpha=0.05$
- Duration on subset w/observed SOM explored descriptively
GC4419 Phase 2b Enrollment & Assignment

N=223 patients
(44 US & Canadian sites)

Randomized

ITT (primary analysis)

Placebo N=74

GC4419 30 mg N=73

GC4419 90 mg N=76

Treated (safety population)

Placebo N=72

GC4419 30 mg N=73

GC4419 90 mg N=72

Evaluable Population*

Placebo N=66

GC4419 30 mg N=62

GC4419 90 mg N=62

* ≥ 60 Gy & ≥ 25 infusions

Randomization Failures; Not treated

n=2

n=0

n=4

n=6

n=11

n=10

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### GC4419 Phase 2b Patient Characteristics (n=223)

**Arms well-balanced**

<table>
<thead>
<tr>
<th></th>
<th>Placebo (N=74)</th>
<th>30 mg GC4419 (N=73)</th>
<th>90 mg GC4419 (N=76)</th>
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</thead>
<tbody>
<tr>
<td>Oropharyngeal (%)</td>
<td>76</td>
<td>84</td>
<td>71</td>
</tr>
<tr>
<td>Oral Cavity (%)</td>
<td>19</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>Unknown (%)</td>
<td>5</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>HPV positive (%)</td>
<td>72</td>
<td>73</td>
<td>71</td>
</tr>
<tr>
<td>negative (%)</td>
<td>28</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td>Definitive (%)</td>
<td>80</td>
<td>77</td>
<td>75</td>
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<tr>
<td>Post-operative treatment (%)</td>
<td>20</td>
<td>23</td>
<td>25</td>
</tr>
<tr>
<td>Cisplatin q3wks (%)</td>
<td>38</td>
<td>37</td>
<td>39</td>
</tr>
<tr>
<td>qw (%)</td>
<td>62</td>
<td>63</td>
<td>61</td>
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<tr>
<td>Normal mucosa sites ≥ 50 Gy (%)</td>
<td>2</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>55</td>
<td>48</td>
</tr>
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<td></td>
<td>5+</td>
<td>39</td>
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# GC4419 Phase 2b Treatment Adherence (n=217)

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<th>30 mg GC4419 (N=73)</th>
<th>90 mg GC4419 (N=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IMRT Mean/Median total dose (range)</strong></td>
<td>66.3/70 (11-70)</td>
<td>64.8/70 (4-72)</td>
<td>65.7/70 (11-74)</td>
</tr>
<tr>
<td>% receiving ≥ 60 Gy</td>
<td>94</td>
<td>89</td>
<td>92</td>
</tr>
<tr>
<td>% of subjects with RT treatment breaks ≥ 5 consecutive fractions</td>
<td>8</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>% w/Cisplatin total dose delivered ≥ 200 mg/m²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>q3week</td>
<td>89</td>
<td>79</td>
<td>87</td>
</tr>
<tr>
<td>qw</td>
<td>80</td>
<td>70</td>
<td>78</td>
</tr>
<tr>
<td>% of planned GC4419/placebo doses received</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>100</td>
<td>97</td>
<td>100</td>
</tr>
<tr>
<td>Mean</td>
<td>93</td>
<td>89</td>
<td>90</td>
</tr>
</tbody>
</table>

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Efficacy Results
Primary Endpoint – Duration of SOM (Grade 3+4)

92% Reduction in Median Duration of SOM

Duration was defined as number of days from 1st occurrence of grade 3 or 4 OM until the first event of grade 2 or less (there being no subsequent grade 3 or 4 events), and was calculated on the ITT population incl. those who did not develop SOM.

- Placebo: 19 days
- 30mg: 8 days, p=0.163
- 90mg: 1.5 days, p=0.024*

Median Days Duration of Severe Oral Mucositis (Grade 3 or 4)

Subjects without SOM had a duration of 0 days.

* Statistically significant (Van Elteren test)
Secondary Endpoint – Incidence of SOM (Grade 3+4) Thru 60 Gy

36% Relative Reduction in Incidence at 90mg dose

Nominal p values
Secondary Endpoint – Incidence of SOM (Grade 3+4) Thru all IMRT

34% Relative Reduction at 90mg dose

Placebo: 65%
30mg: 60%
90mg: 43%

Nominal p value: p=0.009

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Secondary Endpoint – Incidence of Grade 4 OM

Thru all IMRT

47% Relative Reduction at 90mg Dose

<table>
<thead>
<tr>
<th>Dose</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>30%</td>
</tr>
<tr>
<td>30mg</td>
<td>21%</td>
</tr>
<tr>
<td>90mg</td>
<td>16%</td>
</tr>
</tbody>
</table>

Nominal p value: p=0.045
SOM Onset Delayed by GC4419
Cumulative incidence with progressive RT total dose

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Individual Patient “Swimmers’ Plot” — 90 mg v PBO

Grade, timing & duration limited to subjects with observed SOM

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WHO Grading

- <Gr. 3
- Gr. 3
- Gr. 4

Placebo (45 of 74)

90mg (35 of 76)
Safety Results
Comparable Safety Across All 3 Arms

Maximum Grade Toxicity on each Arm (% pts)

- Grade 2 or worse:
  - Placebo (n=72): 95%
  - 30 mg GC4419 (n=73): 97%
  - 90 mg GC4419 (n=72): 99%

- Grade 3 or worse:
  - Placebo (n=72): 94%
  - 30 mg GC4419 (n=73): 97%
  - 90 mg GC4419 (n=72): 95%

- Grade 4 or 5:
  - Placebo (n=72): 45%
  - 30 mg GC4419 (n=73): 50%
  - 90 mg GC4419 (n=72): 45%

- Grade 5 (fatal):
  - Placebo (n=72): 1%
  - 30 mg GC4419 (n=73): 1%
  - 90 mg GC4419 (n=72): 1%
Similar Rates of Cisplatin Toxicity

Grade 3-4 Nausea
- Placebo (n=72): 13%
- 30 mg GC4419 (n=73): 15%
- 90 mg GC4419 (n=72): 11%

Grade 3 Vomiting*
- Placebo (n=72): 11%
- 30 mg GC4419 (n=73): 8%
- 90 mg GC4419 (n=72): 4%

Grade 3 Creatinine
- Placebo (n=72): 3%
- 30 mg GC4419 (n=73): 4%
- 90 mg GC4419 (n=72): 6%

Grade 1-2 Tinnitus
- Placebo (n=72): 26%
- 30 mg GC4419 (n=73): 26%
- 90 mg GC4419 (n=72): 21%

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GC4419 “expected” events were mild and transient

Mechanism-related potentiation of nitric oxide

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Exploratory results
SOM and Patient Subgroups

- SOM duration and incidence not affected by:
  - Cisplatin schedule (weekly vs Q3wk)
  - Tumor HPV status
  - Definitive vs post-op IMRT
  - Patient-reported smoking status
Other Exploratory Assessments

• Grade 2+ (ulcerative) OM comparable across arms
• G-tube use appeared to:
  – Track WHO score
  – Depend on institutional policy (not regulated per protocol)
• Narcotics were used commonly, early, ad lib
  – Likely for multiple reasons, including non-OM
  – Trend toward decreased median total dose on GC4419
Conclusions

- GC4419 (90 mg) provides clinically meaningful reduction in SOM
  - Duration
  - Incidence
  - Severity
- Intermediate results for 30 mg
- Safety profile comparable to placebo

- Future analyses include
  - Tumor control
  - Exploratory cytokine correlates
- FDA Breakthrough Designation & Fast Track Status
- Phase 3
  - 90mg vs Placebo

Presented by: CArryn Anderson, MD
<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Institution</th>
<th>Principal Investigator</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Sharon Gordon, DDS, MPH, PhD</td>
<td>School of Dental Medicine at East Carolina University</td>
<td>Waqas Rehman, MD</td>
<td>Hunterdon Hematology Oncology, LLC</td>
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<td>Philip Kovoor, MD/Mark Engleman, MD</td>
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<td>Leander Cannick III, MD</td>
<td>Armed Health Cancer Center</td>
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<td>Roberto Arevalo-Araujo, MD</td>
<td>Pasco Pinellas Cancer Center</td>
<td>William Wisbeck, MD</td>
<td>Providence Regional Medical Center</td>
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<td>Abhinand Peddada, MD</td>
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<td>Steve P. Lee, MD, PhD</td>
<td>Long Beach Veteran Affairs Healthcare System</td>
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<td>James Wheeler, MD</td>
<td>Goshen Center for Cancer Care</td>
<td>Vernon King, MD</td>
<td>St. Mary’s Regional Cancer Center</td>
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<td>Maria Matsangou, MD</td>
<td>Northwestern University</td>
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<tr>
<td>Kyle Colvett, MD</td>
<td>Mountain States Health Alliance Research Department</td>
<td>Ganesh Kudva, MD/</td>
<td>Henry Ford Allegiance Health</td>
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<td>Bianca de Souza, MD</td>
<td>Charleston Cancer Center</td>
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<tr>
<td>Douglas Miller, MD</td>
<td>Meridian Health Research Services</td>
<td>Francois Vincent, MD</td>
<td>Centre Intégré Universitaire de Santé et de Services Sociaux de la Mauricie et du Centre du Québec</td>
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<tr>
<td>Anshu Jain, MD</td>
<td>Ashland-Bellefonte Cancer Center</td>
<td>Joseph Kelley, MD, PhD</td>
<td>University of Tennessee Medical Center</td>
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<tr>
<td>Madhavi Venigalla, MD</td>
<td>Lakeland Regional Cancer Center</td>
<td>Jorge Nieva, MD</td>
<td>USC Norris Cancer Center</td>
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<tr>
<td>Sanjiv Agarwala, MD</td>
<td>St. Luke's Hospital Cancer Center</td>
<td>Rex Mowat, MD</td>
<td>Toledo Clinic Cancer Center</td>
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<td>Mercedes Porosnicu, MD/</td>
<td>Wake Forest Baptist Health</td>
<td>Maura Barry, MD</td>
<td>The University of Vermont Cancer Center</td>
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<tr>
<td>Marcelo Bonomi, MD</td>
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<td>Celine Ord, MD, Shymal Patel, MD</td>
<td>University of Arizona Cancer Center at Dignity</td>
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<tr>
<td>Madhu Garg, MD</td>
<td>University of Michigan</td>
<td>Patrick Cobb, MD, FACP</td>
<td>Health St. Joseph’s</td>
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<td>Alan Gowan, DO</td>
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<td>Dukagjin Blakaj, MD, PhD</td>
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<td>Khalil Sultanem, MD</td>
<td>Scott &amp; White Memorial Hospital and Clinic</td>
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<td>Elizabeth Feldman, MS, DMD</td>
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<td>Ariel Birnbaum, MD</td>
<td>Ellis Fischel Cancer Center - University of Missouri</td>
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<td>Michael Trendle, MD/Clint Daniel Kingsley, MD</td>
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<td>Ronald Maggiore, MD/Daniel Clayburgh, MD, PhD</td>
<td>Fowler Family Center for Cancer Care</td>
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<td>Kevin Collins, MD, JD</td>
<td>Fowler Family Center for Cancer Care</td>
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Acknowledgements

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  • Alira Health
    – Chelsea Eckman
    – Chris Rao
    – Beth Rayworth
    – Jen Petrillo
  • Galera Therapeutics, Inc.
    – Dennis Riley, Ph.D.
• Statistics Collaborative
  – Janet Wittes, Ph.D.
• Novella Clinical
  – Mariana Hildesheim
Questions?
Interested in Phase 3?
carryn-anderson@uiowa.edu
### SOM duration and incidence similar across other subgroups

**GC4419 effects descriptively similar across subgroups (data not shown)**

<table>
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<tr>
<th>Tumor HPV Status</th>
<th>Treatment setting</th>
<th>Reported smoking status</th>
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<tr>
<td></td>
<td>(+)</td>
<td>(-)</td>
</tr>
<tr>
<td>n</td>
<td>160</td>
<td>63</td>
</tr>
<tr>
<td>Duration (days)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>8.5</td>
<td>8.0</td>
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<tr>
<td>Mean</td>
<td>22.7</td>
<td>19.6</td>
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<table>
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<th>Incidence (%)</th>
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<td>Gr 3-4 through 60 Gy</td>
<td>47</td>
<td>40</td>
<td>49</td>
<td>44</td>
<td>57</td>
<td>40</td>
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<tr>
<td>Gr 3-4 through IMRT</td>
<td>56</td>
<td>57</td>
<td>61</td>
<td>65</td>
<td>63</td>
<td>53</td>
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Source: SAS tables 5.5 and 6.5
**SOM duration and incidence: similar for weekly or Q3wk platinum**

**GC4419 improved SOM for both subgroups**

<table>
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<tr>
<th></th>
<th>Overall (N=223)</th>
<th>90 mg GC4419 (N=76)</th>
<th>30 mg GC4419 (N=73)</th>
<th>Placebo (N=74)</th>
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<tr>
<td></td>
<td>wkly Q3wk</td>
<td>wkly Q3wk</td>
<td>wkly Q3wk</td>
<td>wkly Q3wk</td>
</tr>
<tr>
<td><strong>n</strong></td>
<td>138 85</td>
<td>46 30</td>
<td>46 27</td>
<td>46 28</td>
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<tr>
<td><strong>Duration (days)</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Median</strong></td>
<td>11.5 8.0</td>
<td>2.3 0.8</td>
<td>8.0 8.0</td>
<td>23.5 15.0</td>
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<td><strong>Mean</strong></td>
<td>20.2 20.2</td>
<td>17.9 17.2</td>
<td>19.2 20.9</td>
<td>31.4 22.8</td>
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<tr>
<td><strong>Incidence (%)</strong></td>
<td></td>
<td></td>
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<tr>
<td>Gr 3-4 through 60 Gy</td>
<td>49 39</td>
<td>43 27</td>
<td>37 44</td>
<td>65 46</td>
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<td>Gr 3-4 through IMRT</td>
<td>57 54</td>
<td>48 37</td>
<td>57 67</td>
<td>67 61</td>
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</tbody>
</table>

Source: SAS tables 5.5 and 6.5

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Narcotic use—lower median @ 90 mg vs Placebo
> 50% of patients had no OM (WHO=0) at first narcotic use

<table>
<thead>
<tr>
<th></th>
<th>Placebo (N=72)</th>
<th>30 mg (n=73)</th>
<th>90 mg (N=72)</th>
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</thead>
<tbody>
<tr>
<td>% of patients who took any narcotics</td>
<td>86%</td>
<td>86%</td>
<td>88%</td>
</tr>
<tr>
<td>Median total morphine equivalents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• All OM grades (0-4)</td>
<td>847</td>
<td>818</td>
<td>752</td>
</tr>
<tr>
<td>• Max OM Gr 1-4</td>
<td>950</td>
<td>890</td>
<td>713</td>
</tr>
<tr>
<td>• Gr 2-4</td>
<td>1000</td>
<td>1024</td>
<td>752</td>
</tr>
<tr>
<td>• Gr 3-4</td>
<td>1410</td>
<td>1053</td>
<td>752</td>
</tr>
<tr>
<td>• Gr 4</td>
<td>1287</td>
<td>1308</td>
<td>1202</td>
</tr>
<tr>
<td>Median days to first narcotic</td>
<td>5</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>% of patients with WHO=0 at first narcotic use</td>
<td>51%</td>
<td>58%</td>
<td>51%</td>
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# G-tube placement and use

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<th>90 mg</th>
<th>Difference</th>
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<tr>
<td>G-tubes placed (overall)</td>
<td>50</td>
<td>41</td>
<td>18%</td>
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<tr>
<td>G-tubes placed (“emergent,” post day 1)</td>
<td>16</td>
<td>13</td>
<td>19%</td>
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<tr>
<td>Patients with any G-tube feedings</td>
<td>42</td>
<td>36</td>
<td>14%</td>
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<tr>
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<th>Number with G-tube use</th>
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<tr>
<td></td>
<td></td>
<td>total</td>
<td>emergent</td>
<td>prophylactic</td>
<td></td>
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<tr>
<td>Max WHO of 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PBO</td>
<td>22</td>
<td>19 (86%)</td>
<td>8</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>90 mg</td>
<td>12</td>
<td>10 (83%)</td>
<td>3</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Max WHO of 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PBO</td>
<td>26</td>
<td>14 (54%)</td>
<td>4</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>90 mg</td>
<td>21</td>
<td>12 (57%)</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Max WHO of &lt;3</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PBO</td>
<td>26</td>
<td>9 (35%)</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>90 mg</td>
<td>43</td>
<td>14 (33%)</td>
<td>4</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

Presented by: Carryn Anderson, MD

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