PHALCON-HP PIVOTAL PHASE 3 TOP LINE RESULTS

April 29, 2021

Today's call

Prepared Remarks

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President & Chief Executive Officer

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Chief Operating Officer

Q&A

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Chief Commercial Officer

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SVP, Regulatory Affairs

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PHARMACEUTICALS
CHANGING THE LANDSCAPE IN GI
Going beyond to advance treatments for patients with acid-related disorders
Terrie Curran
President & CEO

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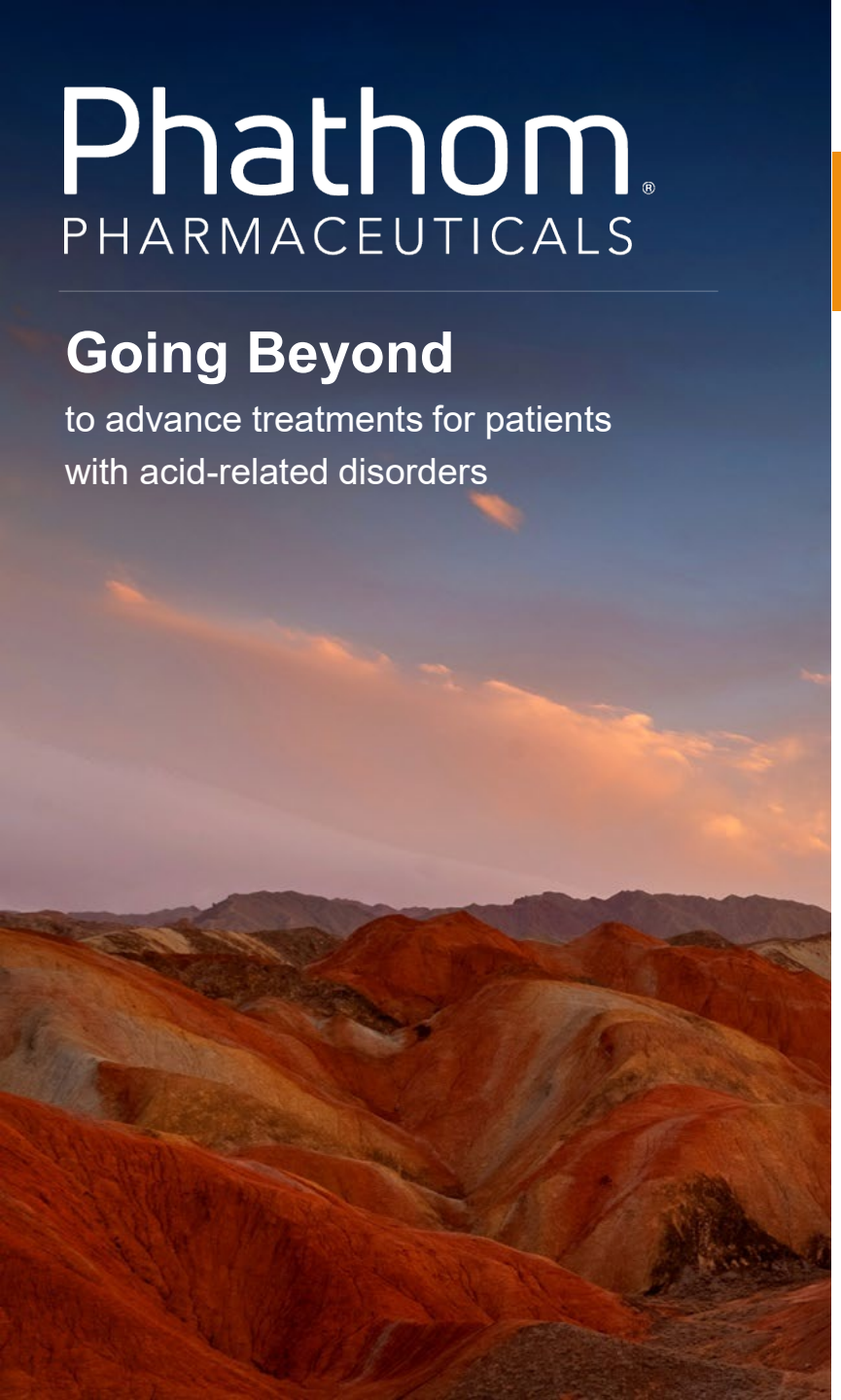
Going Beyond

to advance treatments for patients with acid-related disorders



Vonoprazan: *first innovative therapy for acid-related disorders in more than 25 years*

- Significant unmet medical need
- Large innovation starved markets
- Differentiated MOA and clinical profile
- De-risked asset with established success in Japan
- HCP and patient enthusiasm

pHalcon hp
A research study for *H. pylori* Infection

- Primary endpoint met for both vonoprazan dual and triple therapy
- Vonoprazan dual and triple therapy demonstrated superior eradication rates vs. lansoprazole triple therapy in all patients and in patients with clarithromycin resistant strains
- Vonoprazan-based regimens were generally well tolerated with a safety profile comparable to lansoprazole triple therapy
- New Drug Application (NDA) submissions for both vonoprazan-based regimens targeted by 4Q 2021

Vonoprazan dual therapy = vonoprazan 20 mg BID + amoxicillin 1 g TID
Vonoprazan triple therapy = vonoprazan 20 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID
Lansoprazole triple therapy = lansoprazole 30 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID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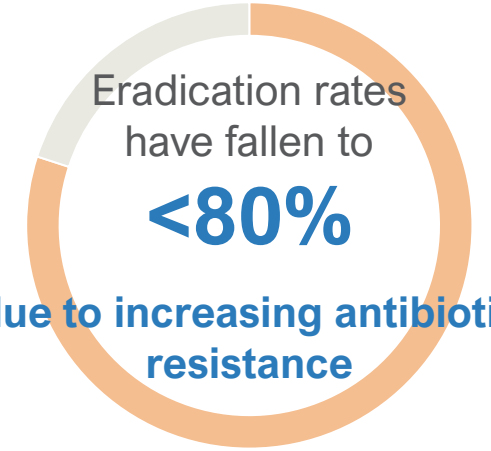
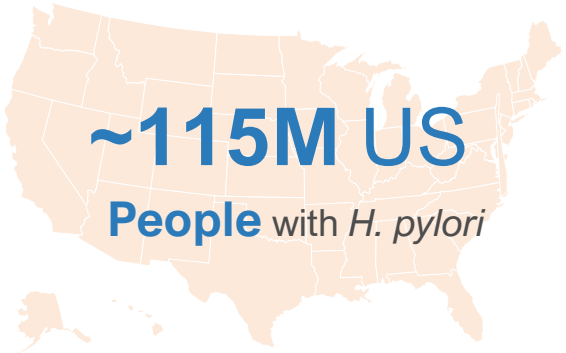
Heliobacter pylori infection *(H. pylori)* - a chronic and serious infection

Most **common chronic** bacterial infection





H. pylori can lead to **dyspepsia**, **peptic ulcers**, **gastric cancer**, and **mucosa-associated lymphoid tissue (MALT) lymphoma**

Peek 2008; Hooi et al, Gastroenterology 2017; Malfertheiner et al. Gut. 2017
Int J Cancer. 2015; Graham et al 2018; Erah et al 1997; Kusters et al 2006

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pHalcon-HP phase 3 study design

14 Day
Treatment Period

4 Weeks
Post-Treatment

Patients with *H. pylori* infection
(n = 992)

- **vonoprazan triple therapy** (n = 338)
- **vonoprazan dual therapy** (n = 324)
- **lansoprazole triple therapy** (n = 330)

Primary Endpoint: non-inferiority
eradication rate, excluding subjects with infection resistant to clarithromycin and amoxicillin

Secondary Endpoint #1: superiority
eradication rate in subjects with clarithromycin resistant strains

Secondary Endpoint #2: superiority
eradication rate in all subjects

Diagnosis of infection and test of cure confirmed by 13C-urea breath test
Vonoprazan dual therapy = vonoprazan 20 mg BID + amoxicillin 1 g TID
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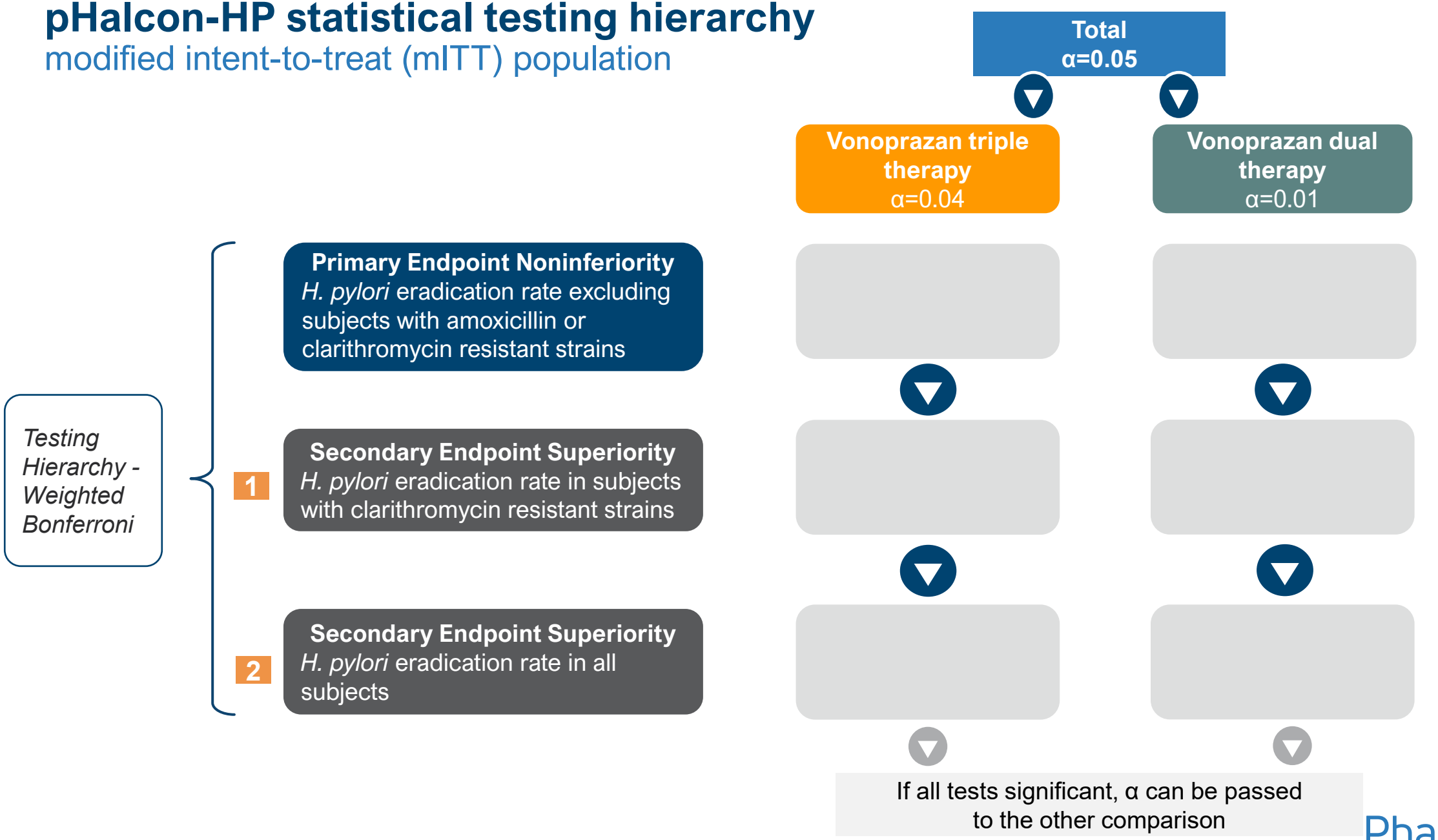
pHalcon-HP statistical testing hierarchy

modified intent-to-treat (mITT) population



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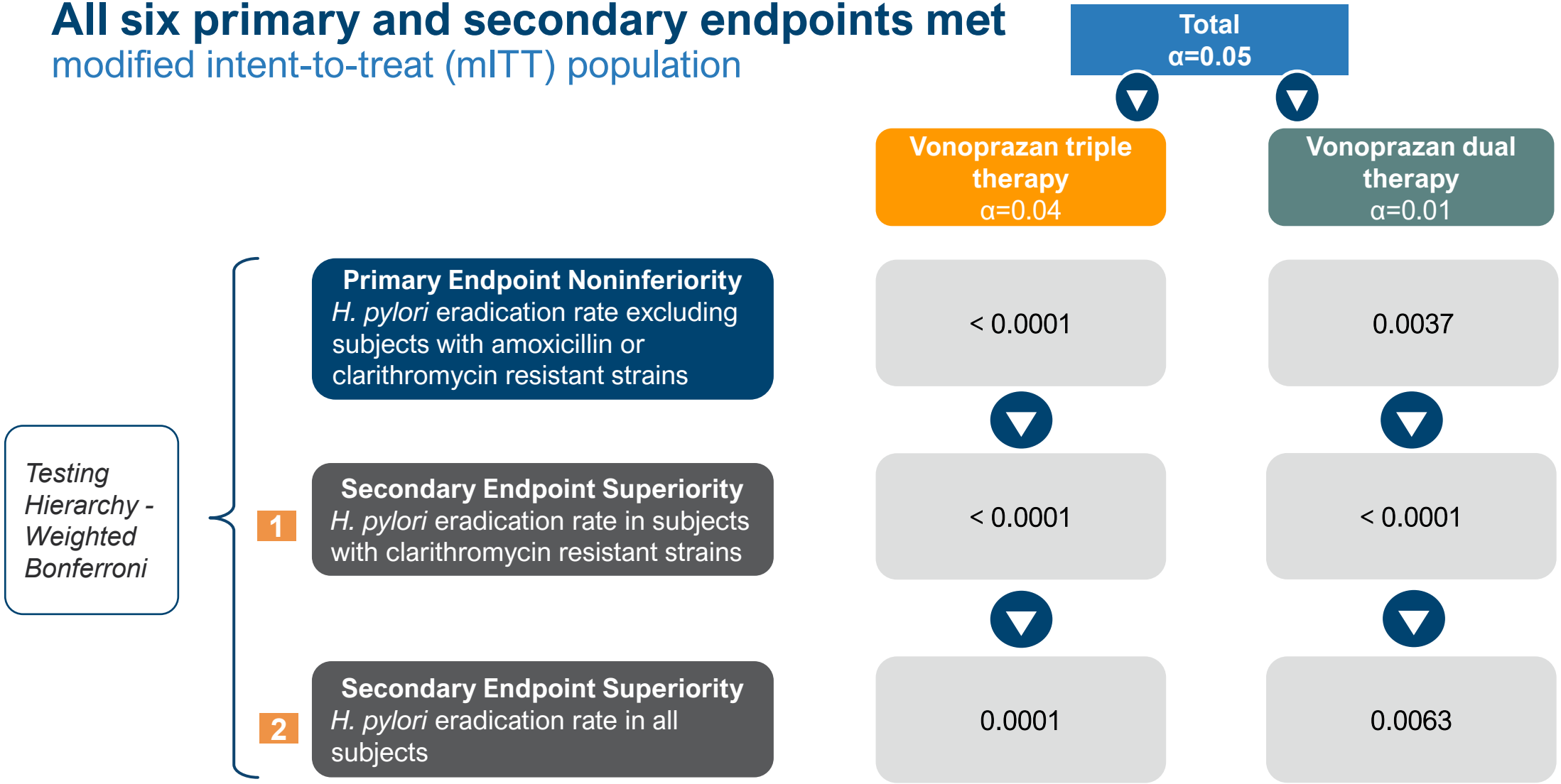
All six primary and secondary endpoints met

modified intent-to-treat (mITT) population



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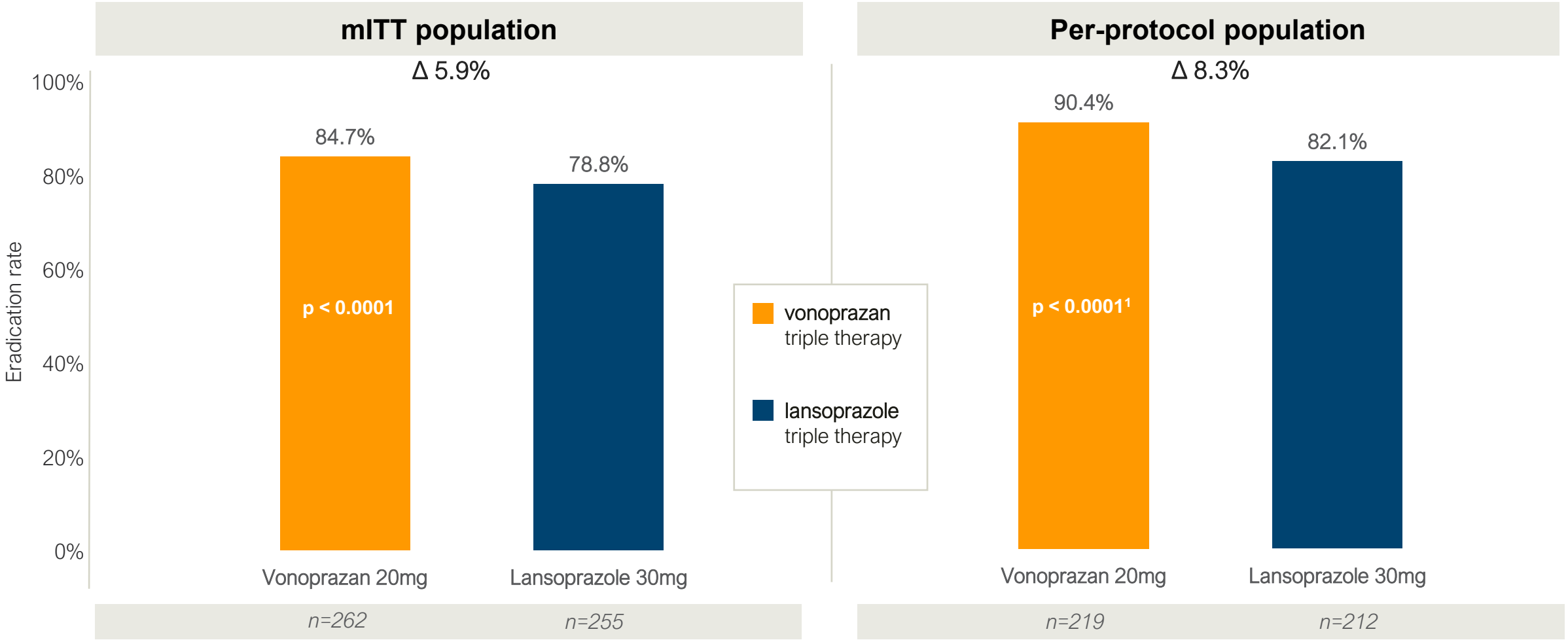
Vonoprazan triple therapy primary endpoint of non-inferiority met

excludes subjects with amoxicillin or clarithromycin resistant strains



[1] *Not adjusted for multiple comparisons*

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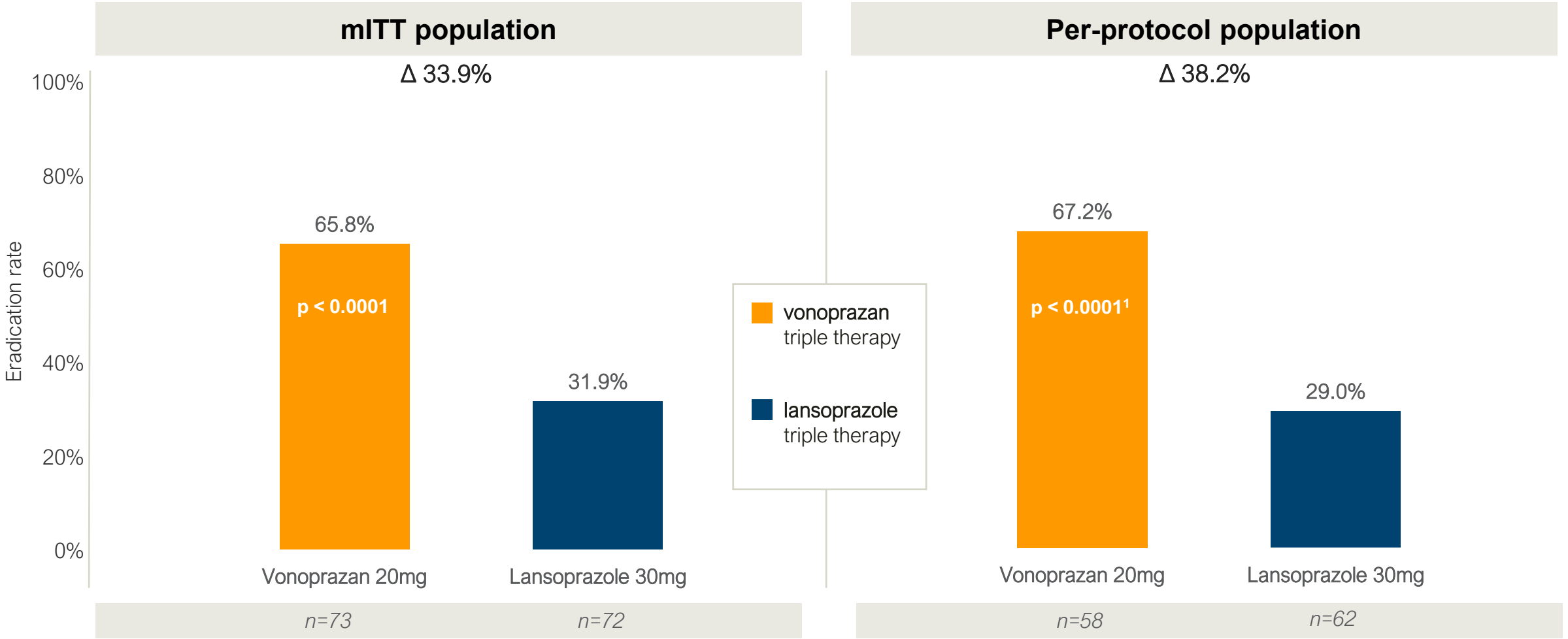
Vonoprazan triple therapy met superiority for secondary endpoint

subjects with clarithromycin resistant strains



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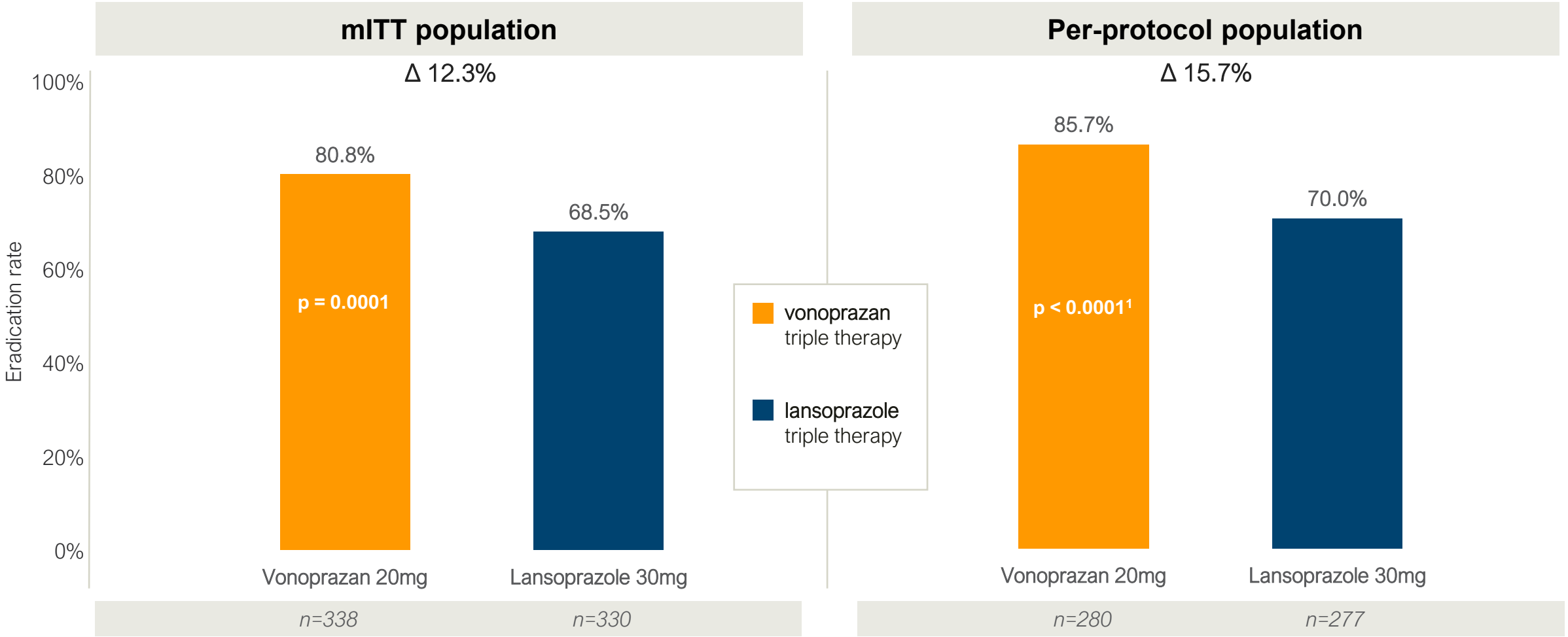
Vonoprazan triple therapy met superiority for secondary endpoint

all subjects



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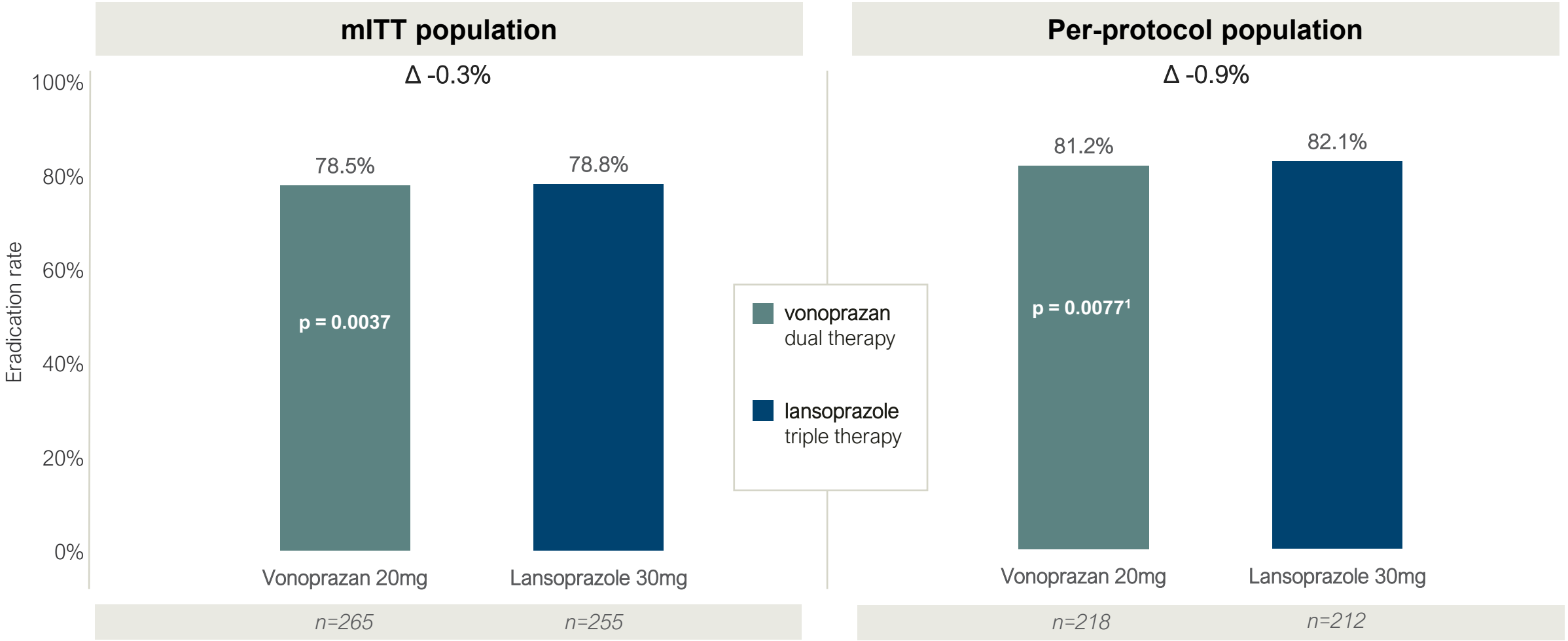
Vonoprazan dual therapy met non-inferior primary endpoint

excludes subjects with amoxicillin or clarithromycin resistant strains



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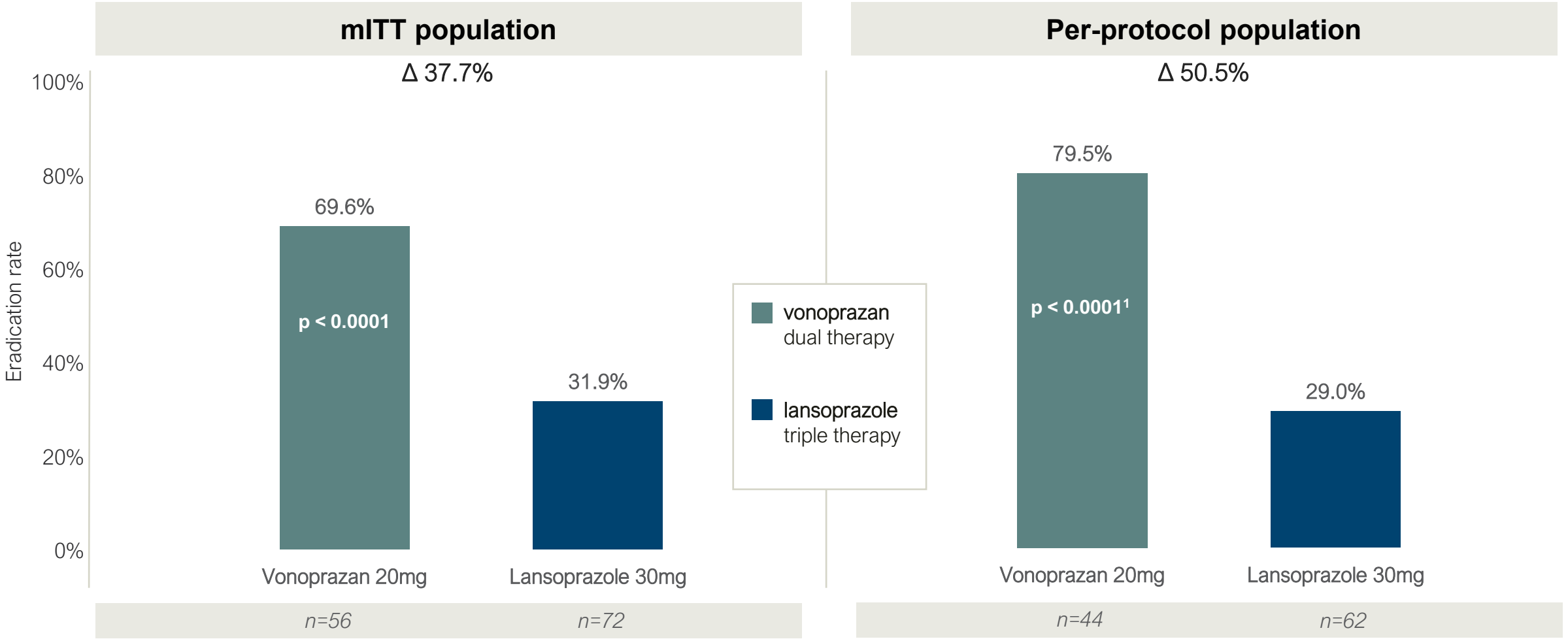
Vonoprazan dual therapy met superiority for secondary endpoint

subjects with clarithromycin resistant strains



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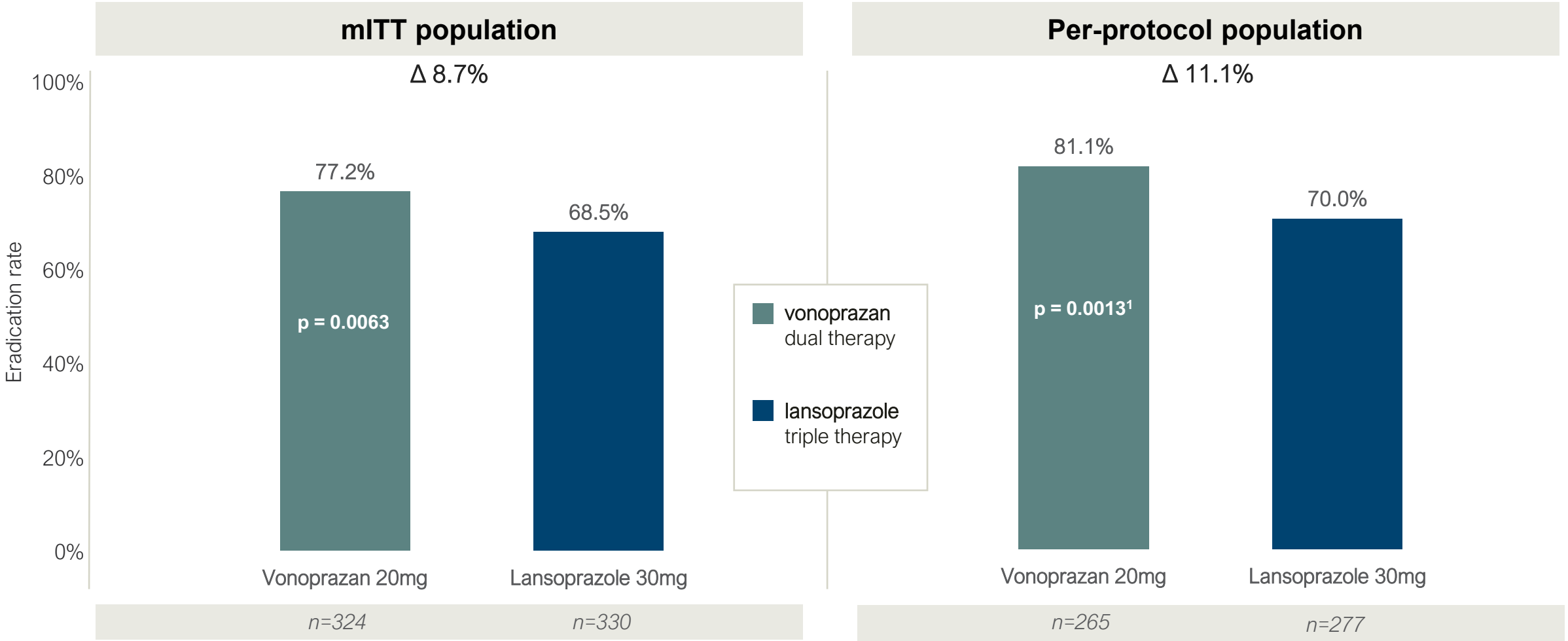
Vonoprazan dual therapy met superiority for secondary endpoint

all subjects



[1] *Not adjusted for multiple comparisons*

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Safety profile

vonoprazan-based regimens generally well tolerated; comparable to lansoprazole triple therapy

Most frequent (>2.0%) adverse events in pHalcon-HP subjects

% (n) with adverse event	Vonoprazan triple therapy (n=346)	Vonoprazan dual therapy (n=348)	Lansoprazole triple therapy (n=345)
Diarrhea	4.0% (14)	5.2% (18)	9.6% (33)
Nausea	1.7% (6)	1.7% (6)	2.6% (9)
Dysgeusia	4.3% (15)	0.6% (2)	6.1% (21)
Headache	2.6% (9)	1.4% (5)	1.4% (5)
Vaginal infection	2.3% (8)	0.9% (3)	0.3% (1)

Safety Set: All subjects who received at least one dose of study medication

Positive Phase 3 results position Phathom for planned 2021 NDA submissions

- All primary and secondary endpoints were met
- Both vonoprazan-based regimens were superior to lansoprazole triple therapy in all patients and in patients with clarithromycin resistant strains
- Dual therapy regimen, if approved, has potential to offer an additional treatment option that is antibiotic sparing with lower pill burden
- Vonoprazan-based regimens were well tolerated with a safety profile comparable to PPI triple therapy
- If approved, vonoprazan-based regimens would provide novel treatment options for the millions of people infected with *H. pylori*

pHalcon hp
A research study for *H. pylori* Infection

Executing on planned key company catalysts

- ✓ > Enrollment completed in Ph 3 pHalcon-EE and pHalcon-HP trials
- ✓ > Ph 2 NERD on-demand trial initiated
- ✓ > Positive topline Ph 3 results presented for pHalcon-HP

4Q21

- > *H. pylori* NDA submission
- > Topline Ph 3 results for pHalcon-EE

2022

- > Topline Ph 2 results for NERD on-demand trial
- > *H. pylori* NDA approval and US launch
- > Erosive Esophagitis NDA submission

2023

- > Erosive Esophagitis NDA approval and US launch

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Appendix

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Data set definitions

Modified intent-to-treat (mITT) set includes subjects who were:

- Randomized (including those who did not receive study drug)
- *H. pylori* infection documented by UBT and biopsy (i.e., culture or histology)

Per-protocol (PP) analysis set includes subjects with all of the following:

- Subject is included in the mITT analysis set
- Visit 4 occurs between 28 and 56 days after the end of treatment with documented 13C-UBT, unless the subject has documented persistence of *H. pylori* infection at any time after the end of treatment
- At least 75% of each study drug was taken, unless caused by treatment failure
- An antimicrobial known to be effective against *H. pylori* infection was not taken within 7 days of Day 1, during treatment, or between end of treatment and test-of-cure visit, unless given for treatment failure
- A proton pump inhibitor or high dose (as per below) H2-receptor antagonist was not taken within 14 days of Day 1, during treatment, or between end of treatment and test-of-cure visit, unless given for treatment failure
  - Subjects can use no more than standard doses of H2-receptor antagonists:
    - Ranitidine less than or equal to 300 mg/day
    - Cimetidine less than or equal to 800 mg/day
    - Famotidine less than or equal to 40 mg/day
    - Nizatidine less than or equal to 300 mg/day