
Phathom
PHARMACEUTICALS
CHANGING THE LANDSCAPE IN GI
Going beyond to advance treatments for patients with acid-related disorders
CORPORATE OVERVIEW
October 2021

# Safe harbor statement

The financial results included in this presentation are unaudited and preliminary estimates that (i) represent the most current information available to management as of the date of this presentation, (ii) are subject to completion of financial closing and procedures that could result in significant changes to the estimated amount, or (iii) do not present all information necessary for an understanding of Phathom's financial condition as of, and its results of operations for the quarter ended, September 30, 2021. Accordingly, undue reliance should not be placed on such preliminary estimates.

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# Phathom PHARMACEUTICALS

## Going Beyond

to advance treatments for patients with acid related disorders

**HEADQUARTERS**
Florham Park, NJ

**FORMED IN 2019**
Listed on NASDAQ: PHAT

## **Vonoprazan:** First innovative therapy for acid related disorders in more than 30 years

**Successful Ph 3** trials in ***H. pylori*** & **Erosive Esophagitis (EE)**

***H. pylori*** NDAs submitted to FDA
**EE** NDA submission planned for H1 2022

Targeted US launches in ***H. pylori*** anticipated H2 2022 and EE in 2023

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Approved in **15** **COUNTRIES** across Asia & Latin America

**>$800M** net sales in Japan.[1] Achieving market leadership of 38% share

[1] US dollars based on conversion rate of 0.0095 dollars to one yen. Sales for the twelve-month period, ended June 30, 2021

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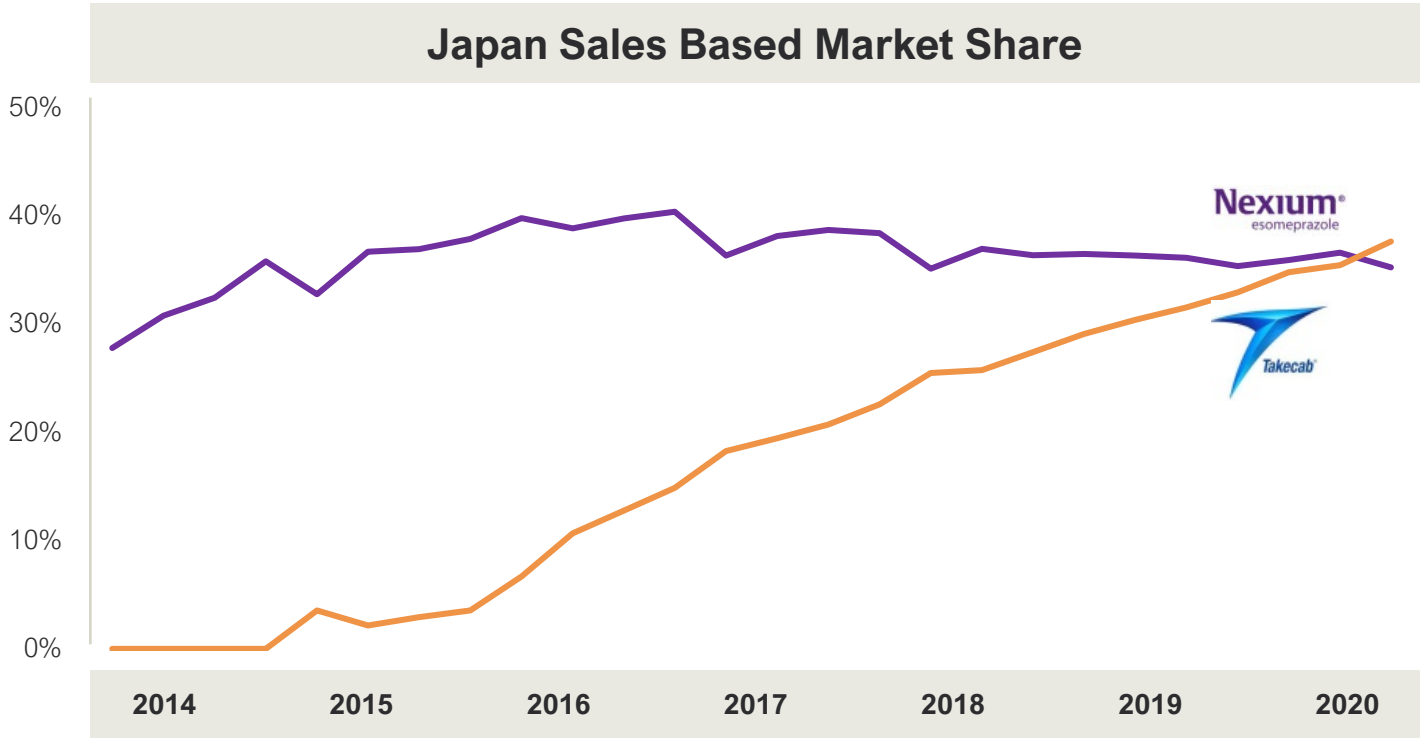
# Vonoprazan has been highly successful in Japan

Current US market has similarities to the Japanese market at launch of Takecab (vonoprazan)




**MARKET LEADER IN JAPAN**

**DOCUMENTED COST-EFFECTIVENESS**

**PREMIUM BRANDED PRICE**

## JAPAN EXPERIENCE

**Vonoprazan has achieved >$800M in net sales**[1]

Driven predominantly by volumetric gains from generic competitors

Majority of vonoprazan sales are in GERD

[1]US dollars based on conversion rate of 0.0095 dollars to one yen. Sales for the twelve-month period, ended June 30, 2021



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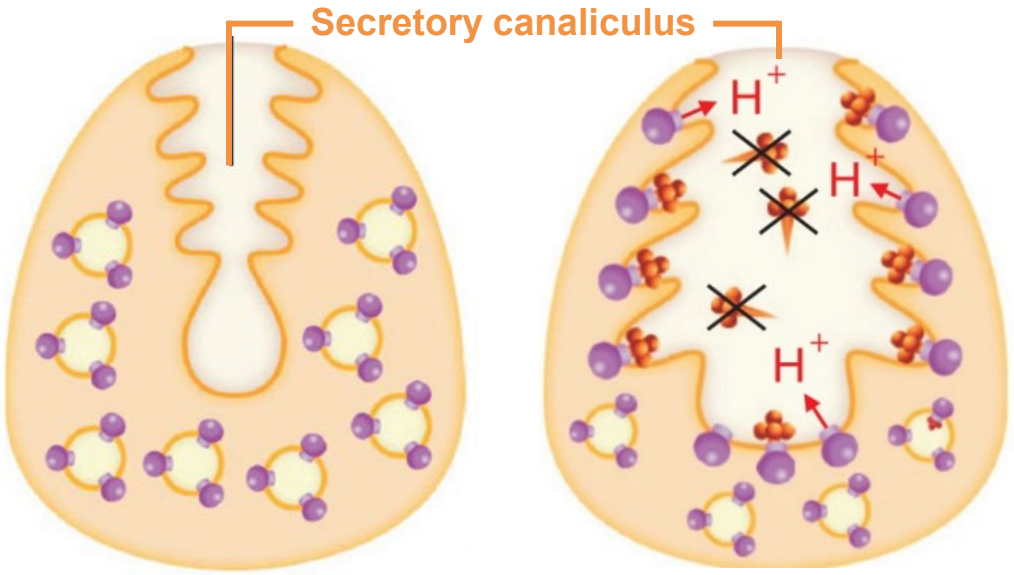
# PPIs: mechanism limits effectiveness

## GASTRIC PARIETAL CELL




*Quiescent phase* *Active phase after meal*

Tubulovesicle  Proton pump ($H^+$, $K^+$ -ATPase)

**PPI:**
COVALENTLY BINDING PRODRUG

- Short plasma half-life
- Acid needed for activation but unstable in presence of acid
- Meal required to stimulate pumps
- Primarily metabolized via CYP2C19

- ✕ **Slow** onset of action
- ✕ **Limited** potency
- ✕ **Limited** duration of activity

Oshima et al, J Neurogastroenterol Motil, 2018



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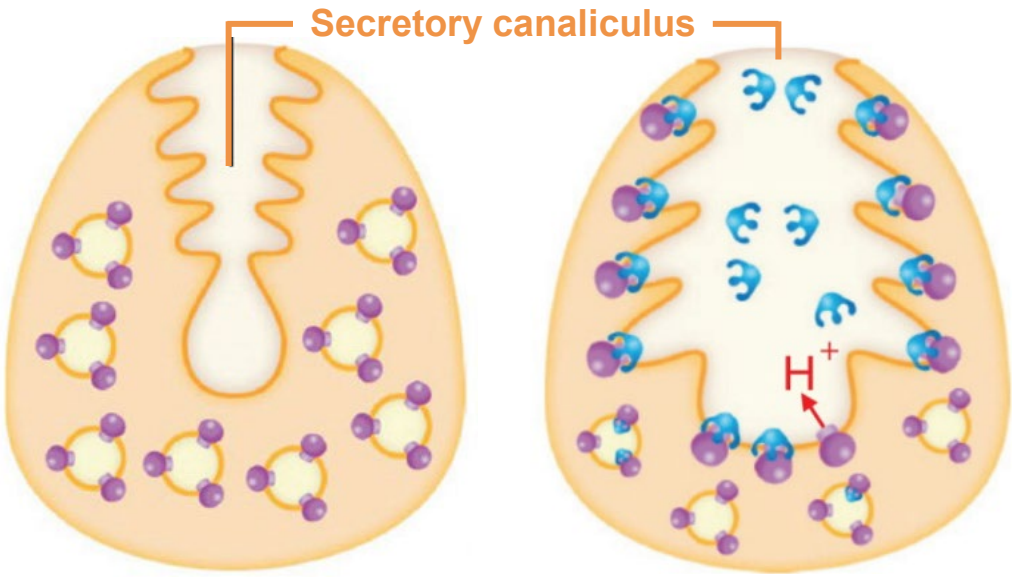
# Vonoprazan: distinct mechanism designed to address PPI shortcomings

## GASTRIC PARIETAL CELL




## Vonoprazan:
COMPETITIVE ENZYME INHIBITOR

- Long plasma half-life
- Stable in acid
- High accumulation in canaliculus
- Very slow dissociation rate
- Primarily metabolized via CYP3A4/5

- ✔ **Rapid** onset of action
- ✔ **Potent** acid control
- ✔ **Durable** 24-hr activity

Oshima et al, J Neurogastroenterol Motil, 2018



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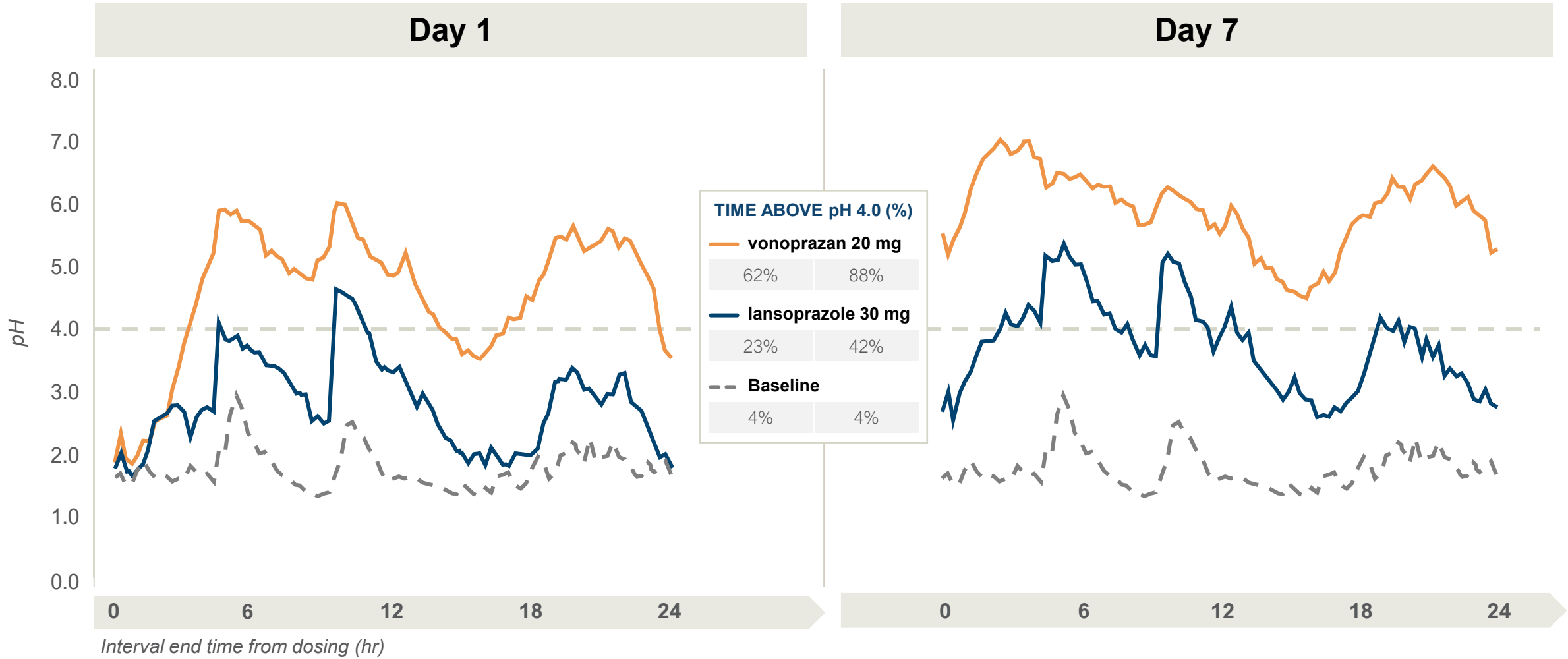
# VONO-103: Mean 0-24 hr gastric pH profiles




Mean gastric pH profiles for vonoprazan were higher than lansoprazole on both Days 1 and 7

. Study evaluating the PK, PD, safety and tolerability of vonoprazan in comparison to lansoprazole in 41 healthy adult subjects



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# Phathom pipeline: promising late-stage opportunities for unmet GI needs

| | Target Indications | Phase 1[1] | Phase 2[1] | Phase 3 | Expected Milestones |
|---|---|---|---|---|---|
| Vonoprazan | **GERD**<br>Healing of Erosive Esophagitis (EE) and relief of heartburn | | | pHalcon ee | *Positive topline results*<br>***NDA submission targeted for H1 22*** |
| | Maintenance of healing of Erosive Esophagitis (EE) and relief of heartburn | | | | |
| | Treatment of heartburn associated with Non-erosive Reflux Disease (NERD) | | | pHalcon nerd | *Enrollment ongoing*<br>***Topline results 1Q 22*** |
| **Vonoprazan + antibiotics** | ***H. pylori* treatment**<br>Dual therapy (vonoprazan + amoxicillin) | | | pHalcon hp | *Positive topline results*<br>***Submitted NDAs to FDA*** |
| | Triple therapy (vonoprazan + amoxicillin + clarithromycin) | | | | |

Phathom has development and commercialization rights to vonoprazan in the United States, Europe, and Canada

[1]Phase 1 and 2 studies in healing of Erosive Esophagitis, maintenance of healing of Erosive Esophagitis, and *H. pylori* treatment conducted by Takeda



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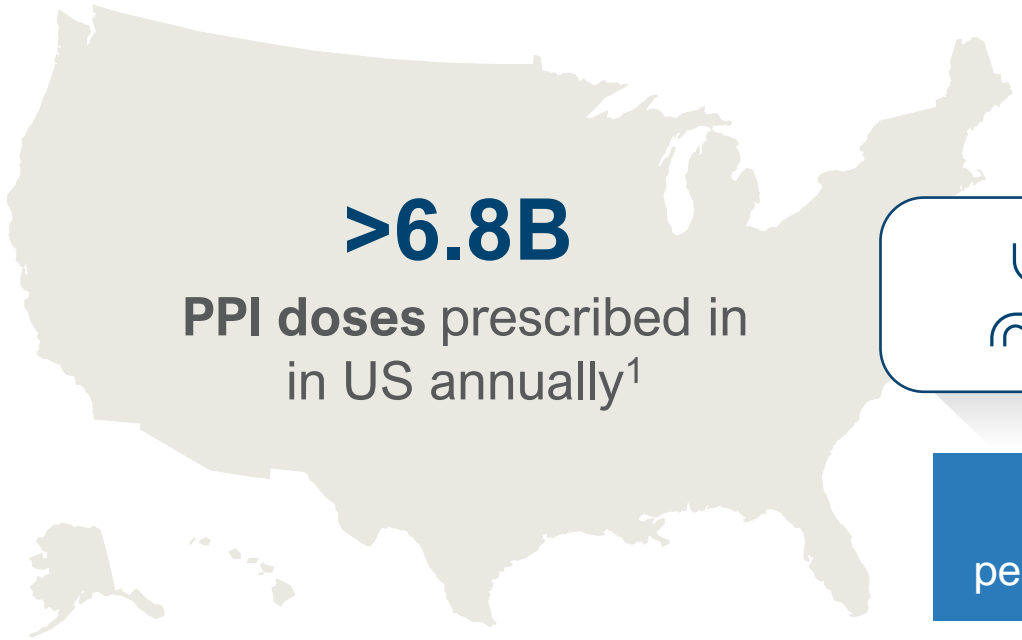
# Large market opportunity



**>6.8B**

**PPI doses** prescribed in in US annually[1]

**~65M** people in the US with GERD

**~20M**
people with EE

**~45M**
people with NERD

[1] For the 12 months ended October 31, 2020; IQVIA data



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# Clinically meaningful results from PHALCON-EE study

## PHALCON-EE outcomes expected to support submission of NDA with important indications

- Healing of EE and relief of heartburn
- Maintenance of EE healing and relief of heartburn

## Superiority data provides clinical differentiation from lansoprazole, a proton pump inhibitor (PPI)

- Superior healing at 2 weeks in patients with moderate-to-severe disease[1]
- Superior maintenance of healing in all patients
- Superior maintenance of healing in patients with moderate-to-severe disease

[1]Healing rate in all patients was also numerically greater at week 2 but could not be deemed statistically significant due to hierarchical testing



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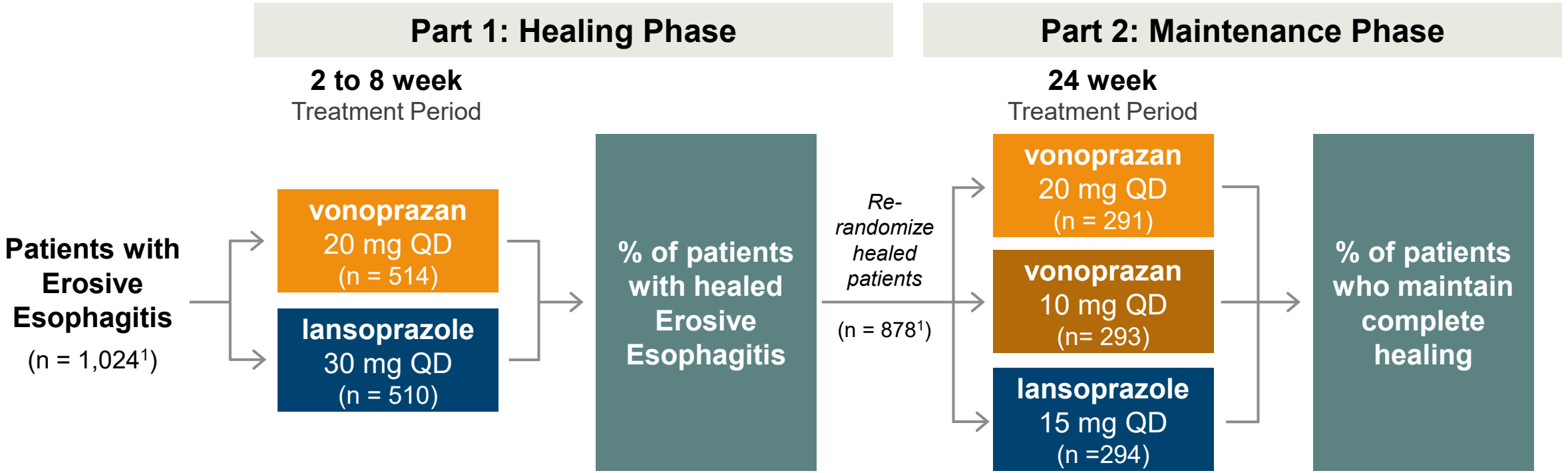
# PHALCON-EE phase 3 study design

## US/Europe study in Erosive Esophagitis

pHalcon ee
A research study for Erosive Esophagitis




[1] Represents modified intent to treat (mITT) population



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# PHALCON-EE met primary and key secondary endpoints

## Healing Phase

| | Vonoprazan 20mg |
|---|---|
| ☆ *Noninferiority:* % of subjects with complete healing of EE by Week 8 | p<0.0001* |
| *Noninferiority:* % of 24-hour heartburn-free days over the Healing Period | 95%CI: (-1.60,7.03) |
| *Superiority:* % of Grades C/D subjects who have healing at Week 2 | p=0.0004 |
| *Superiority:* % of subjects with onset of sustained resolution of heartburn by Day 3 | p=0.2196 |
| *Superiority:* % of Grades C/D subjects who have healing by Week 8 | *not tested in hierarchy* p<0.0001 (nominal) |
| *Superiority:* % of subjects (All Grades) who have healing at Week 2 | *not tested in hierarchy* p=0.0174 (nominal) |

## Maintenance Phase

| | Vonoprazan 20mg | Vonoprazan 10mg |
|---|---|---|
| ☆ *Noninferiority:* % of subjects who maintained healing through Week 24 | p<0.0001^ | p<0.0001^ |
| *Superiority:* % Grades C/D maintain healing through Week 24 | p=0.0098 | p=0.0245 |
| *Superiority:* % all Grades maintain healing through Week 24 | p=0.0068 | p=0.0218 |
| *Noninferiority* % of 24-hour heartburn-free days through Week 24 | 95%CI: (-2.63, 6.72) | 95%CI: (-2.27, 6.84) |

☆ Denotes primary endpoints tested for noninferiority; endpoints were also tested for superiority

*Healing phase primary endpoint, exploratory superiority comparison, nominal p<0.0001
^Maintenance phase primary endpoint, prespecified secondary superiority comparison: Vonoprazan 20 mg: p=0.0068; vonoprazan 10 mg p=0.0218



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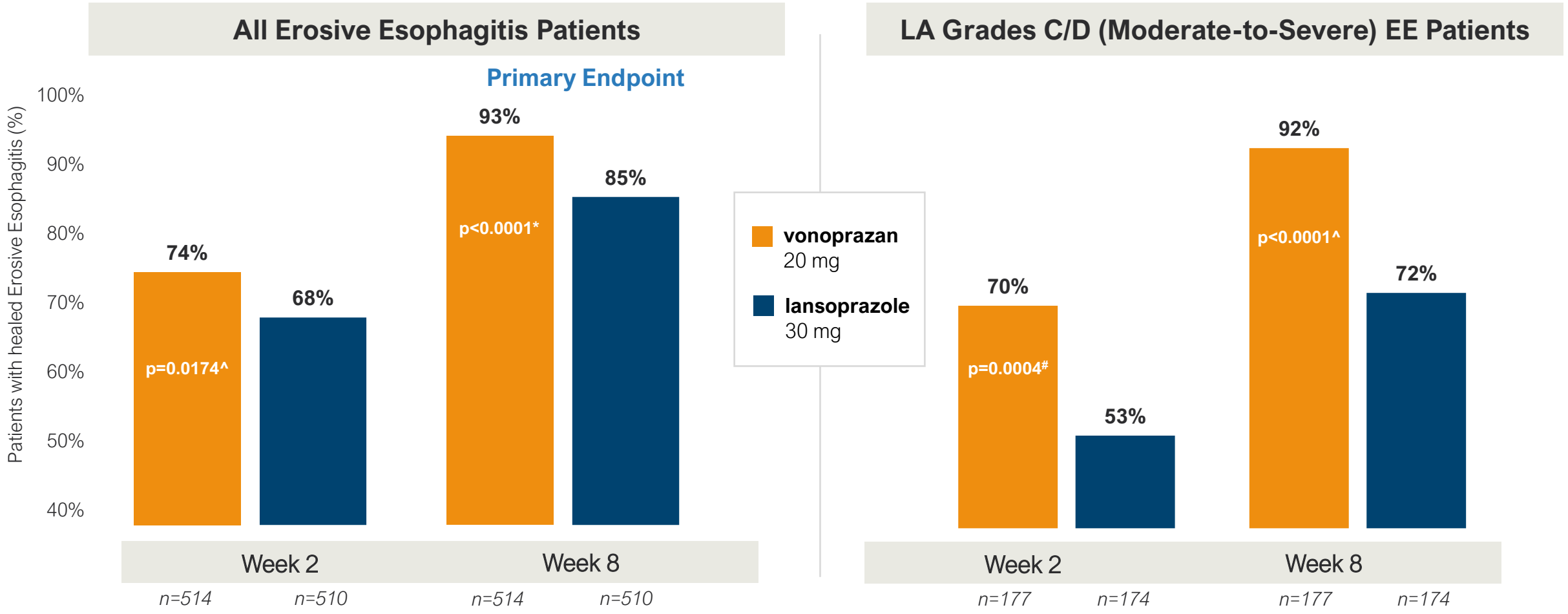
# Healing endpoints




^nominal p-value presented, superiority comparison, not significant based on pre-specified testing hierarchy
*p-value for both primary non-inferiority endpoint and nominal p-value for exploratory superiority comparison
#p-value for pre-specified secondary endpoint superiority comparison



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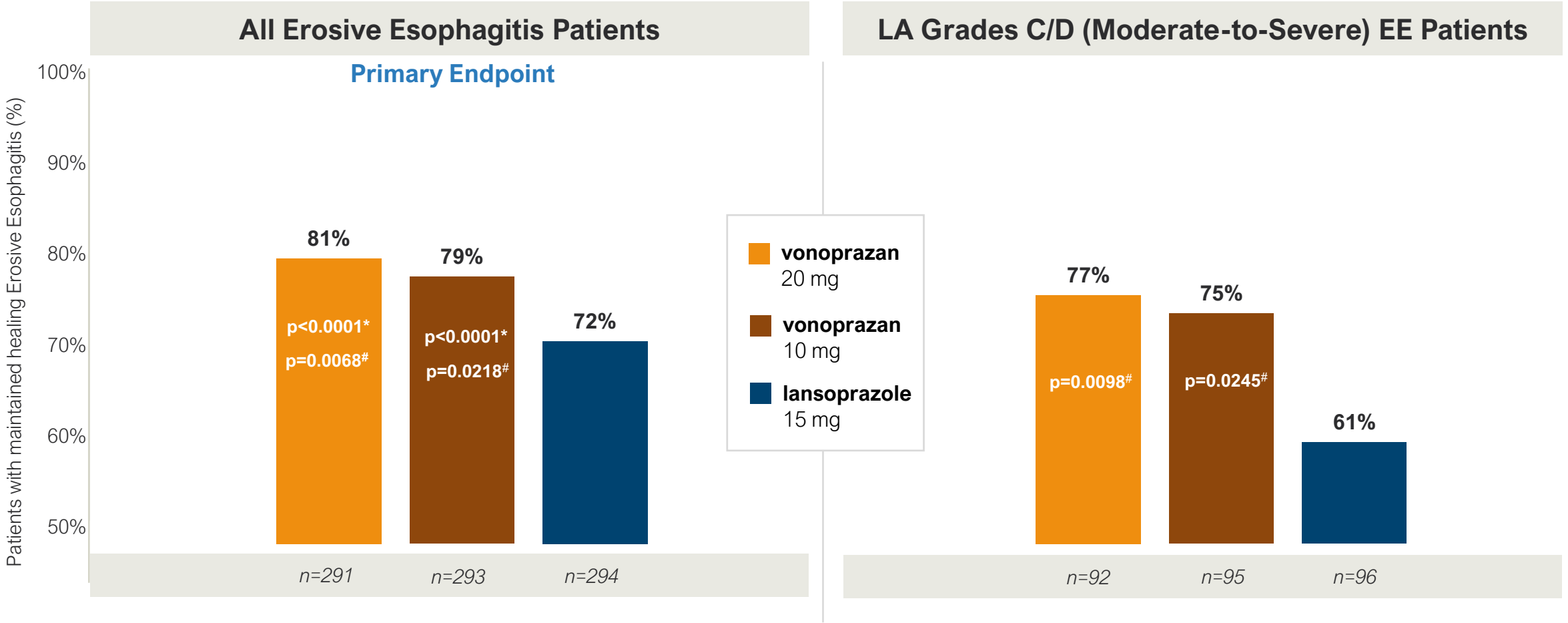
# Maintenance of healing endpoints




*p-value for primary endpoint non-inferiority comparison
#p-value for pre-specified secondary endpoint superiority comparison



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# Summary of PHALCON-EE safety data

**Overall, the safety results for vonoprazan observed in PHALCON-EE were consistent with those observed in prior clinical studies**

## Healing Phase

### Most Common Adverse Events

| % (n) | Vonoprazan 20 mg | Lansoprazole 30 mg |
|---|---|---|
| Diarrhea | 2.1% (11) | 2.5% (13) |

## Maintenance Phase

### Most Common Adverse Events (≥ 5%)

| % (n) | Vonoprazan 20 mg | Vonoprazan 10 mg | Lansoprazole 15 mg |
|---|---|---|---|
| Abdominal Pain | 5.4% (16) | 4.1% (12) | 2.4% (7) |
| Gastritis | 2.7% (8) | 6.4% (19) | 2.7% (8) |
| COVID-19 | 10.1% (30) | 6.1% (18) | 6.7% (20) |

## Both Phases

### Serious Adverse Events (>1 patient)

| | Vonoprazan 20 mg | Vonoprazan 10 mg | Lansoprazole 15 mg |
|---|---|---|---|
| COVID-19* (n) | 5 | 2 | 0 |

*No COVID-19 SAEs were deemed related to the study drug by the investigator | Safety Set: All subjects who received at least one dose of study medication



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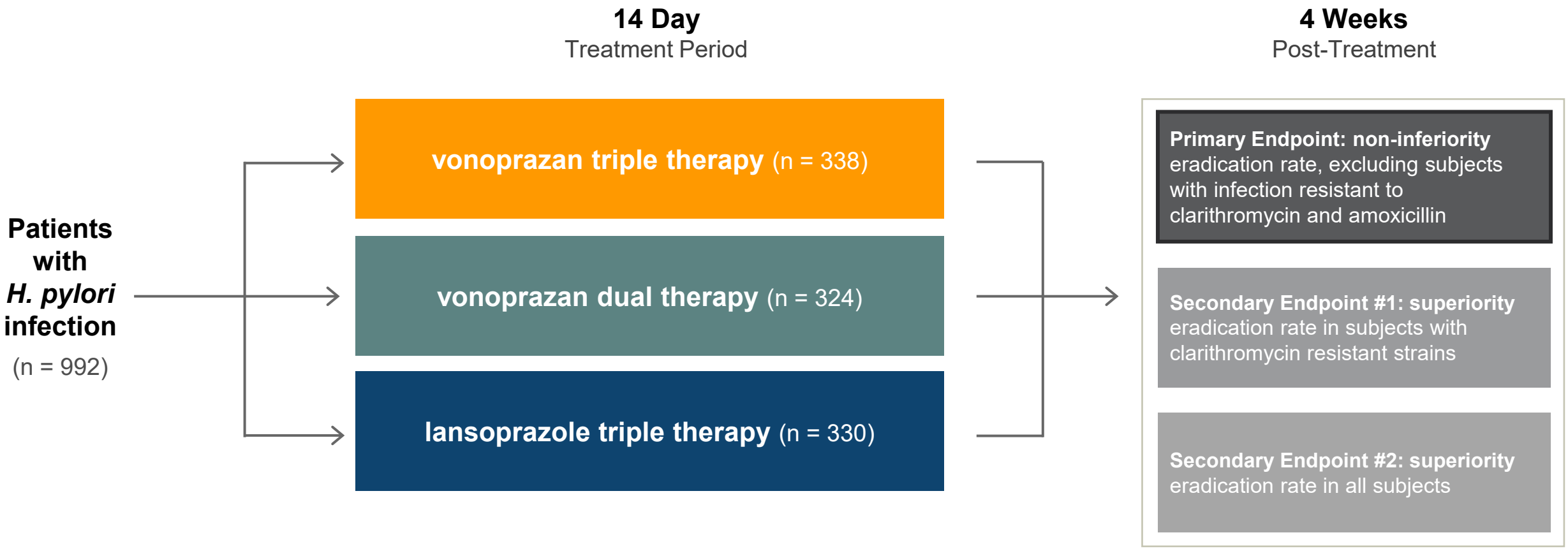
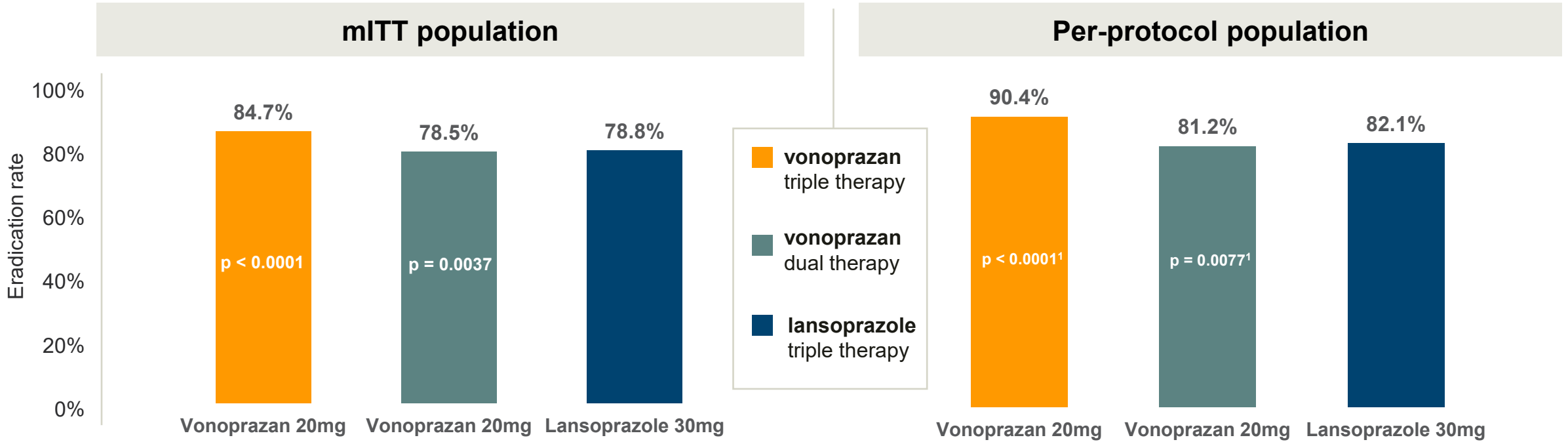
# PHALCON-HP phase 3 study design




Diagnosis of infection and test of cure confirmed by 13C-urea breath test
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

# PHALCON-HP primary endpoint analysis

## Eradication rates (%) among patients without clarithromycin- or amoxicillin-resistant strains

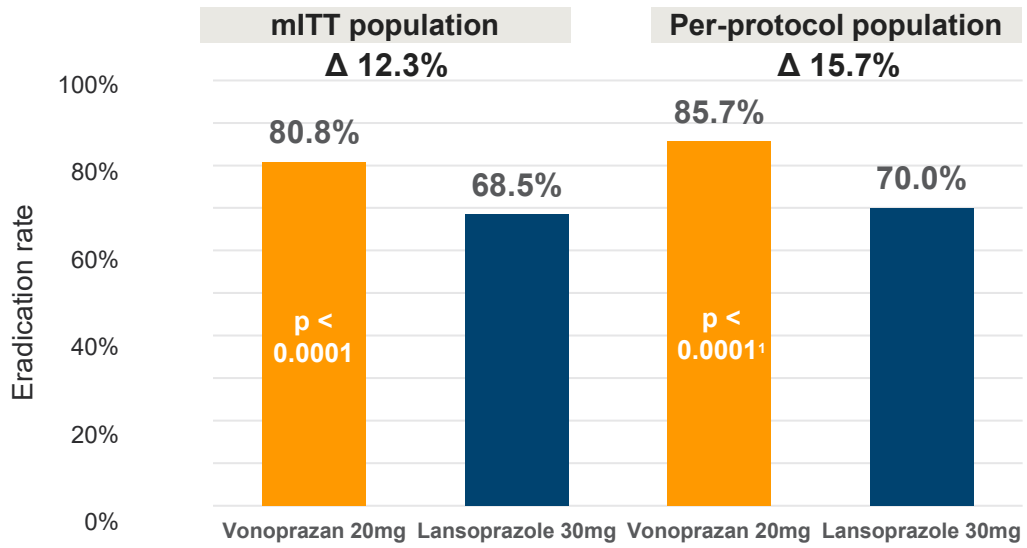



[1] Not adjusted for multiple comparisons

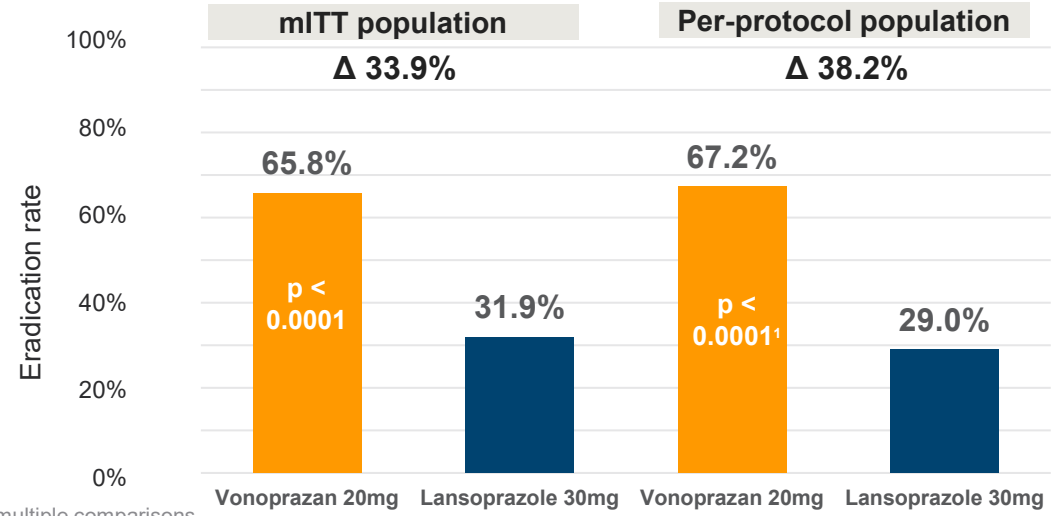
# Both vonoprazan-based therapies met superiority for secondary endpoints

## Vonoprazan triple therapy

### all subjects

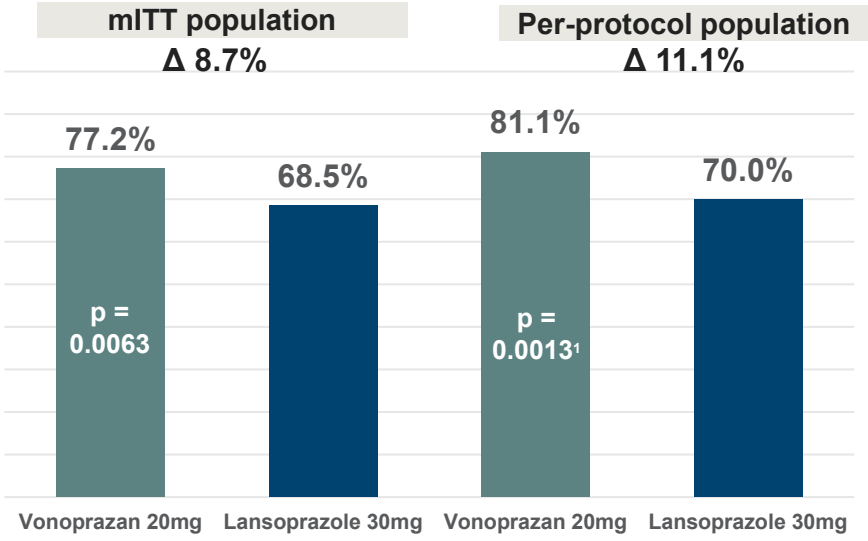


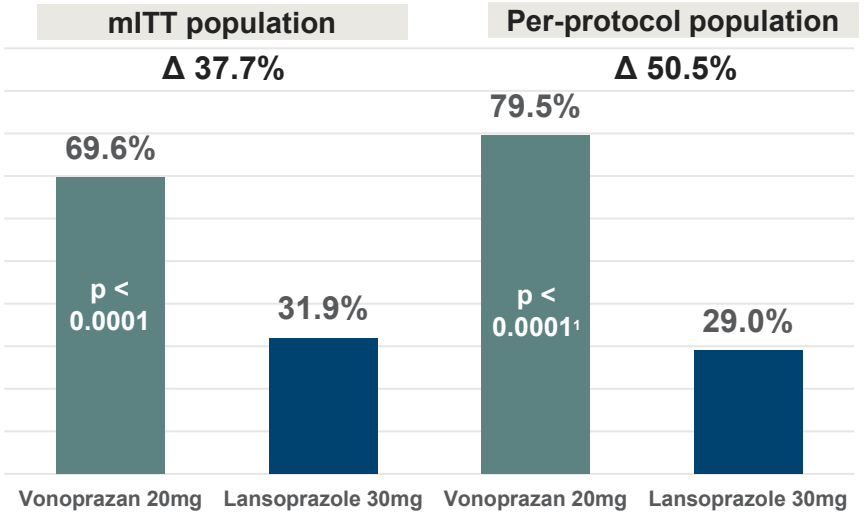

### subjects with clarithromycin resistant strains




[1] Not adjusted for multiple comparisons

## Vonoprazan dual therapy



# PHALCON-HP safety profile

## vonoprazan-based regimens generally well tolerated

**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

# NERD development strategy

## UNMET NEED

**~45M US**

PEOPLE with **NERD**

- PPIs must be taken daily and are not approved for on-demand use in US
- Massive need for effective on-demand therapy
- Approximately 50% of patients progress lines of therapy annually[1]

Vonoprazan's **speed** of onset, **potency,** and **duration** have the potential to satisfy unmet NERD needs

## DEVELOPMENT STRATEGY

- Initiated phase 2 NERD on-demand study (April 2021); topline results expected 1Q22
- Plan to initiate phase 3 program evaluating both vonoprazan continuous and on-demand dosing regimens

[1] Symphony Health claims analysis (Jul 2017 – Jan 2020)



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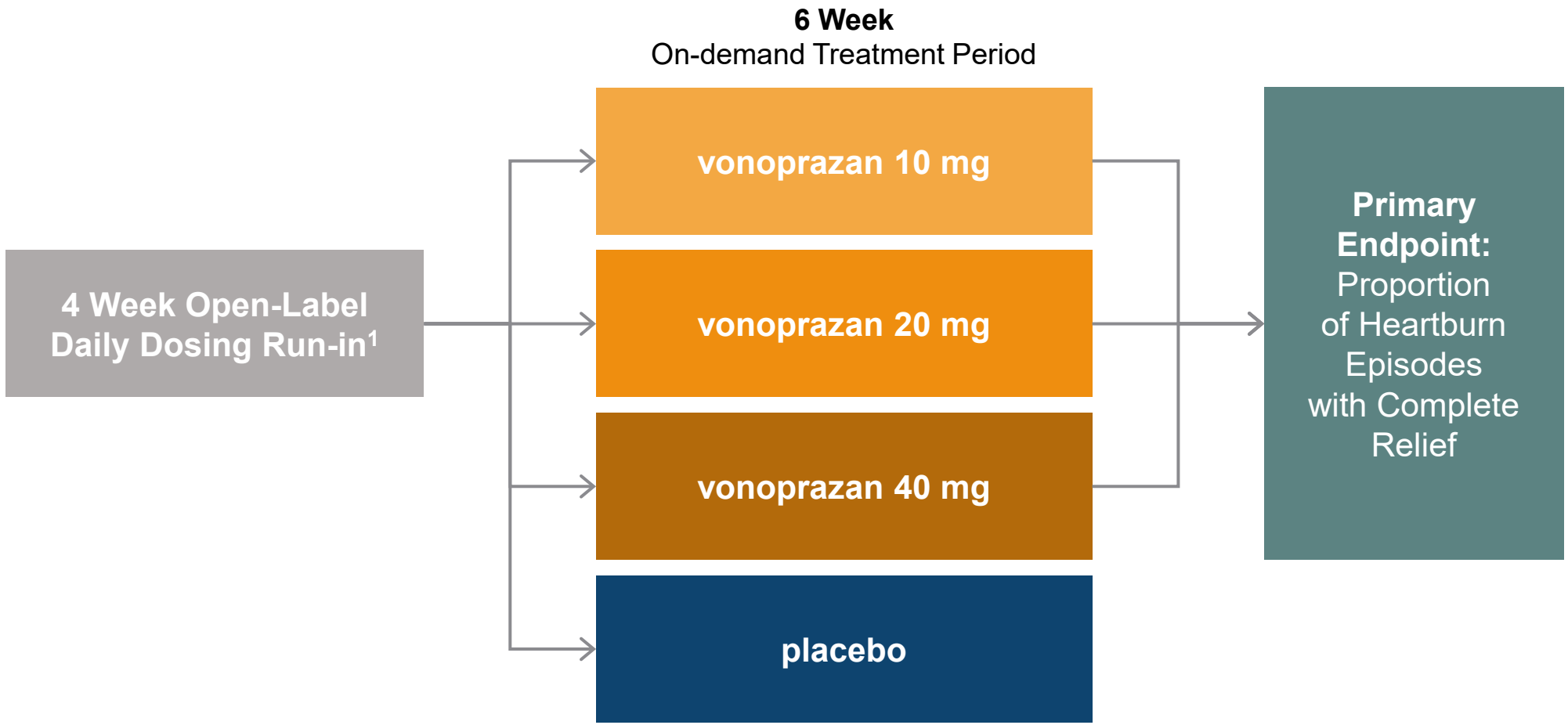
# Phase 2 PHALCON-NERD on-demand trial design



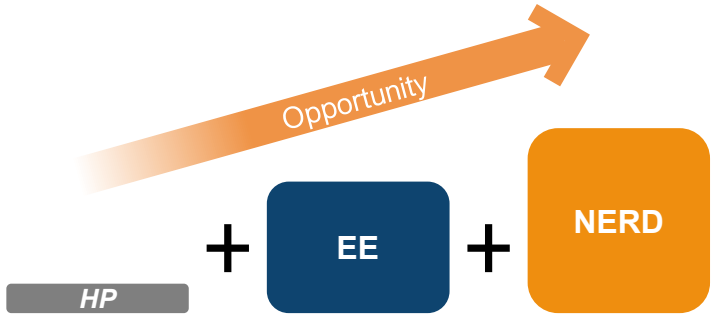

**Trial initiated in April 2021 with topline results expected 1Q 22**

[1] Dosing initiated at onset of a heartburn episode; rescue antacid medication allowed after 3 hours of taking test medication

# Significant opportunity and attractive commercial dynamics

65M people in the US with GERD

6.8B PPI doses prescribed in in US annually[1]




**Large Populations + Unmet Need**

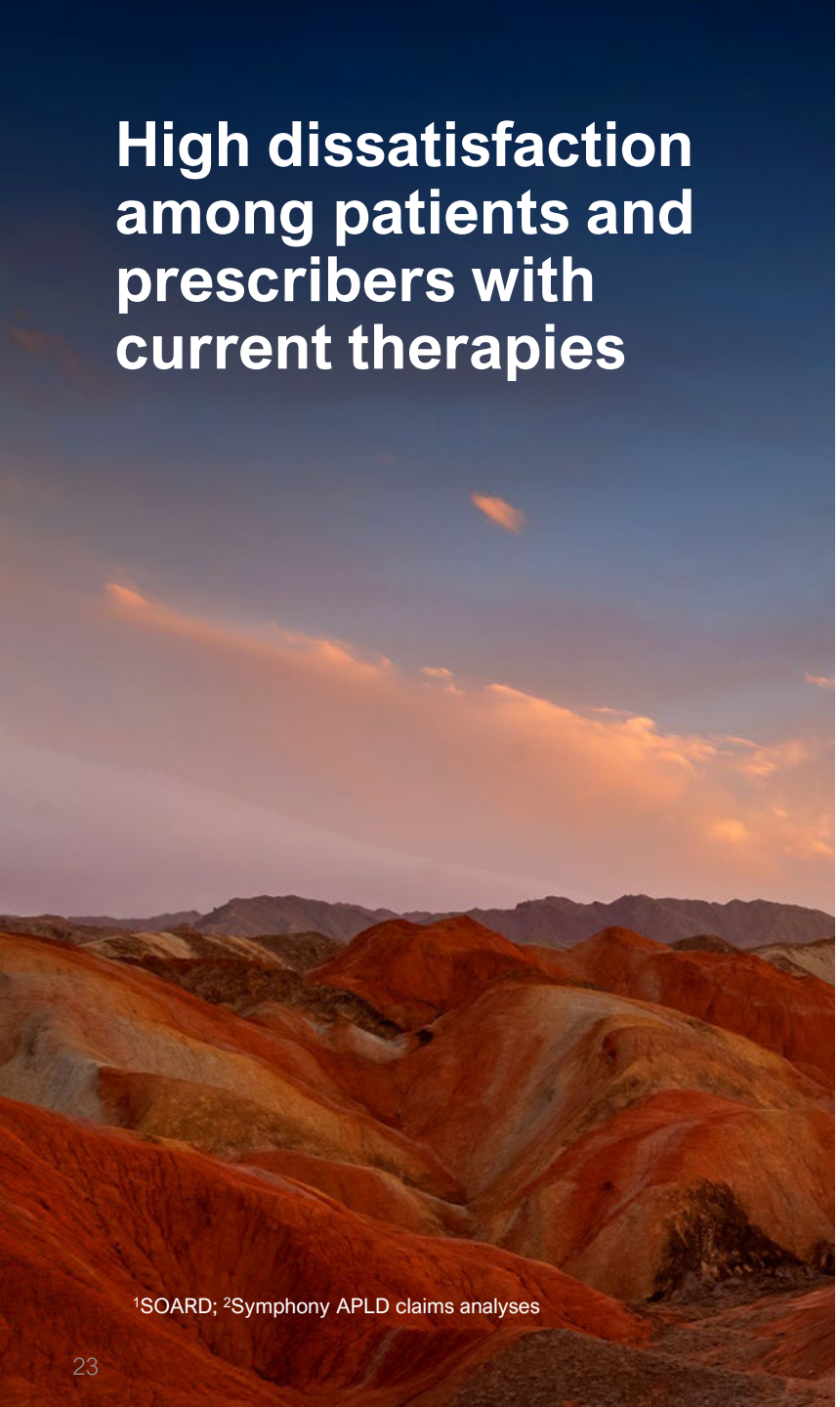
**Strong Physician Preference + Concentrated High Prescribers**

**Minimal Branded Competition + Share of Voice Ownership**

**Clinical Differentiation & Value**

[1] For the 12 months ended October 31, 2020; IQVIA data;

# High dissatisfaction among patients and prescribers with current therapies



**<1/3** **of HCPs are satisfied** with current treatment options for their patients[1]


**of patients** believe better control can be achieved, regardless of satisfaction with current treatment[1]


**of EE & NERD** patients progress lines of therapy annually[2]

[1]SOARD; [2]Symphony APLD claims analyses



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# Market research shows significant unmet need in EE across all stakeholders

## Patients

Need for sustained healing

Looking for new therapy options

Convenience to use without a meal

## Physicians

Desire for improved efficacy to adequately address healing and maintenance of healing

Desire alternatives to PPI treatments

Want innovative mechanism of action

## Payers

Desire enhanced efficacy in all patients, including difficult-to-treat groups

Want lower reoccurrence rates

Need for cost-effective treatments

SRI, June 2020 | Qualitative patient interviews | Study of Acid Related Disorders (SOARD) | Payer qualitative research



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**70%**

a different **MOA**

**HCPs agree vonoprazan is differentiated vs. existing treatments by having…**

**62%**

**superiority in healing** of EE erosions among moderate-to-severe patients

**58%**

**superiority efficacy in maintenance** of healed esophageal erosions

SRI Buying Process, October 23, 2020



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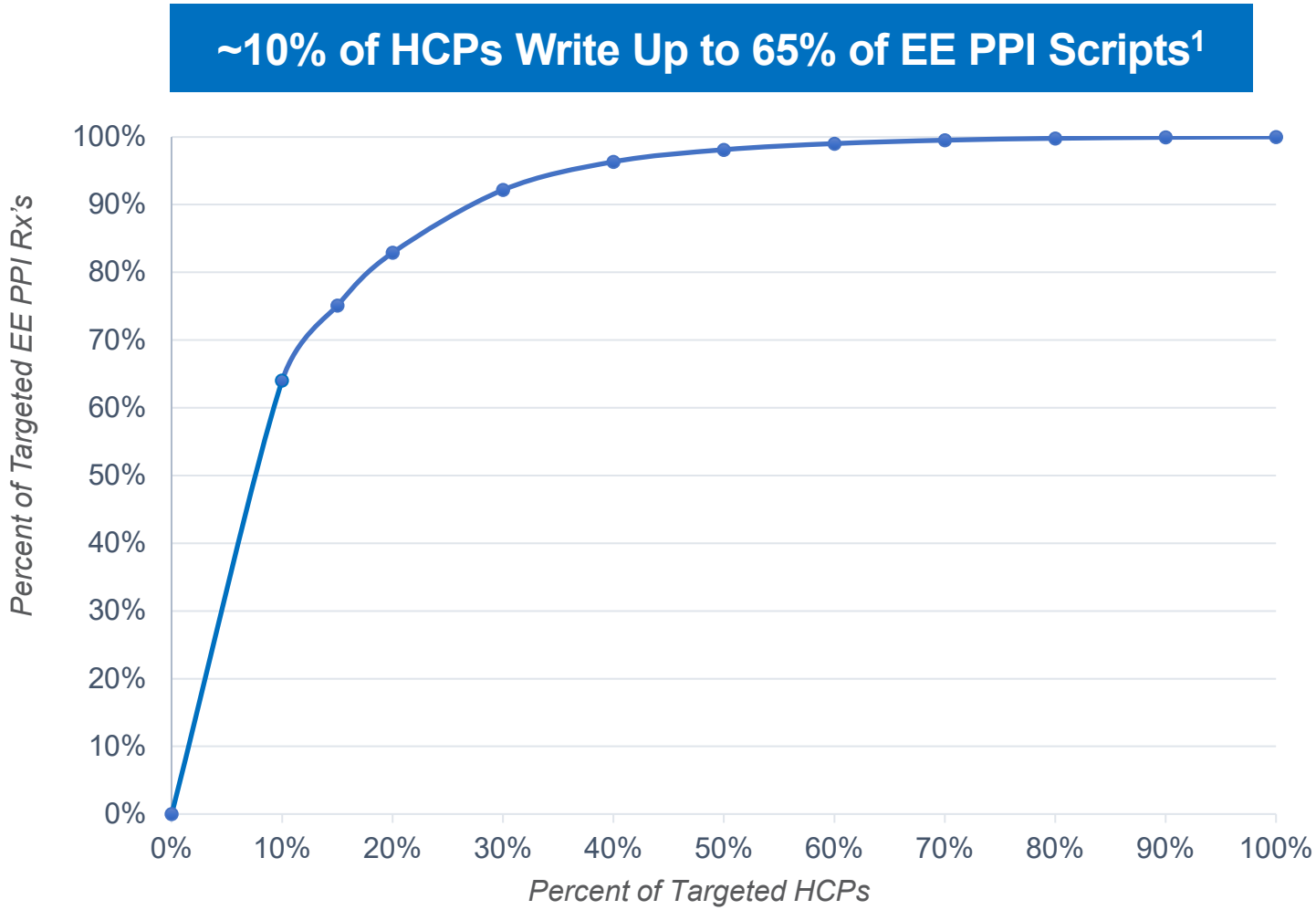
# Highly concentrated Erosive Esophagitis prescriber base allows for focused targeting of impactful HCPs




[1]Concentration curves reflect HCPs and PPI Rx volume among only focused specialties (i.e., GI, PCP, NP, PA). Other specialties and their associated volume are excluded.
Source: Internal analysis of IQVIA Xponent Retail PPI Rx data (2020) in conjunction with Symphony Health claims analysis (2017-2019)



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# Profile and PHALCON-EE data further support vonoprazan's blockbuster potential

**IF APPROVED**

Vonoprazan would be the first innovative therapy for gastric acid related disorders in more than 30 years

## Vonoprazan profile

- Novel MOA
- Faster and superior healing in moderate-to-severe patients at week 2 versus lansoprazole
- Superior maintenance of healing in patients of all disease severity versus lansoprazole
- Relief and maintenance of heartburn
- Potential for label differentiated from PPIs
- Generally well-tolerated with large global safety database

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# Expected milestones

- Positive Ph 3 results for PHALCON-HP
- *H. pylori* NDAs submitted to FDA
- Positive Ph 3 results for PHALCON-EE

**1Q22**

Topline Ph 2 results for NERD on-demand trial

**1H22**

Erosive Esophagitis NDA submission

*H. pylori* approval

**2H22**

*H. pylori* US launch

**2023**

Erosive Esophagitis approval

Erosive Esophagitis US launch

~$225M cash and cash equivalents as of September 30, 2021[1], plus up to an additional $100M remaining under existing term loan facility

[1] Unaudited, preliminary and subject to change



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