

# ***CHANGING THE LANDSCAPE IN GI***

*Going beyond to advance treatments for patients with acid-related disorders*

## **Corporate Overview**

---

December 2024

# Safe harbor statement

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding the ultimate decision by the FDA on the action requested in the CP and the timing of any FDA action regarding the CP; and the possible extension of NCE exclusivity to VOQUEZNA tablets; our future results of operations and financial position, anticipated milestones, anticipated cash runway, expectations regarding patent and non-patent regulatory exclusivity, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors include, without limitation: our ability to successfully commercialize VOQUEZNA, which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; estimates of the number of patients with H. pylori and erosive and non-erosive GERD and our estimates on potential market size for VOQUEZNA; the inherent risks of clinical development of vonoprazan; the possibility that the FDA may reject our request to correct the Orange Book listings to reflect the correct expiration date for the NCE exclusivity period on the VOQUEZNA tablets; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of vonoprazan that may limit its development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; our ability to obtain and maintain intellectual property protection, including patent term extensions, and non-patent regulatory exclusivity for vonoprazan; our ability to comply with our license agreement with Takeda; our ability to achieve and maintain adequate levels of coverage and reimbursement for vonoprazan; the availability of additional funds under our revenue interest financing agreement and term loan agreement; the sufficiency of our capital to fund our operations; our cash and cash equivalents and other anticipated capital may not be sufficient to enable us to reach cashflow positivity; we may face competition earlier than expected if we lose or fail to obtain any of our patent protection or non-patent regulatory exclusivity for VOQUEZNA tablets; and other risks described in our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K and any subsequent filings with the SEC. You are cautioned to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Phathom, the Phathom logo, and other trademarks or service marks of Phathom appearing in this presentation are the property of Phathom. This presentation also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

# Phathom is focused on building VOQUEZNA® into a blockbuster

**NEW**

**NOW APPROVED for  
a NEW Indication:  
Non-Erosive GERD**



**Only FDA-approved treatment of  
its kind** from a new class of acid  
suppressants called Potassium  
Competitive Acid Blockers (PCAB)

## 1<sup>st</sup> novel treatment in over 30 years

- Approved for the treatment of Erosive GERD, Non-Erosive GERD, and *H. pylori* infection
- VOQUEZNA is the first-ever acid suppressant to demonstrate superiority vs. a PPI across multiple indications<sup>1</sup>

## High unmet need & attractive commercial dynamics

- ~22M+ patients with GERD are diagnosed and treated annually, many of which are unsatisfied with their therapy and seeking innovative treatment options
- No branded competition in the space

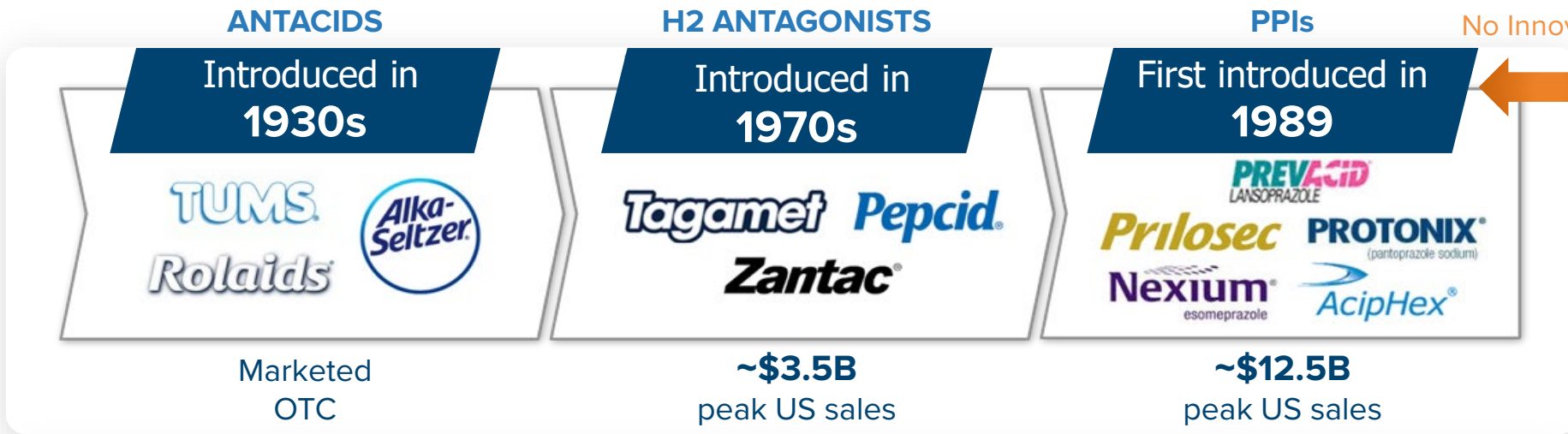
## Building upon demonstrated success

- Approved in 10+ countries worldwide with >60 million patients treated
- Blockbuster in Japan: #1 prescribed acid suppressant<sup>2</sup>

<sup>1</sup> Superiority of vonoprazan demonstrated versus lansoprazole in studies of Erosive GERD and *H. pylori* infection

<sup>2</sup> IQVIA MIDAS as of March 31, 2024, amongst all PPI and PCAB molecules

# Commercial success of acid suppression treatments



25 YEARS  
No Innovation

**PCAB**  
Introduced in Japan **2015**



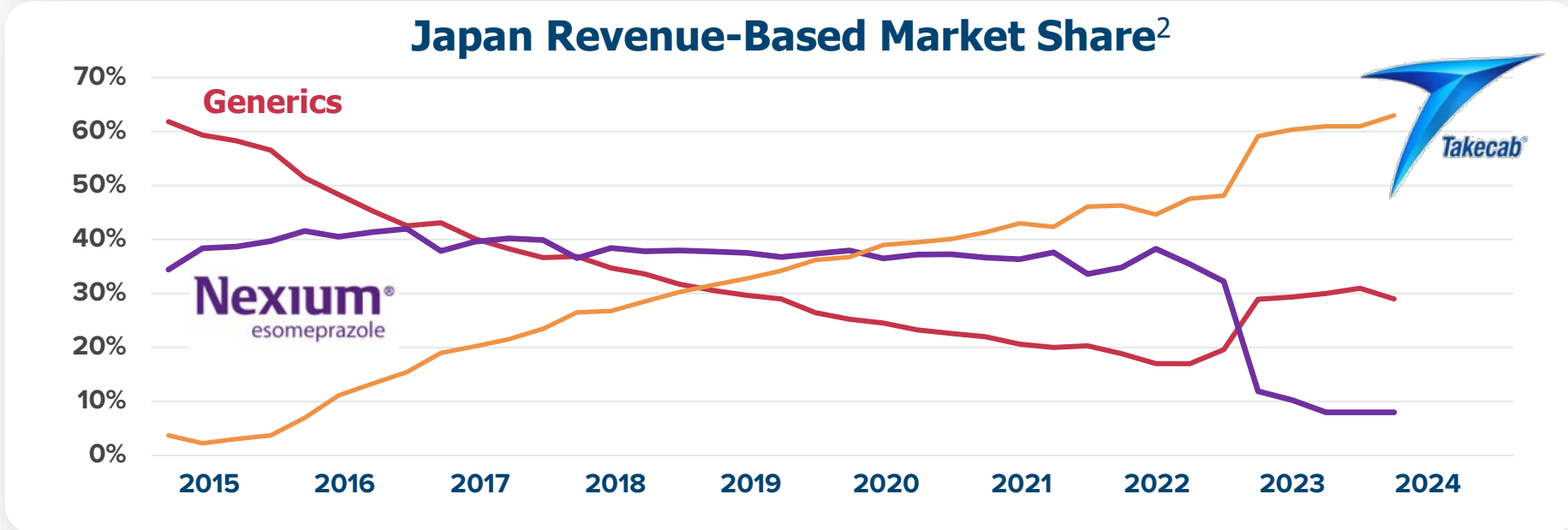
**>\$850M annual**  
net sales in Japan<sup>1</sup>

**Vonoprazan has been highly successful in Japan**

Driven predominantly by volumetric gains from generic competitors

Branded premium price

Majority of vonoprazan sales are in GERD



<sup>1</sup> US dollars based on conversion rate of 0.0090 dollars to one yen. Annual net sales figure reflects the twelve-months ended Dec. 31, 2021.

<sup>2</sup> IQVIA MIDAS as of March 31, 2024, amongst all PPI and PCAB molecules

# VOQUEZNA has a differentiated mechanism of action and is the first and only approved PCAB in the United States

## Rapid

Increased pH within 2-3 hours, reaching pH >4 within 4 hours

## Durable

Maintains continuous acid suppression over 24 hours



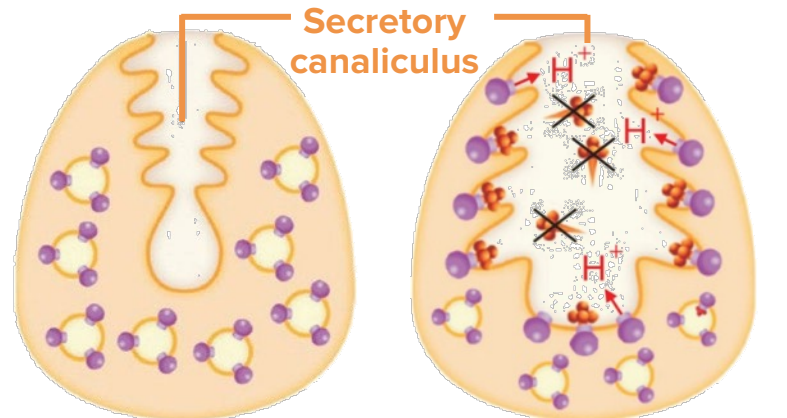
## Potent

Achieved strong acid suppression on Day 1, with a mean pH of 4.6

# Mechanistic differences between PPIs and PCABs



## PPI: COVALENTLY BINDING PRODRUG



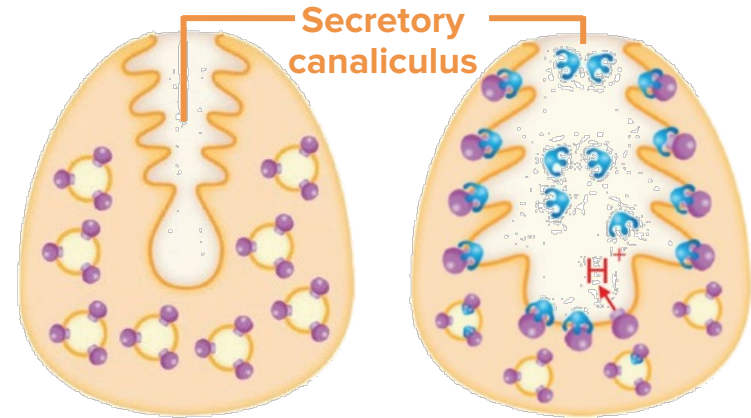
**Quiescent phase**     **Active phase after meal**



- **Short** plasma half-life
- Acid needed for activation but **unstable in presence of acid**
- **Meal required** to stimulate pumps
- ✗ **Slow** onset of action
- ✗ **Limited potency**
- ✗ **Limited duration** of activity



## VOQUEZNA: COMPETITIVE ENZYME INHIBITOR

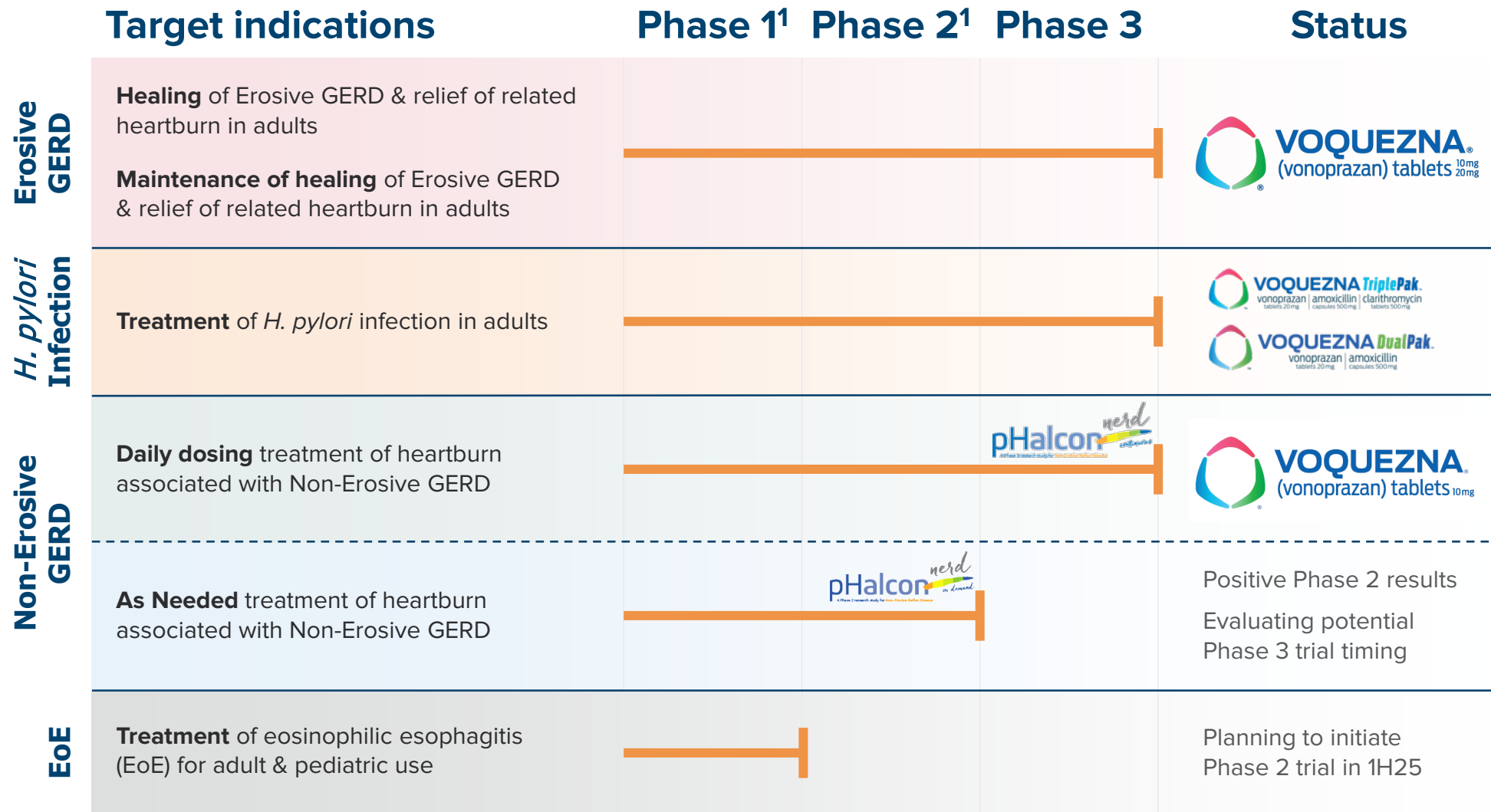


**Quiescent phase**     **Active phase after meal**



- **Long** plasma half-life
- **Stable** in acid
- **High** accumulation in canaliculus
- **Very slow** dissociation rate
- ✓ **Rapid** onset of action
- ✓ **Potent** acid control
- ✓ **Durable** 24-hr activity

# Three approved products across three indications



<sup>1</sup> Phase 1 and 2 studies supporting applications for Erosive GERD and *H. pylori* were conducted by Takeda; Phathom has development & commercialization rights to vonoprazan in the US, Europe, & Canada

# GERD represents a large US market with high unmet need

~65M people in the US with GERD<sup>1,2</sup>

**~45M**  
people with Non-Erosive GERD<sup>1,2</sup>

**~15M adults**  
diagnosed & treated  
with **Non-Erosive GERD**



**\$3 Billion\***  
**VOQUEZNA US**  
potential peak revenue  
opportunity

**~20M**  
people with  
Erosive GERD<sup>1,2</sup>

**~7M adults**  
diagnosed & treated  
with **Erosive GERD\***



## Prescription Based

~85% of the total PPI volume-based market is driven by Rx vs. OTC<sup>3</sup>

~110M PPI TRx are written and filled annually (all indications)<sup>4</sup>



## High Dissatisfaction

Less than 50% of patients are satisfied with their current treatment<sup>5</sup>

<sup>1</sup> El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. Gut. 2014;63(6):871-880. doi:10.1136/gutjnl-2012-304269

<sup>2</sup> Machicado J.D., Greer J.B., Yadav D. (2020) Epidemiology of Gastrointestinal Diseases. In: Pitchumoni C., Dharmarajan T. (eds) Geriatric Gastroenterology. Springer, Cham. [https://doi.org/10.1007/978-3-319-90761-1\\_7-1](https://doi.org/10.1007/978-3-319-90761-1_7-1)

<sup>3</sup> IQVIA NPA & Consumer Health Care Data Q1-3 2022;

<sup>4</sup> IQVIA Xponent retail & mail-order Rx data (2022)

<sup>5</sup> Vaezi MF, Brunton S, Mark Fendrick A, et al. Patient journey in erosive esophagitis: real-world perspectives from US physicians and patients. BMJ Open Gastroenterology 2022


\* Company estimates based on its market research.



# VOQUEZNA vision builds on each indication with the potential to transform the landscape of acid-related disorders and displace PPIs

## Planned Launch Sequence


**Combined  
First Launch**  
4Q 2023




***H. pylori* infection  
(or HP)**  
Increased eradication

**Second Launch**  
3Q 2024

**GERD**



**Erosive GERD**  
(Erosive Esophagitis / EE)  
Improved healing and maintenance



**Non-Erosive GERD**  
Daily dosing  
Lasting symptom control

## GERD Market Opportunity

**~22M<sup>1</sup>**

total treated patients

**~7M**

treated  
Erosive GERD patients

**~15M**


treated  
Non-Erosive GERD patients

**Goal to  
Displace PPIs**

<sup>1</sup> Company estimates based on its market research.

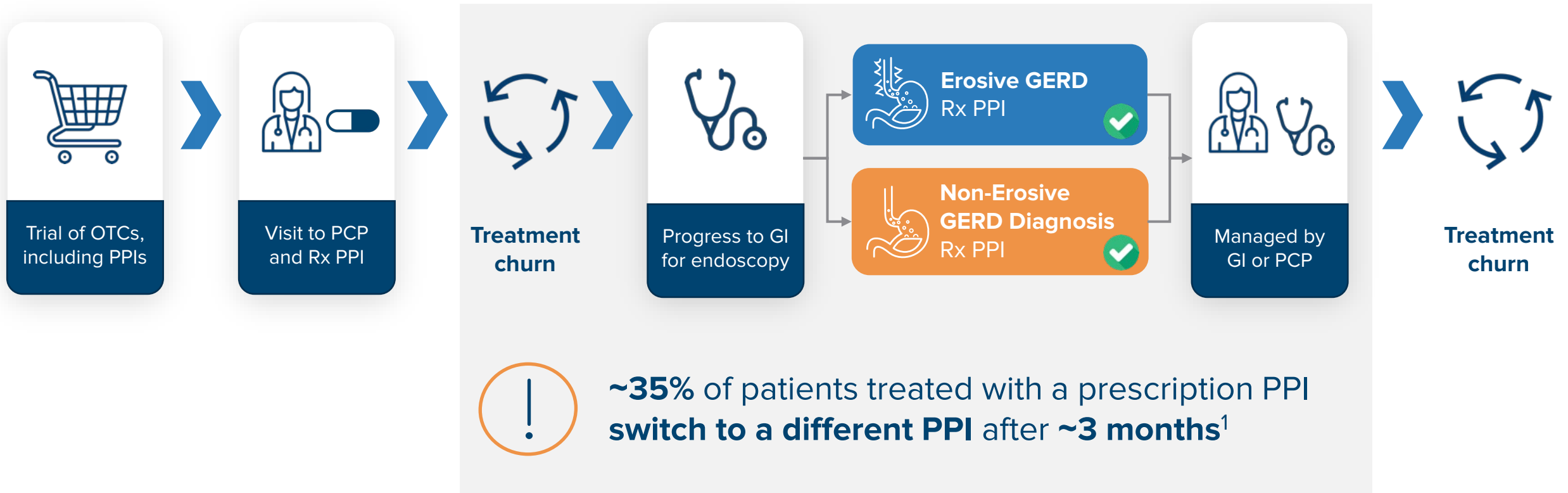
# VOQUEZNA's pharmacologic profile is differentiated compared to existing acid suppression alternatives

|                               | VOQUEZNA® | PPIs | H2R blockers | Antacids | Unsatisfied attribute |
|-------------------------------|-----------|------|--------------|----------|-----------------------|
| Rapid effect                  |           |      |              |          |                       |
| Potent acid suppression       |           |      |              |          |                       |
| Durability of effect          |           |      |              |          |                       |
| Flexibility of administration |           |      |              |          |                       |


 FDA-approved for the treatment of heartburn associated with Non-Erosive GERD in adults as well as the healing and maintenance of healing of Erosive GERD in adults and relief of associated heartburn

# Typical GERD patient journey highlights current dissatisfaction

Erosive & Non-Erosive GERD patient journeys are similar; both include multiple lines of PPI therapy



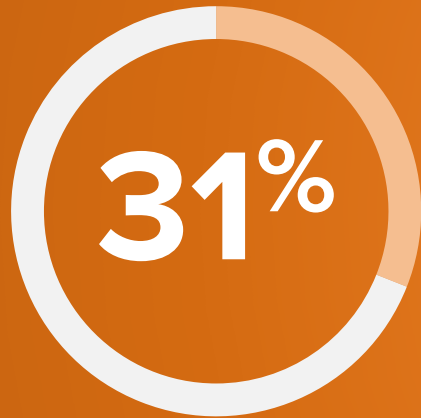
<sup>1</sup> Phathom data on file, diagnosed Erosive GERD patients between Jan. 2016 - Feb. 2022 (n=265,717)  
Source: Visual represents a summary of patient journey qualitative market research, May 2020

# Physician research indicates high intention to prescribe VOQUEZNA



## Erosive GERD

HCPs expect to prescribe VOQUEZNA to 42% of their Erosive GERD patients<sup>1</sup>



## Non-Erosive GERD

HCPs expect to prescribe VOQUEZNA to 31% of their Non-Erosive GERD patients<sup>2</sup>

<sup>1</sup> Erosive GERD Demand Study / Jan 2022 / n=301 (151 GI; 100 PCP; 50 APP)

<sup>2</sup> Non-Erosive Demand Study / July 2023 / n=252 (101 GIs, 100 PCPs and 51 APPs)

# Executing on three core goals during the early stages of launch

**Unique & differentiated profile resonates across all customer segments**

## Consumer

Driving brand awareness and increasing demand



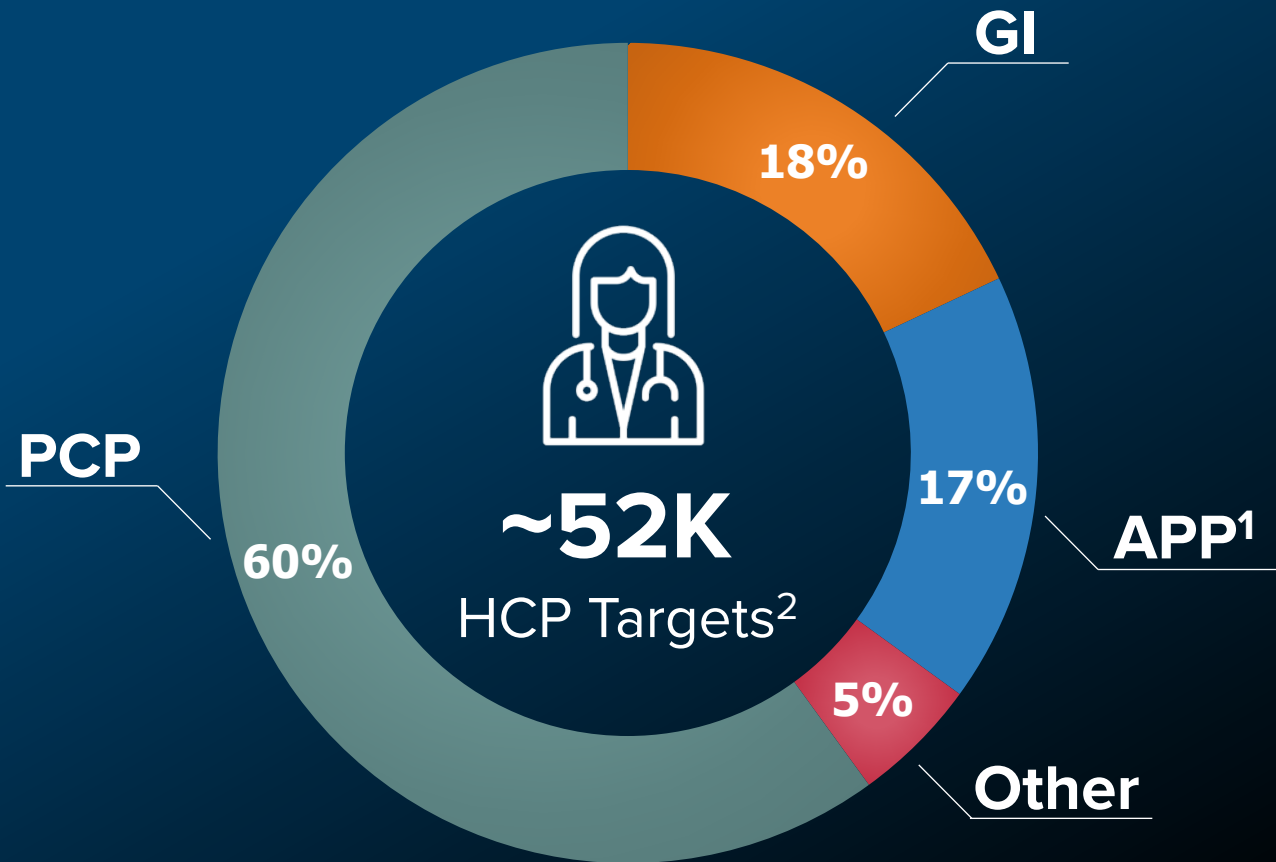
## Physician

Communicating clinical superiority vs. a PPI<sup>1</sup> and establishing VOQUEZNA as a treatment of choice

## Payer

Building widespread access for patients

# The VOQUEZNA sales force is targeting high volume PPI prescribers



**320**

Sales Reps



Targeting high prescribing physicians who write an average **~1,200 PPI TRx annually<sup>2</sup>**

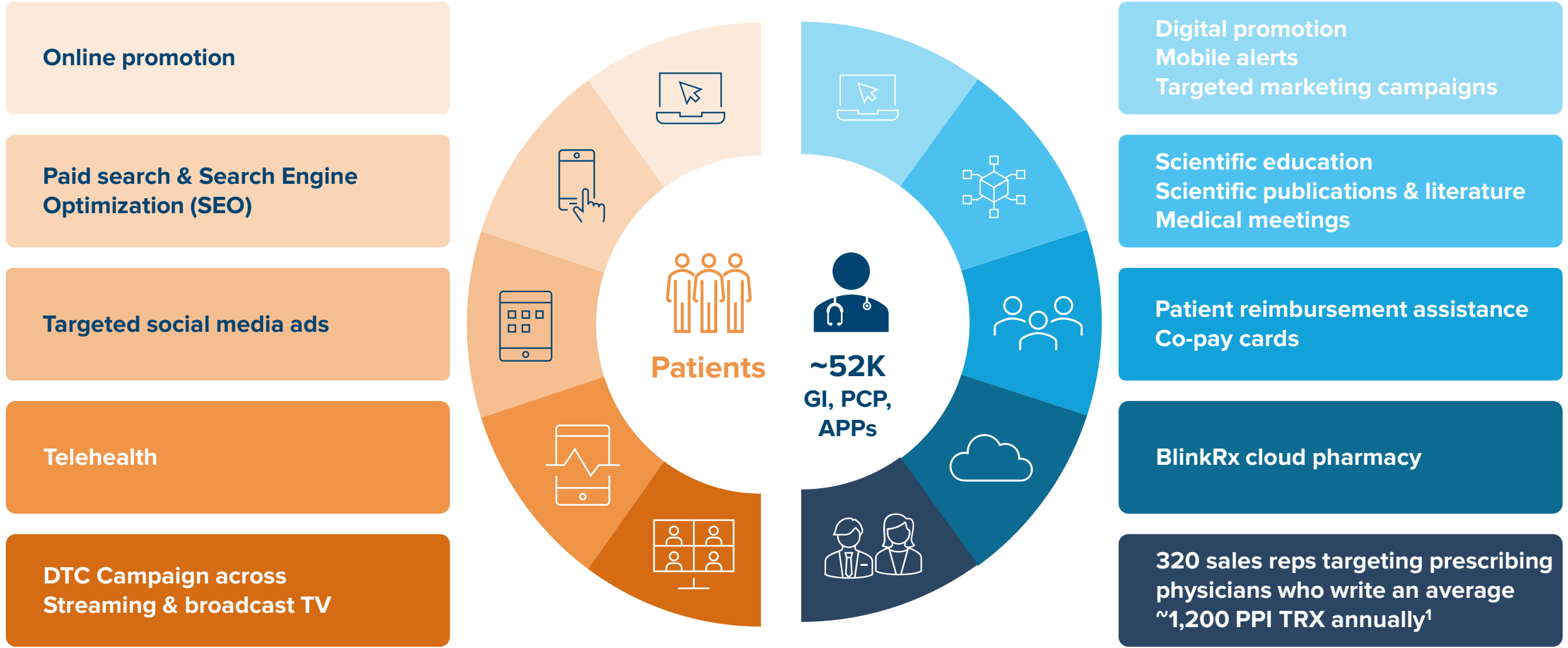
<sup>1</sup> APPs = advanced practice provider (i.e., nurse practitioners and physician assistants)

<sup>2</sup> IQVIA APLD (Nov 2020 – Oct 2022) and IQVIA Xponent (Dec 2020 – Nov2022); Annual PPI prescription metric is based on total prescribing across all indications

# Promotional plans active across consumer and physician audiences

Consumers are responsive to comprehensive launch activation tactics resulting in high demand for VOQUEZNA

High volume HCPs are being reached by salesforce coupled with broad and aggressive communication campaign



<sup>1</sup> IQVIA APLD (Nov 2020 – Oct 2022) and IQVIA Xponent (Dec 2020 – Nov 2022); Annual PPI prescription metric is based on total prescribing across all indications

# Full-scale DTC Campaign aims to motivate patients to request VOQUEZNA

**VOQUEZNA CAN KICK SOME ACID**

ONCE-DAILY PILL

PROVEN TO HELP RELIEVE HEARTBURN

NOW APPROVED FOR  
**NON-EROSIVE  
GERD**

**LIVE**  
ON BROADCAST  
TELEVISION!

**VOQUEZNA**  
(vonoprazan) tablets 10mg 20mg



# Widespread commercial coverage with large payers and additional support in place for patients who face access or affordability challenges



>80%

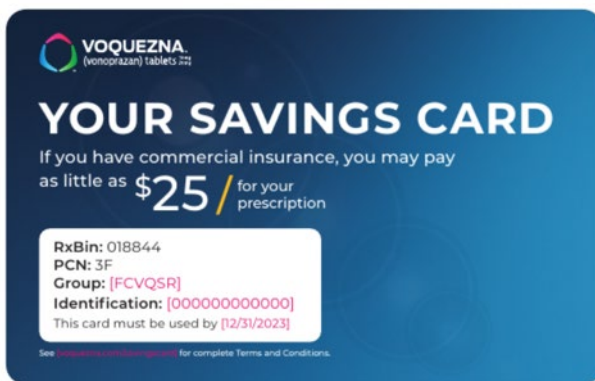
commercial coverage<sup>1</sup>

>120M

commercial lives covered<sup>1</sup>

Broad access with placement on major commercial formularies

## Patient Co-Pay Assistance<sup>2</sup>



## Enhanced Patient Access



- Low out-of-pocket cost for eligible patients
- Simple patient experience
- Prior Authorization support
- Free at-home delivery
- Available nationwide
- Dedicated customer support

<sup>1</sup> Per MMIT formulary lookup tool as of 11/1/2024.

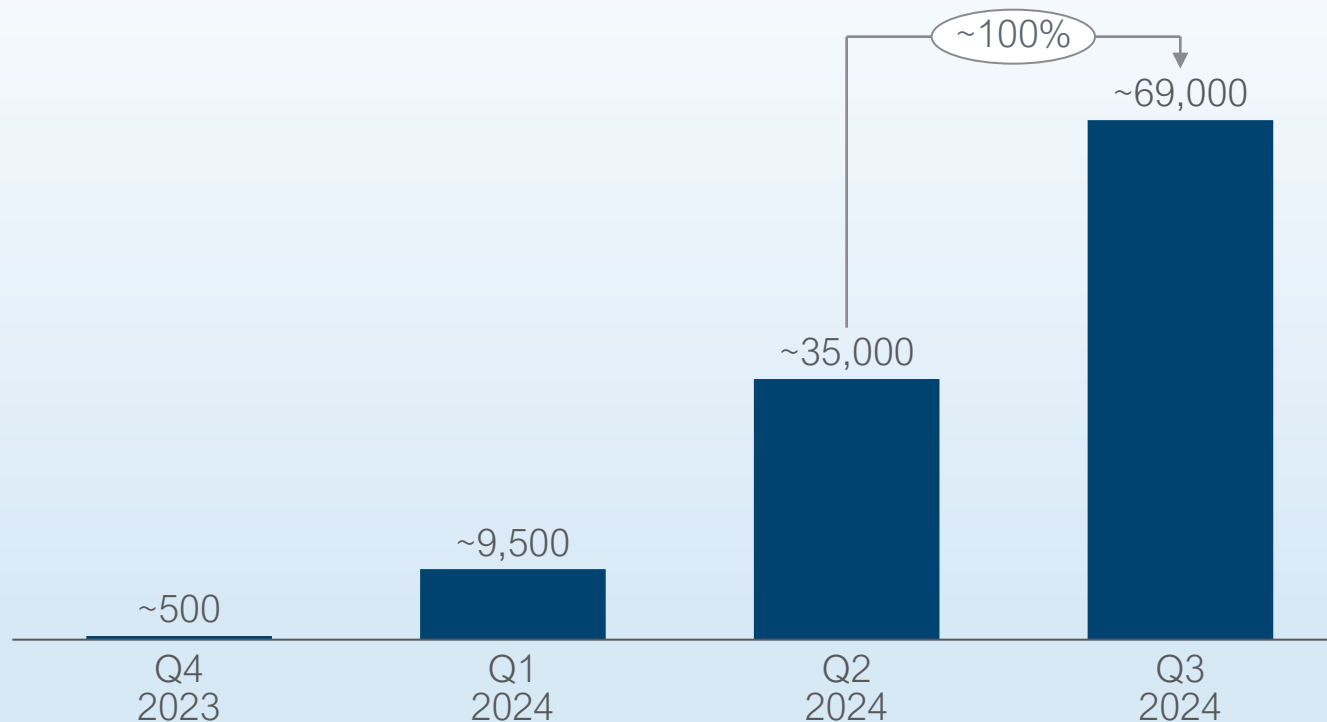
<sup>2</sup> Eligible, commercially insured patients may pay as little as \$25 per prescription fill of VOQUEZNA; Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs; See [VOQUEZNA.com](https://voquezna.com) for full program eligibility terms and conditions

# Early Non-Erosive GERD launch data fueled continued growth in Q3



  
**143,000+**  
Filled Prescriptions  
Launch-to-Date<sup>1</sup>  
Previously: 60,000+ (as of 7/26/24)

### Quarterly Filled Prescriptions<sup>1</sup>

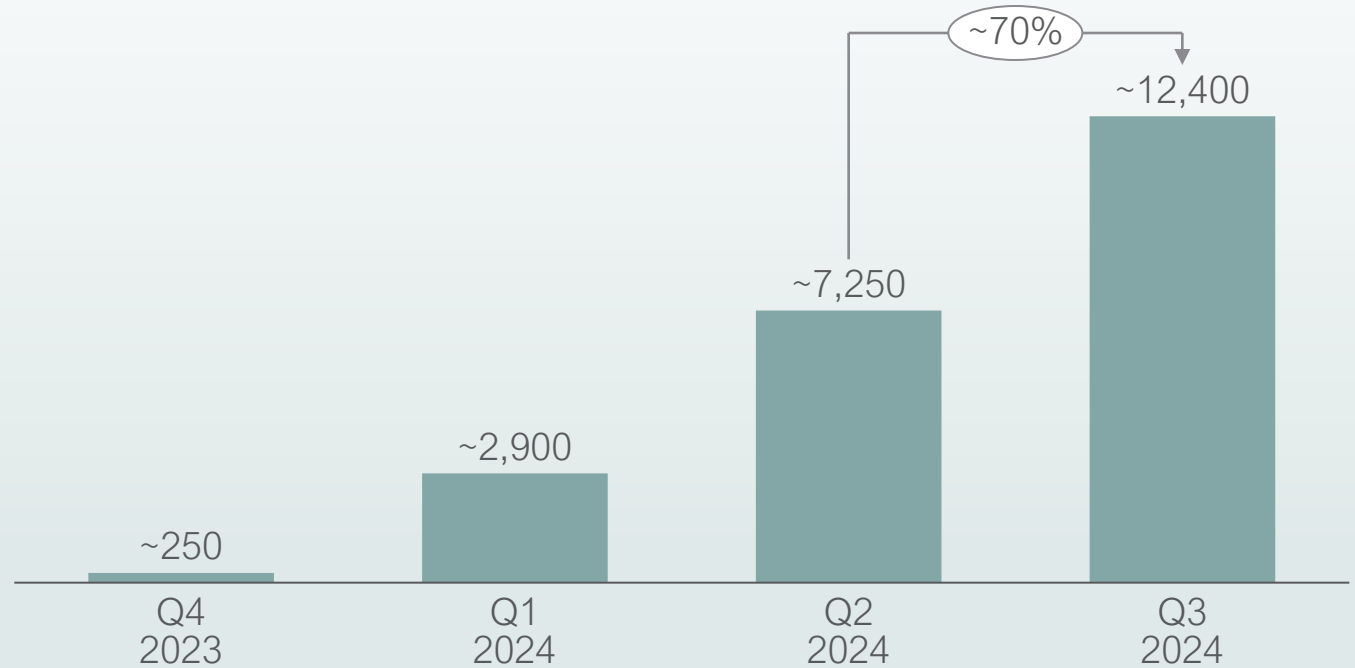


# Growth in writers continues to indicate strong adoption



  
**13,600+**  
Cumulative Writers  
Launch-to-Date<sup>1</sup>  
Previously: 8,200+ (as of 7/19/24)

Quarterly Cumulative Writers<sup>1</sup>



# Significant opportunity and attractive commercial dynamics exist for blockbuster potential

## High Unmet Needs



Large population & high level of dissatisfaction

## Differentiated Profile



Novel MOA & clinical differentiation

## Physician Attractiveness



Strong physician interest & concentrated high prescribers

## No Branded Competition



No branded competition & share of voice ownership

**Goal to displace PPIs and become the #1 selling acid suppressant**

# Financial highlights

Revenues:  
**\$16.4M**

in Q3 2024  
net revenues

*(as of September 30, 2024)*

Cash Balance:  
**\$334.7M**

in cash and  
cash equivalents

*(as of September 30, 2024)*

Equity Offering:  
**\$130M**

gross proceeds  
from August 2024  
equity offering<sup>1</sup>

*(closed August 20, 2024)*

Debt Facility:  
**\$300M**

**\$175M** principal  
outstanding

**\$125M** potentially  
available<sup>2</sup>

**Based on our current operating plan:**

We believe our existing cash, cash equivalents, and other anticipated capital<sup>3</sup>  
will be sufficient to **enable us to reach cashflow positivity**

<sup>1</sup> Gross and net proceeds include pre-funded warrants. Net proceeds were approximately \$121.7M, which reflects deductions for underwriting discounts and commissions and estimated offering expenses.

<sup>2</sup> The remaining \$125M of the \$300M term loan, is potentially available in three tranches: (1) \$25M through December 15, 2024 (2) \$50M subject to the achievement of a specified revenue milestone through June 30, 2025 (3) \$50M subject to the achievement of a specified revenue milestone through December 31, 2025.

<sup>3</sup> Assumes full drawdown and availability of the remaining \$125M under the amended term loan and anticipated future product sales, pursuant to the operating plan.

# Regulatory exclusivity potentially through November 2032



## Potential Regulatory Exclusivity

**5 years NCE** exclusivity +  
**5 years GAIN Act NCE\*** exclusivity +  
**6 months pediatric** exclusivity\*\* =  
**November 2032**



## Key Considerations

- GAIN Act NCE exclusivity tied to the active moiety, vonoprazan, with potential to apply to all Phathom products containing vonoprazan, regardless of indication
- First ANDA seeking approval of a generic vonoprazan cannot be filed until expiration of regulatory exclusivity
- Subsequent generic launch timing subject to FDA review and approval



## Patent Exclusivity\*\*\*

### Vonoprazan Species

**Vonoprazan Species  
US Patent**  
7,977,488 expires  
Aug. 11, 2028

**Expiration date**  
with expected patent  
term extension:  
April 2030\*\*\*\*

### Vonoprazan Fumarate

**Vonoprazan Fumarate  
Formulation US Patent**  
9,186,411 expires  
Aug. 11, 2030

\* On December 11, 2024 we submitted a Citizen Petition seeking correction of our VOQUEZNA Orange Book listings to reflect the full 10 years of NCE exclusivity

\*\* Subject to timely completion of pediatric studies and reports

\*\*\* All patent terms will be extended by 6 months if pediatric exclusivity is granted, subject to timely completion of pediatric studies and reports

\*\*\*\* Subject to grant of patent term extension by USPTO



**VOQUEZNA**<sup>®</sup>  
(vonoprazan) tablets <sup>10mg</sup>  
<sup>20mg</sup>

**RAPID**

**POTENT**

**DURABLE**

# Appendix: Phathom's Clinical Trial Results

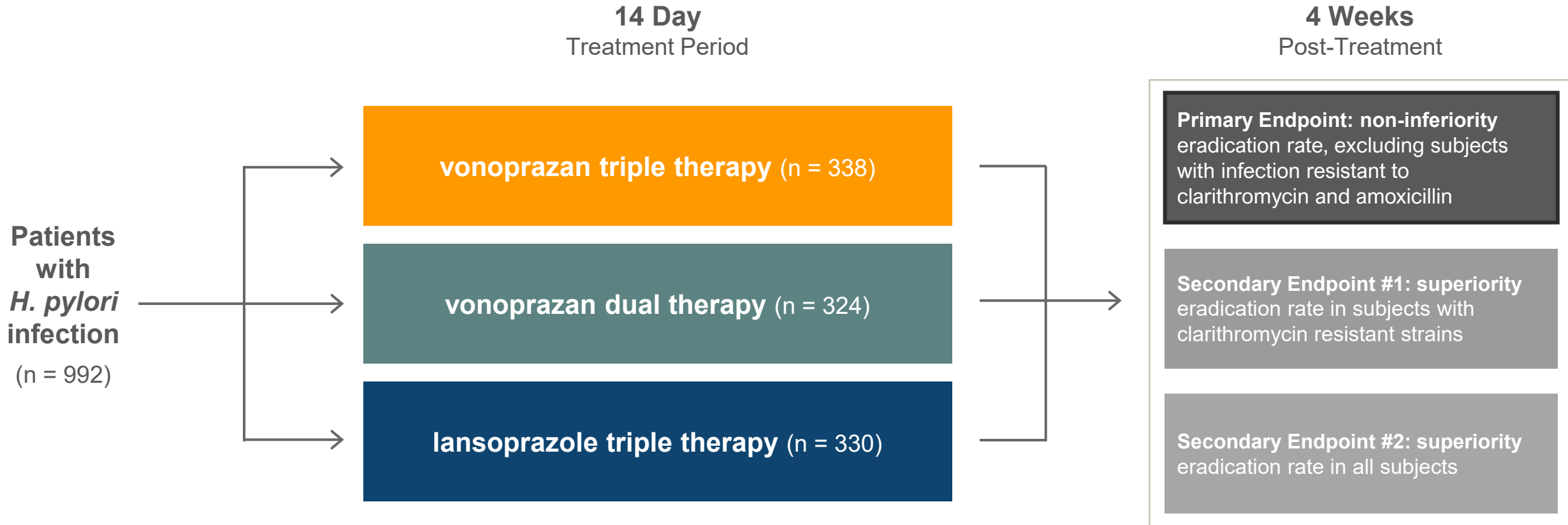


# PHALCON-HP

Phase 3 trial for *H. pylori* infection

Phathom<sup>®</sup>  
PHARMACEUTICALS

# PHALCON-HP Phase 3 study design



Diagnosis of infection and test of cure confirmed by <sup>13</sup>C-urea breath test

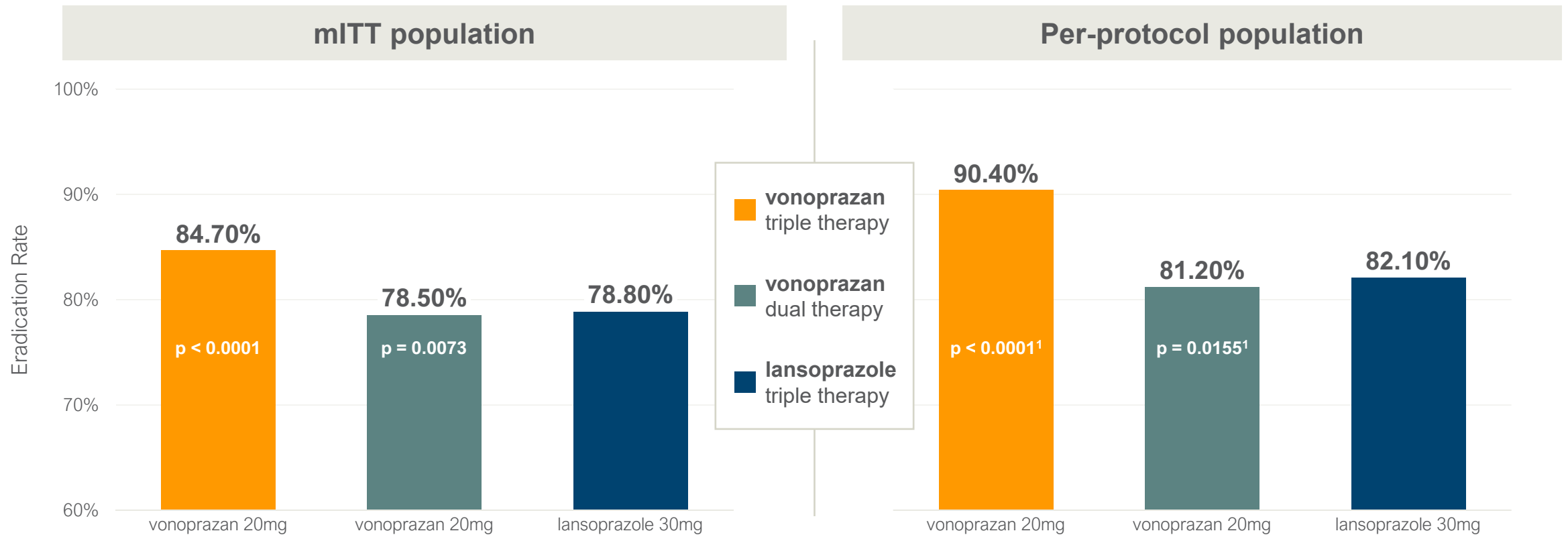
Vonoprazan dual therapy = vonoprazan 20 mg BID + amoxicillin 1 g TID

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 met primary endpoints

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

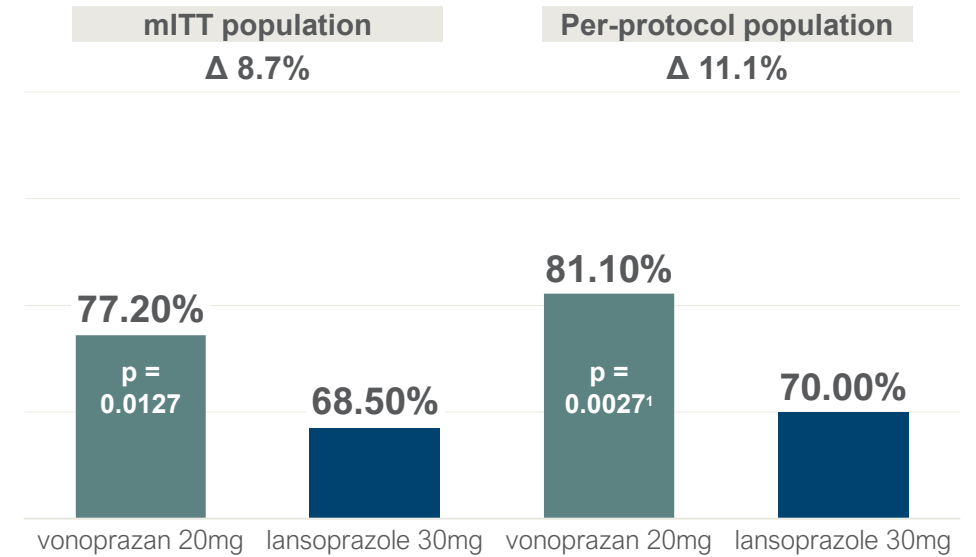
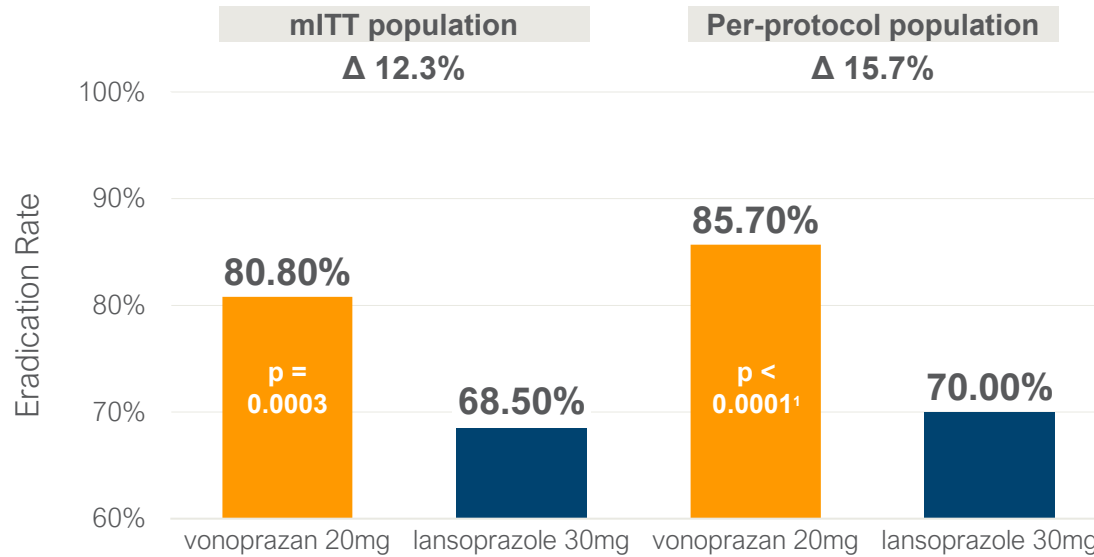


# Both vonoprazan-based therapies met superiority for secondary endpoints

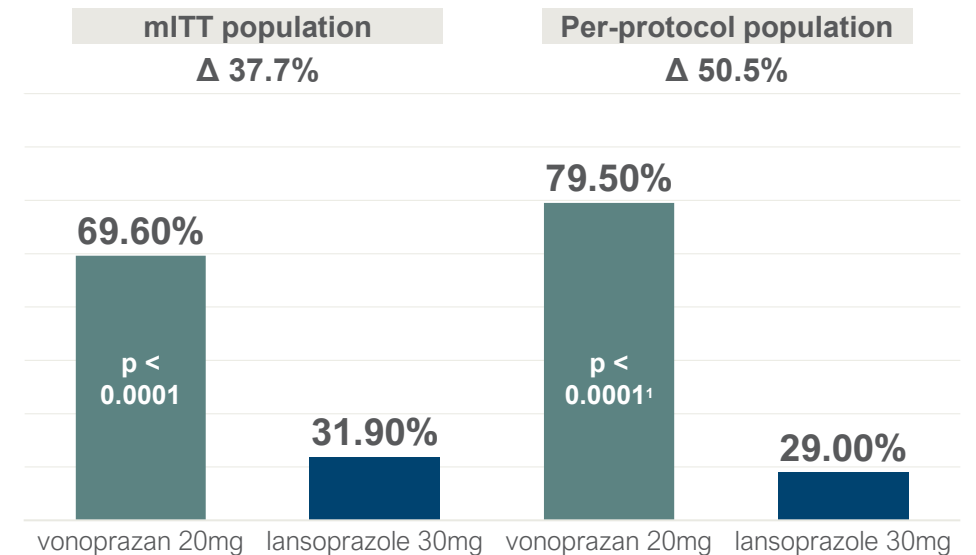
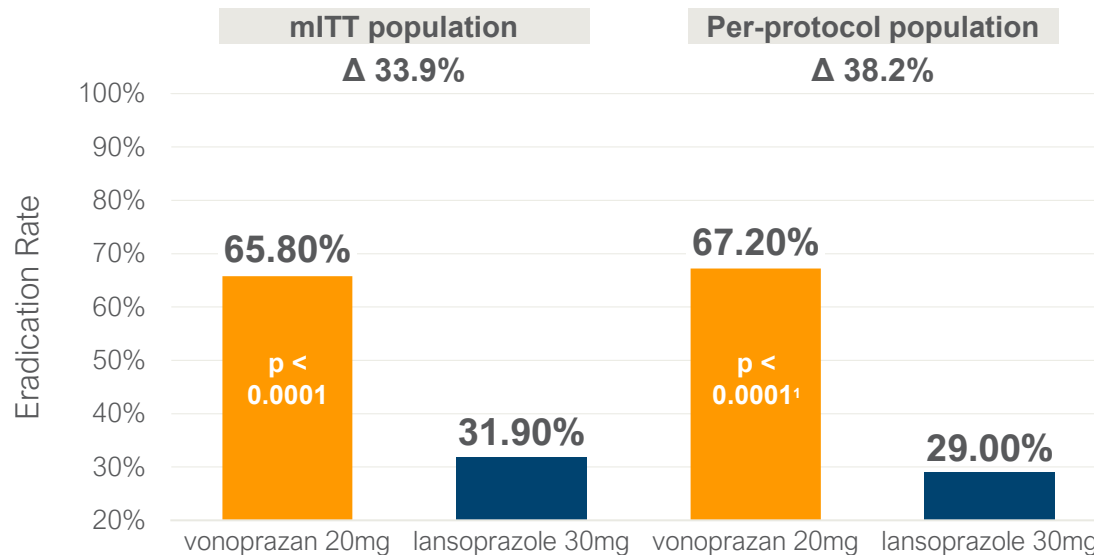
## Vonoprazan triple therapy

## Vonoprazan dual therapy

all subjects



subjects with clarithromycin resistant strains



# 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

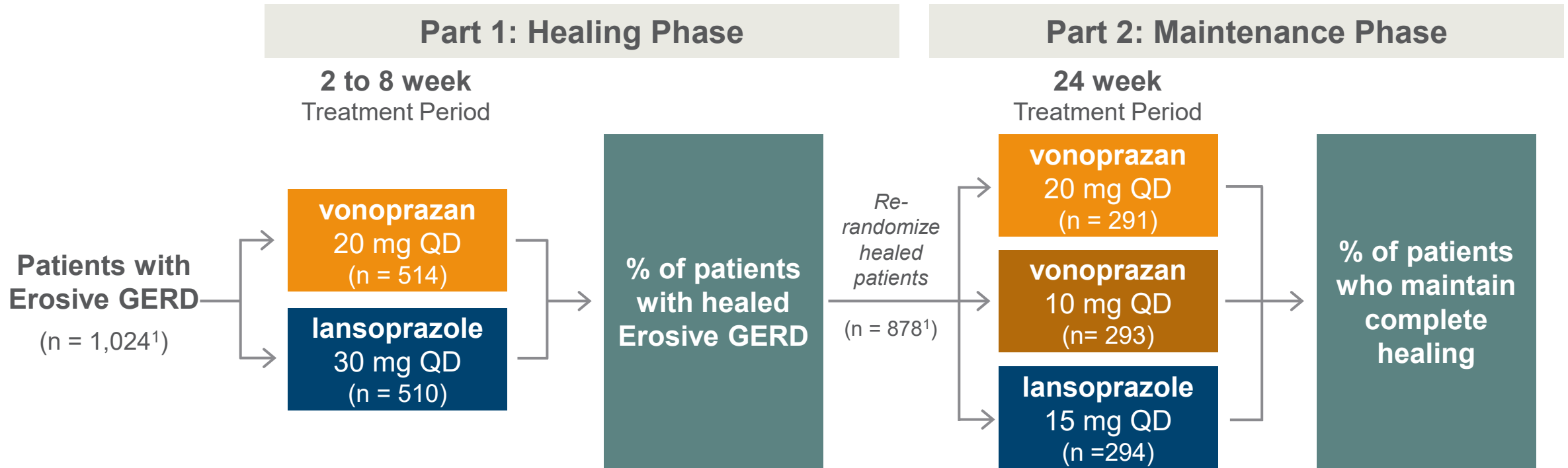
# PHALCON-EE

Phase 3 trial for Erosive GERD

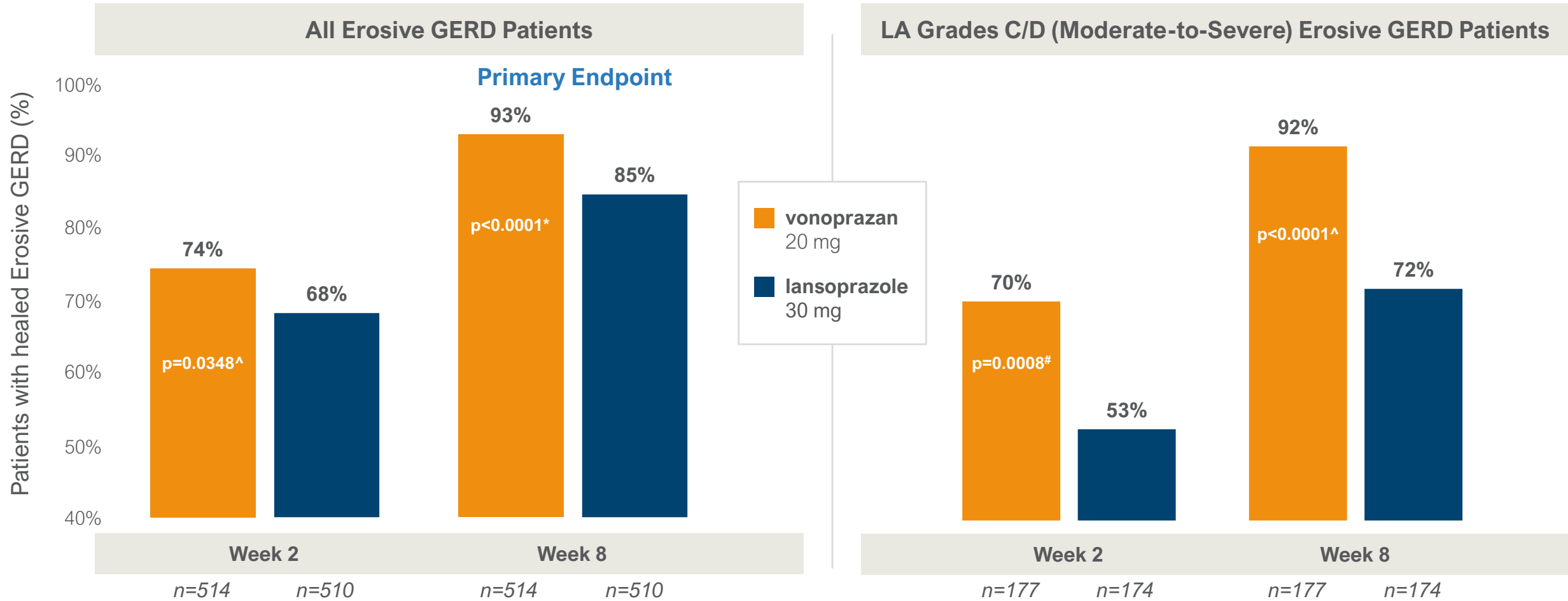
Phathom<sup>®</sup>  
PHARMACEUTICALS

# PHALCON-EE Phase 3 study design

## US/Europe study in Erosive GERD



# PHALCON-EE Phase 3 met primary and key secondary healing endpoints



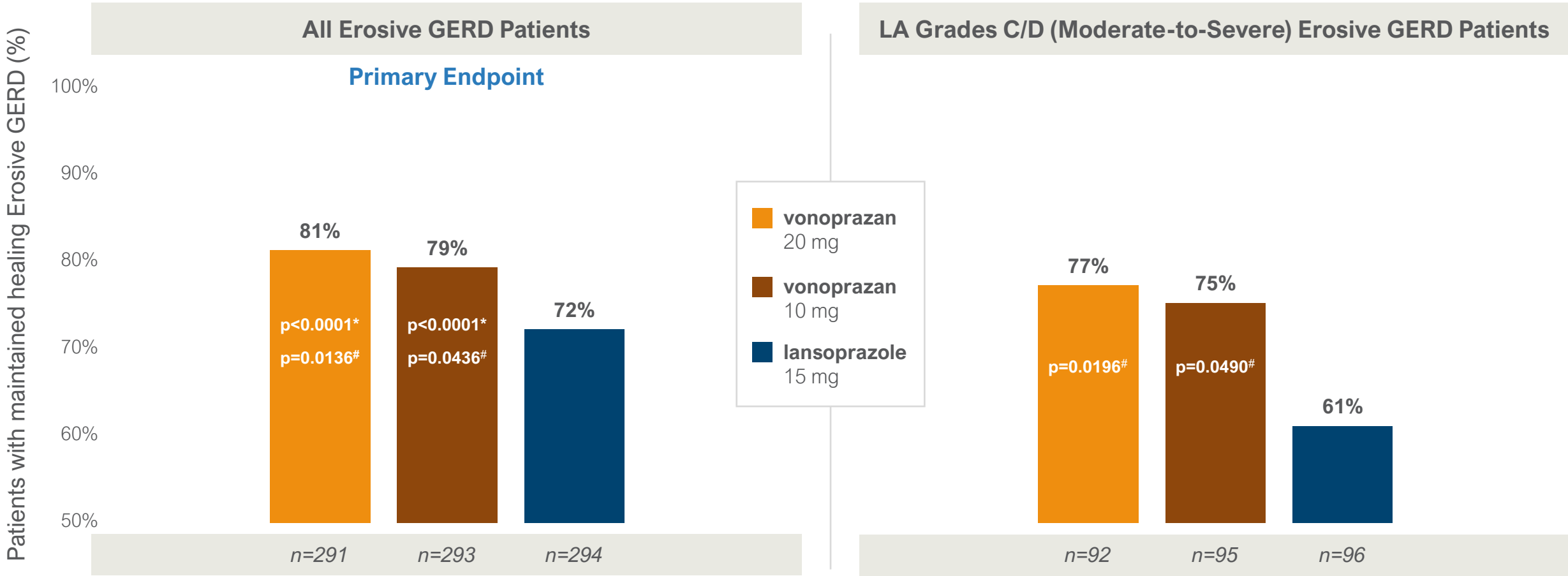
^ nominal p-value presented, superiority comparison, not formally tested based on pre-specified testing hierarchy

\* p-value for both primary non-inferiority endpoint and unadjusted p-value for exploratory superiority comparison

# p-value for pre-specified secondary endpoint superiority comparison



# PHALCON-EE Phase 3 met all maintenance of healing endpoints



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

# Summary of PHALCON-EE Phase 3 safety data

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

## Healing Phase

### Most Common Adverse Events

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

## Maintenance Phase

### Most Common Adverse Events (≥ 5%)

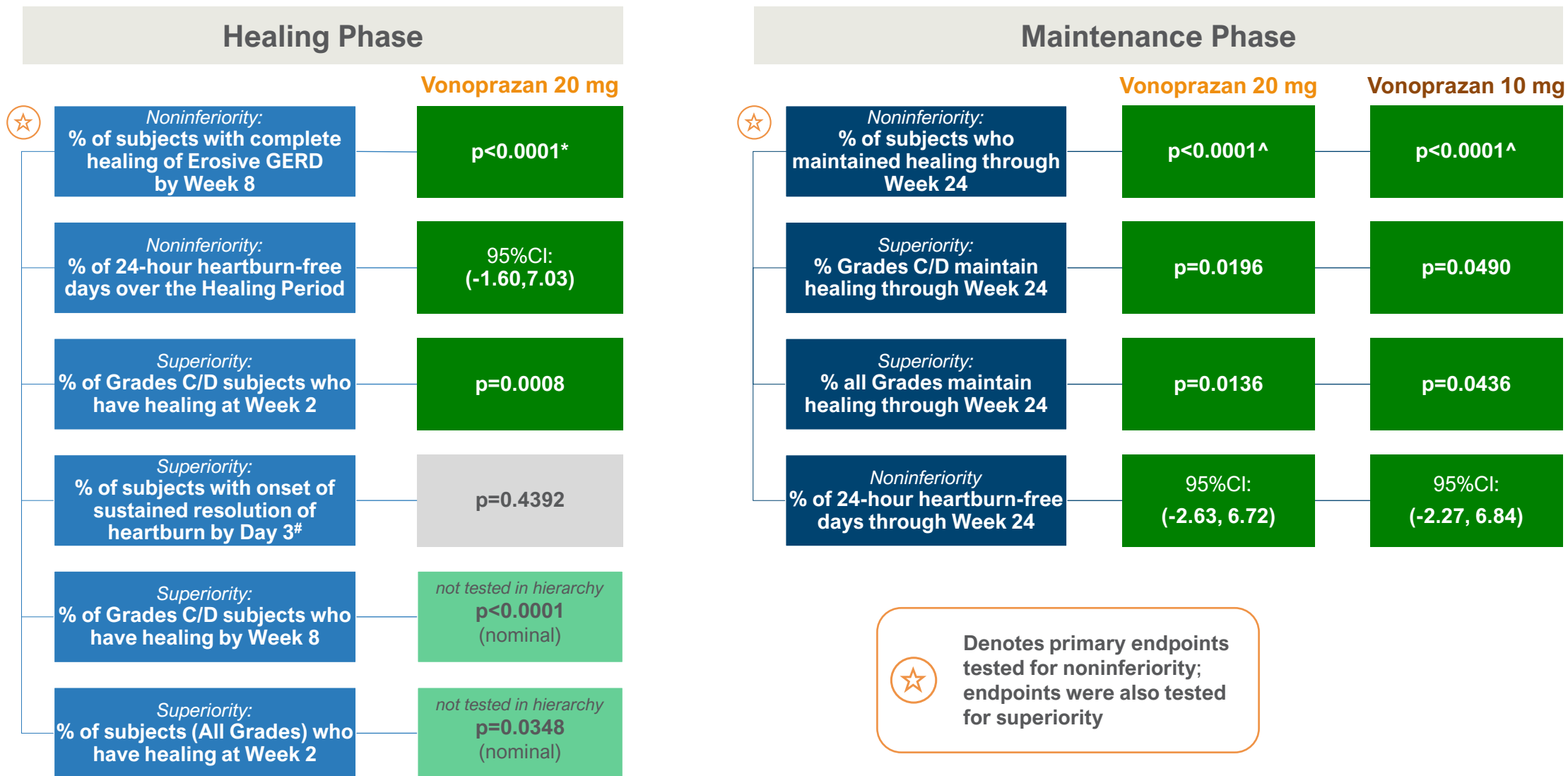
| % (n)          | Vonoprazan<br>20 mg | Vonoprazan<br>10 mg | Lansoprazole<br>15 mg |
|----------------|---------------------|---------------------|-----------------------|
| Abdominal Pain | 5.4% (16)           | 4.1% (12)           | 2.4% (7)              |
| Gastritis      | 2.7% (8)            | 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<br>20 mg | Vonoprazan<br>10 mg | Lansoprazole<br>15 mg |
|---------------------------|---------------------|---------------------|-----------------------|
| COVID-19 <sup>1</sup> (n) | 5                   | 2                   | 0                     |

# PHALCON-EE Phase 3 met primary and key secondary endpoints



\* Healing phase primary endpoint, exploratory superiority comparison, nominal p<0.0001

^ Maintenance phase primary endpoint, prespecified secondary superiority comparison: vonoprazan 20 mg: p=0.0136; vonoprazan 10 mg: p=0.0436

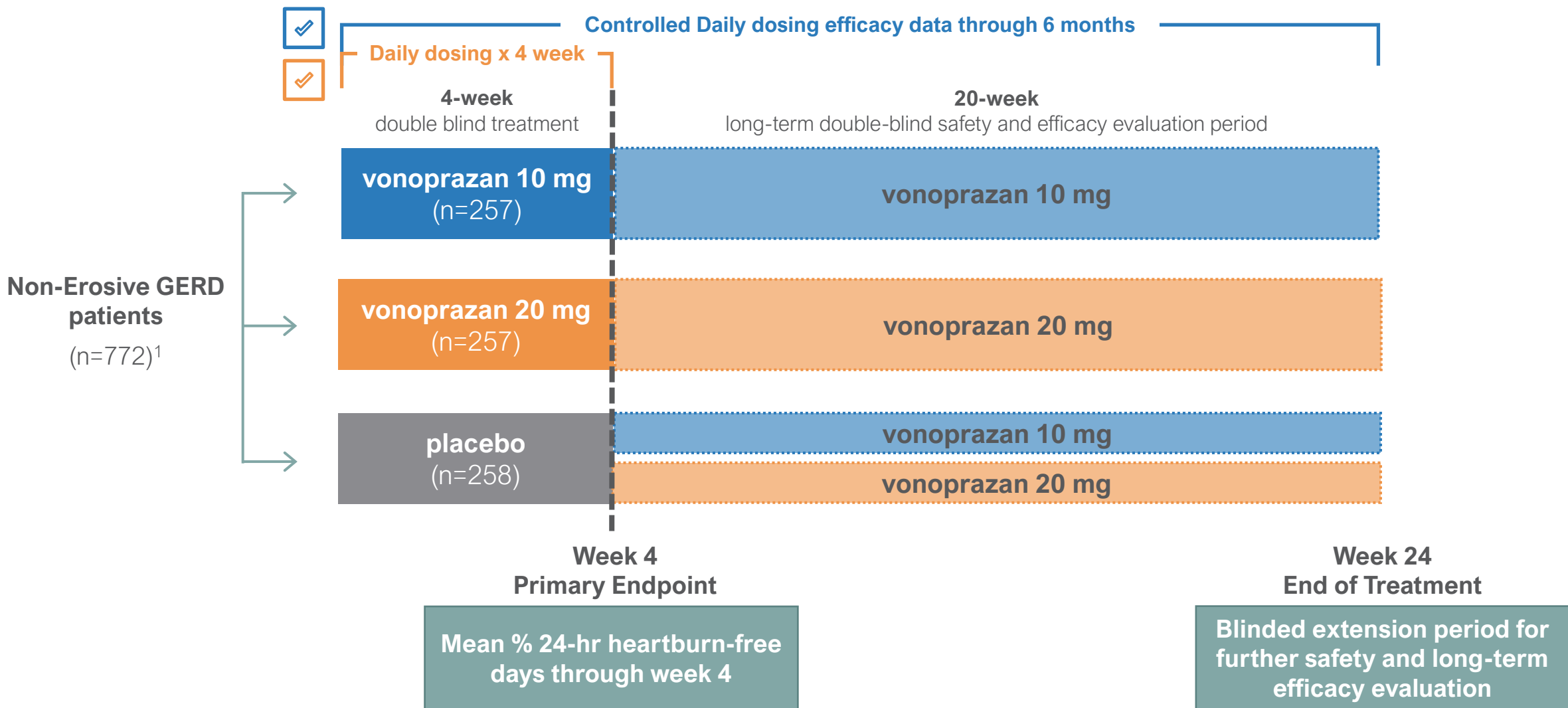
# Sustained resolution of heartburn is defined as seven (7) consecutive days without heartburn symptoms. For this test to be satisfied a patient must commence the seven consecutive day period on either day 1, 2 or 3 and last, respectively, up to day 7, day 8 or day 9.

# PHALCON-NERD-301

Phase 3 trial for Non-Erosive GERD

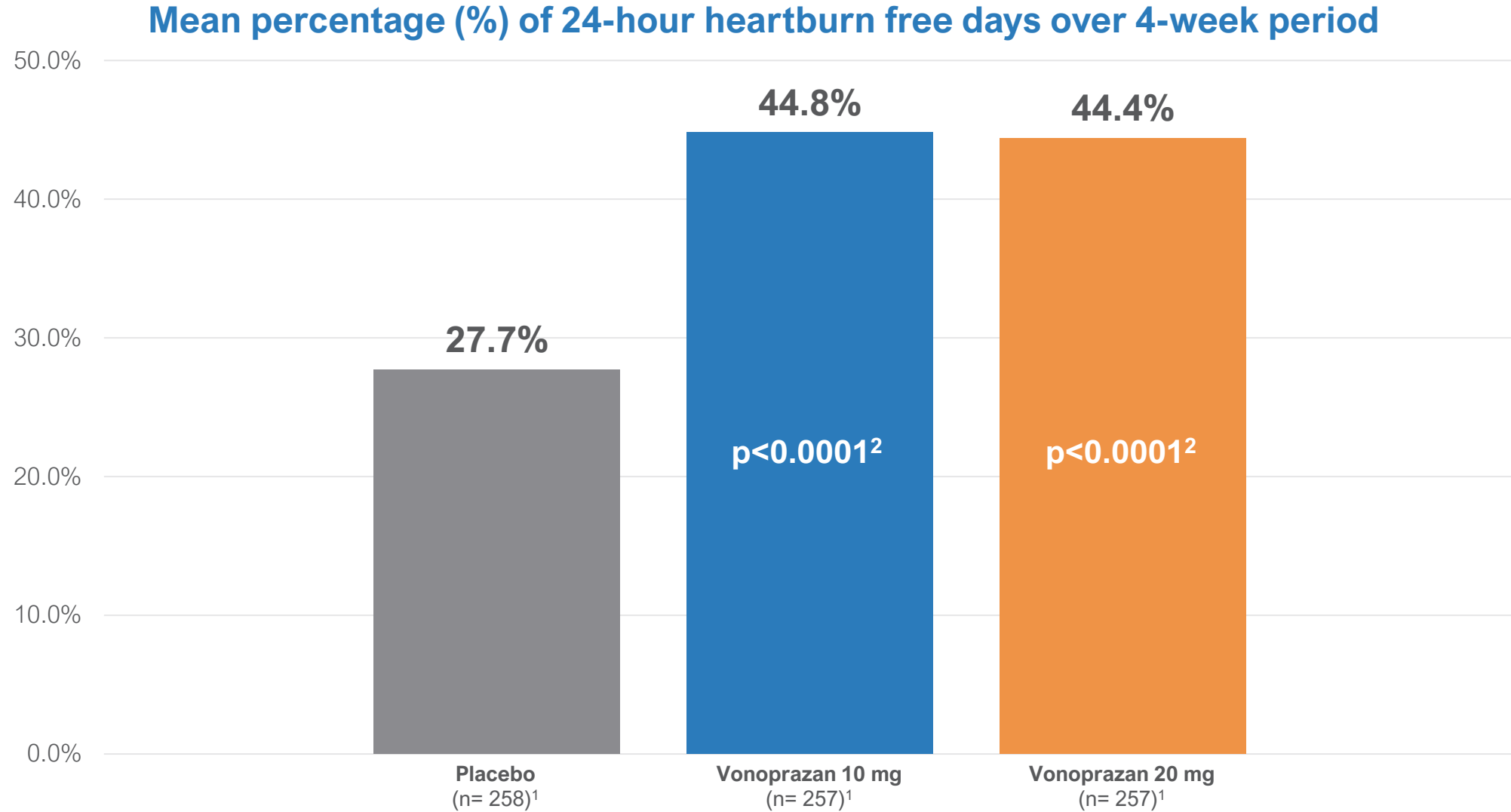
# PHALCON-NERD-301 Phase 3 Daily dosing trial design

Vonoprazan 10 mg dose was submitted in sNDA for treatment of Non-Erosive GERD



<sup>1</sup> A total of 772 patients with Non-Erosive GERD were randomized and dosed

# PHALCON-NERD-301 met the primary endpoint for both doses



<sup>1</sup> Intent-to-Treat Set: All subjects who received at least one dose of study medication, randomized treatment

<sup>2</sup> p-values from general linear model with treatment group as a factor and severity and frequency of heartburn at baseline as covariates

# Summary of 4-week placebo-controlled period of PHALCON-NERD-301

Primary endpoint: mean percentage of 24-hour heartburn free days

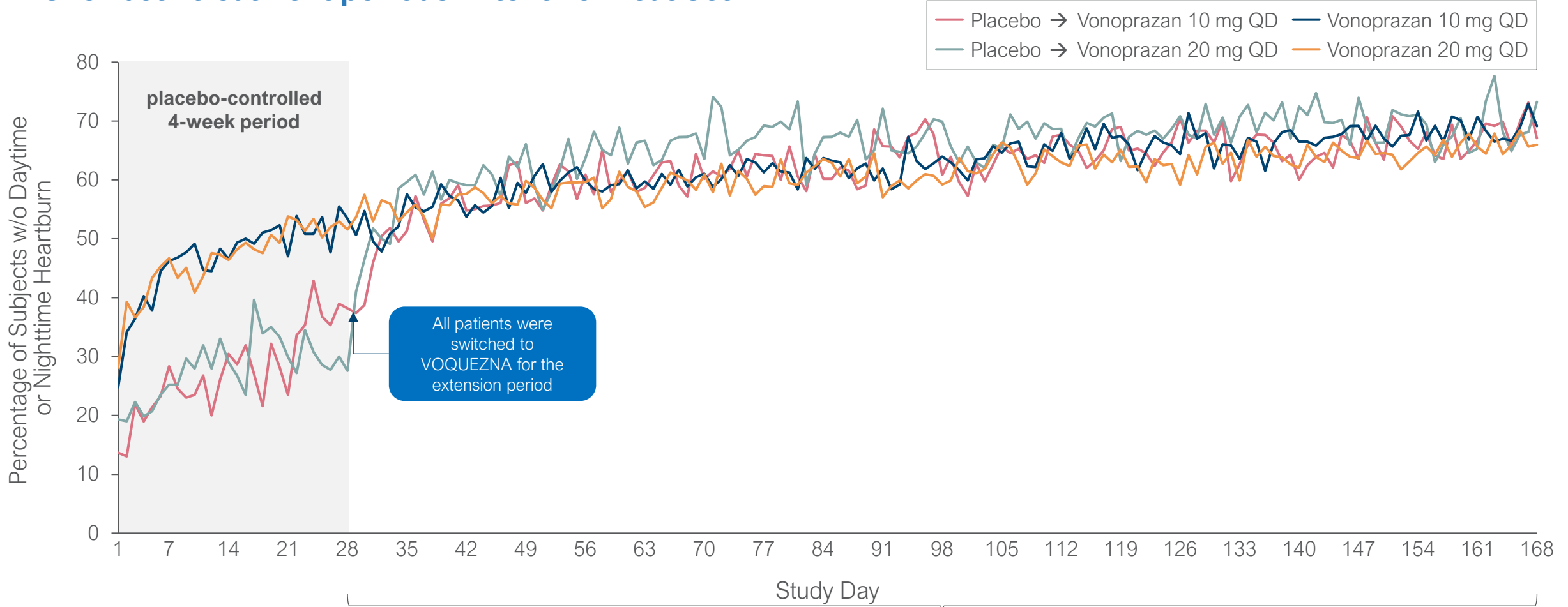
| <b>% of 24-hr heartburn free days</b>  | <b>Placebo<br/>(n=258)<sup>1</sup></b> | <b>Vonoprazan 10 mg<br/>(n=257)<sup>1</sup></b> | <b>Vonoprazan 20 mg<br/>(n=257)<sup>1</sup></b> |
|--|--|---|---|
| <b>Mean</b>                            | <b>27.7%</b>                           | <b>44.8%</b>                                    | <b>44.4%</b>                                    |
| <b>P-value vs. Placebo<sup>2</sup></b> | <b>--</b>                              | <b>p&lt;0.0001</b>                              | <b>p&lt;0.0001</b>                              |
| <b>Median</b>                          | <b>16.7%</b>                           | <b>48.1%</b>                                    | <b>46.4%</b>                                    |

<sup>1</sup> Intent-to-Treat Set: All subjects who received at least one dose of study medication, randomized treatment

<sup>2</sup> p-values from general linear model with treatment group as a factor and severity and frequency of heartburn at baseline as covariates

# PHALCON-NERD-301 percentage of subjects without heartburn

## Over both treatment periods: Intent-To-Treat Set<sup>1</sup>



| Exploratory 20-Week Extension Period (Not Placebo-Controlled): Mean % of 24-hr Heartburn Free Days <sup>2</sup> |                            |                  |                  |
|---|----------------------------|------------------|------------------|
| Placebo → Vonoprazan 10 mg  | Placebo → Vonoprazan 20 mg | Vonoprazan 10 mg | Vonoprazan 20 mg |
| 61.9%   | 62.9%                      | 62.6%            | 60.7%            |

<sup>1</sup> Intent-to-Treat Set: All subjects who received at least one dose of study medication, randomized treatment

<sup>2</sup> The 20-week extension period was not placebo-controlled; descriptive analysis only; no statistical comparisons were conducted



# Summary of PHALCON-NERD-301 safety data

## Most Common Adverse Events<sup>1</sup> (≥ 2%), Safety Set<sup>2</sup>

Overall, the safety results observed in PHALCON-NERD-301 were consistent with those observed in prior clinical studies of vonoprazan

### 4-week placebo-controlled period

| % (n)          | Placebo<br>(n=256) | Vonoprazan<br>10 mg<br>(n=259) | Vonoprazan<br>20 mg<br>(n=257) |
|----------------|--------------------|--------------------------------|--------------------------------|
| Abdominal Pain | 0.8% (2)           | 1.5% (4)                       | 2.3% (6)                       |
| Constipation   | 0.8% (2)           | 2.3% (6)                       | 0.8% (2)                       |
| Diarrhea       | 1.2% (3)           | 2.3% (6)                       | 0.4% (1)                       |
| Nausea         | 0.4% (1)           | 2.3% (6)                       | 3.1% (8)                       |

Serious Adverse Events<sup>1</sup> from the Safety Set<sup>2</sup> (n):

- Placebo: n/a (--)
- Vonoprazan 10 mg: viral pericarditis (1)
- Vonoprazan 20 mg: salivary gland calculus (1), fibula/tibia fracture (1)

### 20-week extension period

| % (n)                             | Placebo →<br>Vonoprazan 10 mg<br>(n = 118) | Placebo →<br>Vonoprazan 20 mg<br>(n = 121) | Vonoprazan<br>10 mg<br>(n = 248) | Vonoprazan<br>20 mg<br>(n = 236) |
|-----------------------------------|--|--|----------------------------------|----------------------------------|
| Upper Respiratory Tract Infection | 1.7% (2)                                   | 0.8% (1)                                   | 4.8% (12)                        | 2.1% (5)                         |
| Sinusitis                         | 1.7% (2)                                   | 1.7% (2)                                   | 3.2% (8)                         | 1.3% (3)                         |
| Influenza                         | 3.4% (4)                                   | 1.7% (2)                                   | 2.0% (5)                         | 1.3% (3)                         |
| Urinary Tract Infection           | 1.7% (2)                                   | --   | 2.0% (5)                         | 2.5% (6)                         |
| Nasopharyngitis                   | 1.7% (2)                                   | --   | --                               | 2.1% (5)                         |
| Gastroenteritis                   | 1.7% (2)                                   | 0.8% (1)                                   | 0.4% (1)                         | 2.1% (5)                         |
| Nausea                            | 0.8% (1)                                   | 0.8% (1)                                   | 1.2% (3)                         | 2.1% (5)                         |

<sup>1</sup> Summary results only include adverse events that are treatment emergent (i.e., started after treatment)

<sup>2</sup> Among all subjects who received at least one dose of study medication, actual treatment received

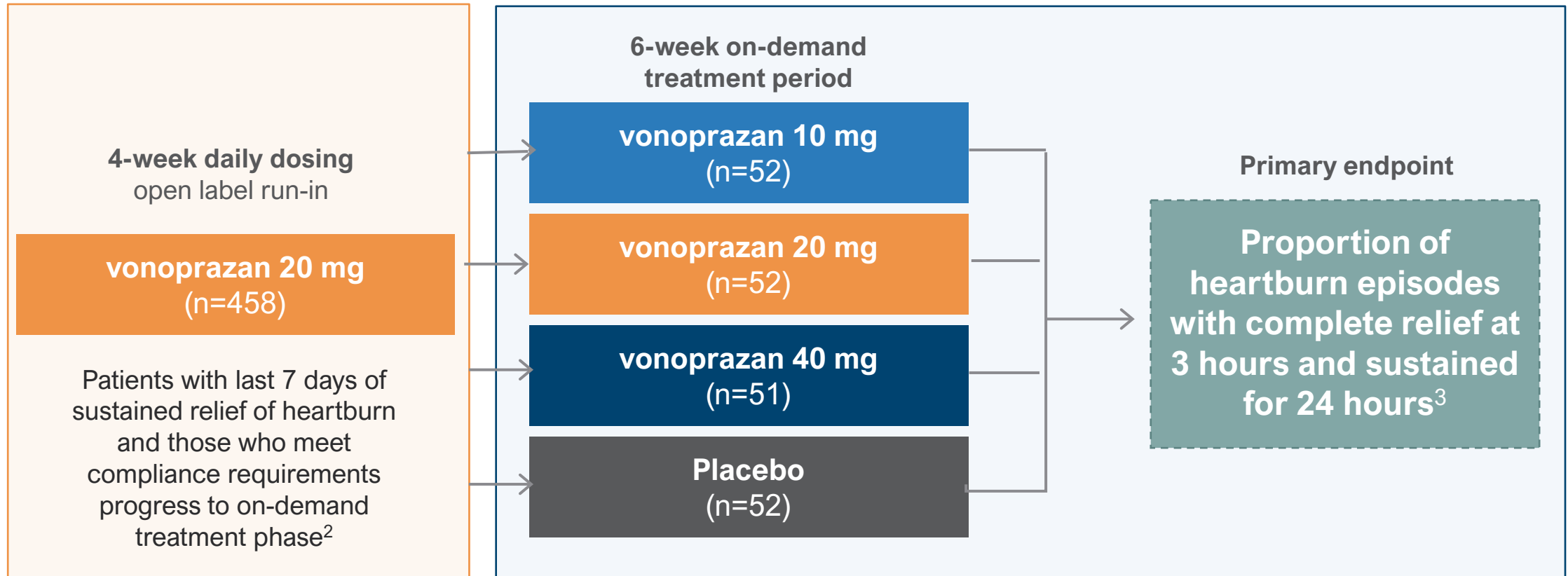
# PHALCON-NERD-201

Phase 2 trial for Non-Erosive GERD

# PHALCON-NERD-201 phase 2 trial design (*completed*)

## Daily dosing treatment phase

## On-demand treatment phase<sup>1</sup>



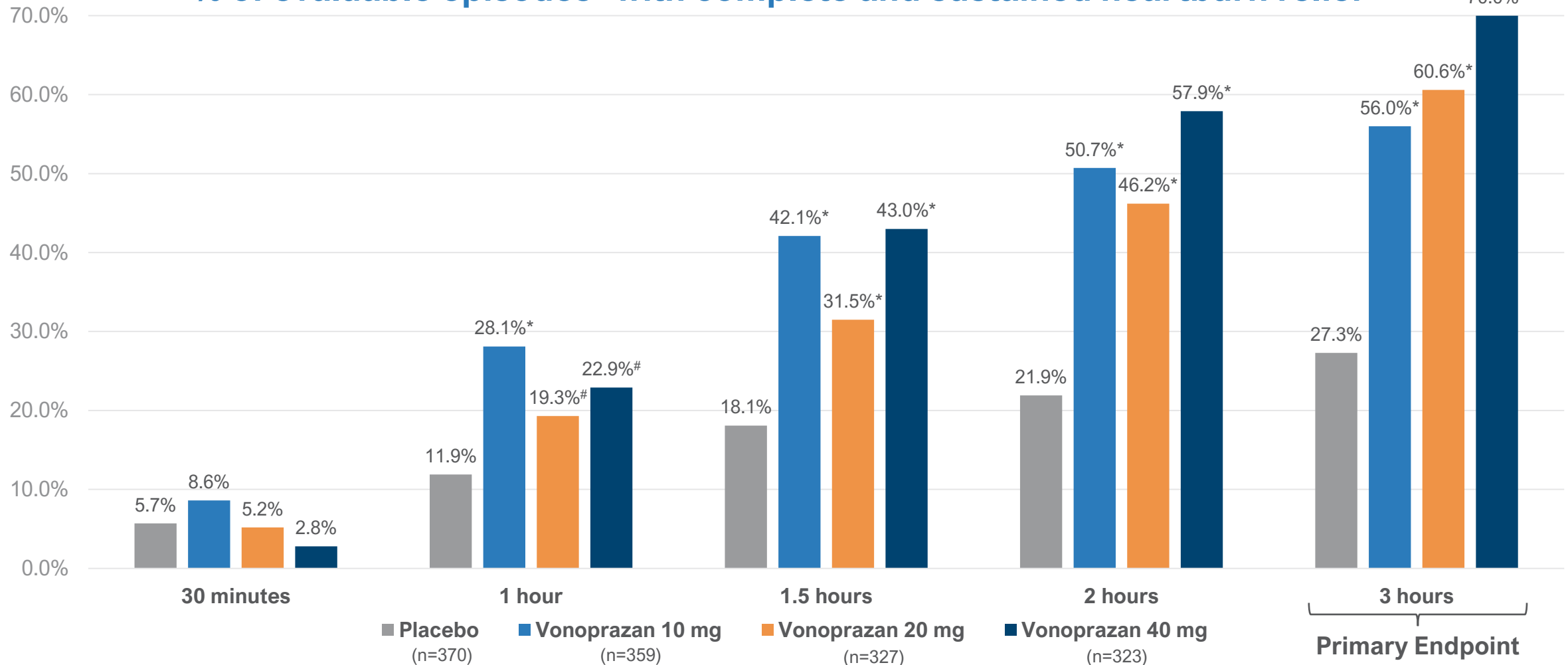
<sup>1</sup> Dosing initiated at onset of a heartburn episode; rescue antacid medication allowed after 3 hours of taking test medication

<sup>2</sup> Patients must meet study drug and diary completion compliance requirements

<sup>3</sup> Primary endpoint for NERD phase 2 trial is complete heartburn relief at 3 hours that is sustained for 24 hours. Primary endpoint for phase 3 trial will be based on NERD phase 2 results and subsequent FDA discussions

# PHALCON-NERD-201 met the primary endpoint for all doses and demonstrated significance over placebo for all doses as early as 1-hour

% of evaluable episodes<sup>^</sup> with complete and sustained heartburn relief<sup>^^</sup>



\* Denotes p < 0.0001 statistically significant difference from placebo

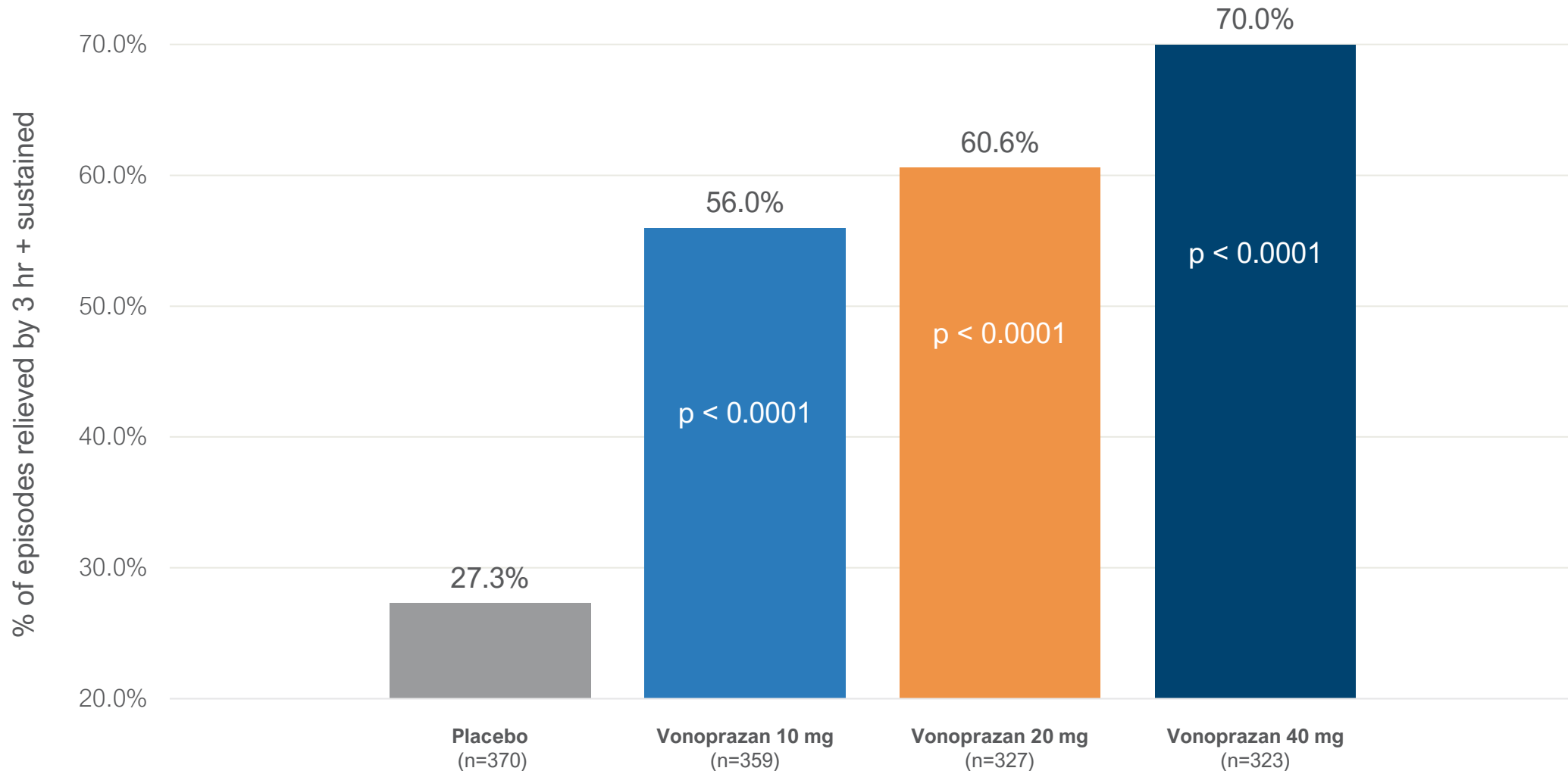
# Denotes p < 0.01 statistically significant difference from placebo

<sup>^</sup> Evaluable episode: heartburn episode for which subject completes a minimum of one timed assessment

<sup>^^</sup> Complete relief: Full symptom relief with no rescue antacid taken (must be achieved within 3 hours of study drug); Sustained relief: No further episodes recorded within following 24 hours

# PHALCON-NERD-201 met the primary endpoint for all doses

% of evaluable episodes\* with complete and sustained heartburn relief within 3 hours<sup>^</sup>

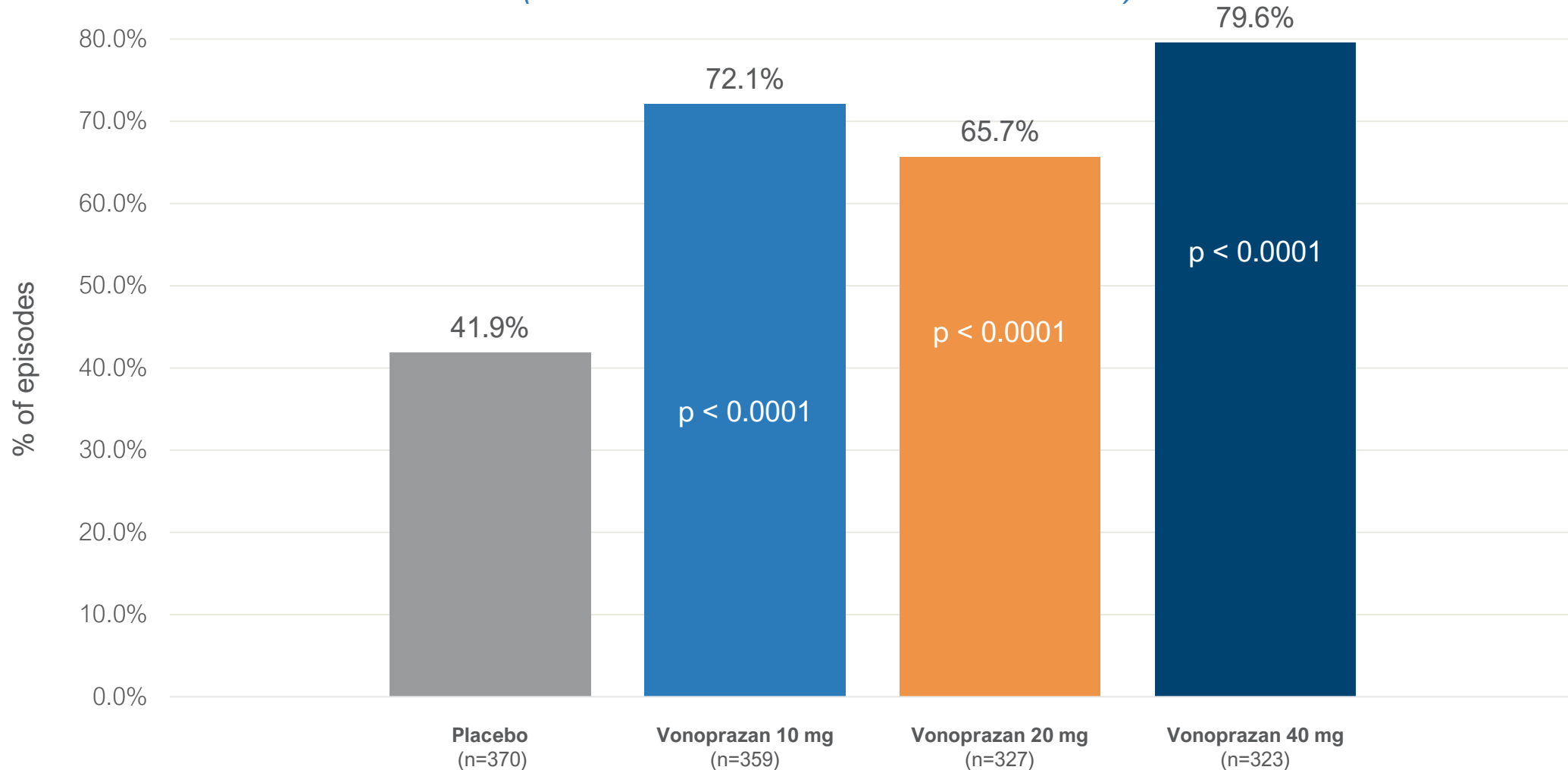


\* Evaluable episode: heartburn episode for which subject completes a minimum of one timed assessment

<sup>^</sup> Complete relief: Full symptom relief with no rescue antacid taken (must be achieved within 3 hours of study drug); Sustained relief: No further episodes recorded within following 24 hours

# PHALCON-NERD-201 met the key secondary endpoint with all doses resulting in more complete relief of heartburn episodes vs. placebo

% of evaluable episodes\* with complete heartburn relief within 3 hours^  
(with or without 24-hour sustained relief)



\* Evaluable episode: heartburn episode for which subject completes a minimum of one timed assessment

^ Complete relief: Full symptom relief with no rescue antacid taken (must be achieved within 3 hours of study drug)

# PHALCON-NERD-201 safety data

The safety data for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies

## Daily dosing treatment phase Vonoprazan 20 mg QD

- Most commonly reported events (> 1% of subjects)
  - Abdominal distension 1.3%
  - Diarrhea 1.5%
  - Nausea 1.3%
- 4 SAEs
  - 1 study drug related SAE (anaphylactic reaction)

## As Needed treatment phase

|                                      | Placebo (n=52) | Vonoprazan 10 mg (n=52) | Vonoprazan 20 mg (n=52) | Vonoprazan 40 mg (n=51) |
|--------------------------------------|----------------|-------------------------|-------------------------|-------------------------|
| % (n) of subjects with at least 1 AE | 21.3% (10)     | 16.3% (8)               | 18.4% (9)               | 16.7% (8)               |

- No individual AE was reported by more than one subject in a treatment group
- No SAEs