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## Phathom **PHARMACEUTICALS**

#### **Going Beyond**

to advance treatments for patients with acid related disorders



#### **HEADQUARTERS**

Florham Park, NJ

#### RAISED \$209M | OCT 2019

**Gross Proceeds in IPO** 

#### **FORMED IN 2019**

Listed on Nasdaq: PHAT



#### P-CAB

Potassium competitive acid blocker



**Topline data from** two pivotal phase 3 trials in 2021







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Approved in

#### 14 COUNTRIES

across Asia and Latin America

#### >\$725M

net sales in Japan for the 12 months ended Sept 30, 2020<sup>1</sup>



volume-driven sales growth in the 6<sup>th</sup> year on the market2

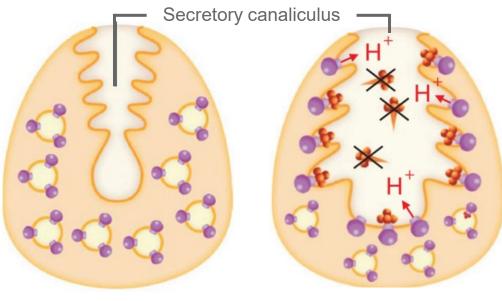
<sup>1</sup> US dollars based on September 30, 2020 conversion rate of 0.0095 dollars to one yen

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

	Target Indications	Phase 1 <sup>1</sup>	Phase 2 <sup>1</sup>	Phase 3	<b>Expected Milestones</b>
	GERD			pHalcon <sup>ee</sup>	
Vonoprazan	Healing of Erosive Esophagitis (EE) and relief of heartburn				Enrollment complete
	Maintenance of healing of Erosive Esophagitis (EE) and relief of heartburn				Topline results 2H21
	Treatment of heartburn associated with Non-erosive Reflux Disease (NERD)				Phase 2 FSI mid-21
	H. pylori treatment			pHalcon	
Vonoprazan + antibiotics	Dual therapy (vonoprazan + amoxicillin)		A research study for is, pylori infection	Enrollment complete	
	Triple therapy (vonoprazan + amoxicillin + clarithromycin)				Topline results 2Q21

#### PPIs: mechanism limits effectiveness

#### **GASTRIC PARIETAL CELL**



Quiescent phase Active phase after meal





#### PPI:

#### **COVALENTLY BINDING PRODRUG**

Short plasma half-life

Acid needed for activation but unstable in presence of acid

Meal required to stimulate pumps

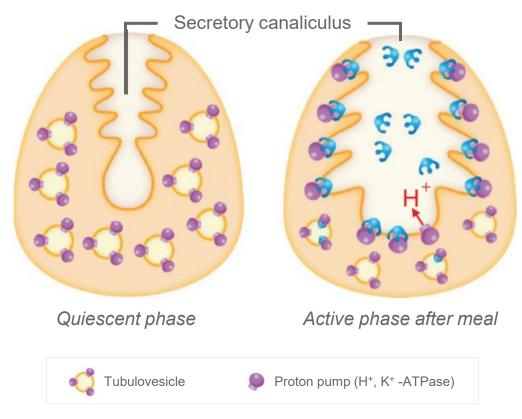
Primarily metabolized via CYP2C19



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

#### Vonoprazan: distinct mechanism designed to address PPI shortcomings

#### **GASTRIC PARIETAL CELL**





Long plasma half-life

Stable in acid

High accumulation in canaliculus

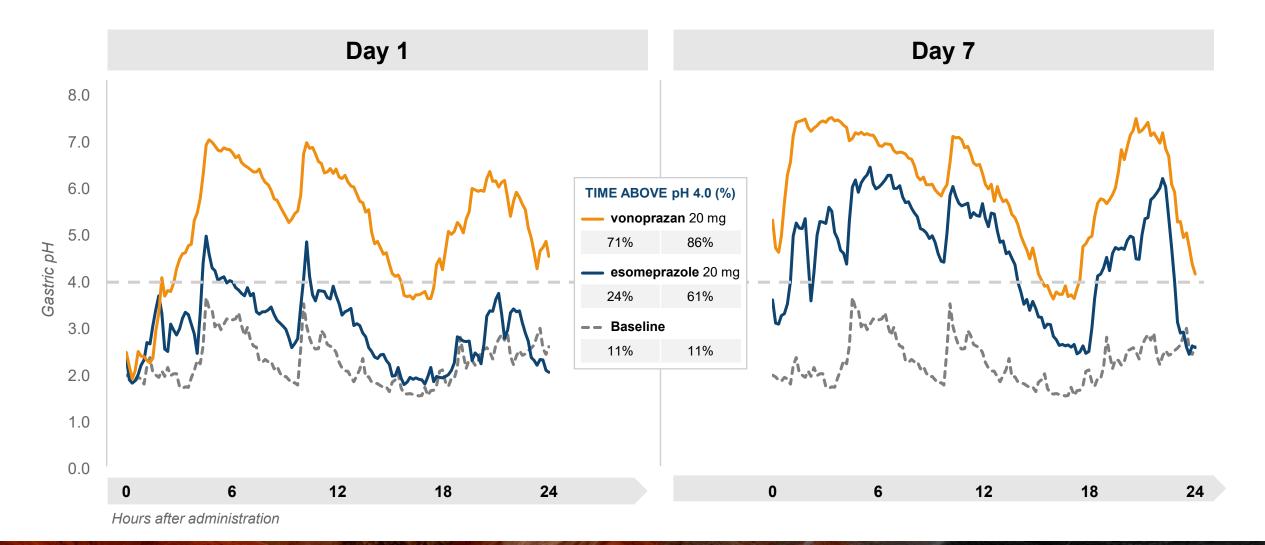
Very slow dissociation rate

Primarily metabolized via CYP3A4/5



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

#### Vonoprazan demonstrated faster, more potent, and more durable acid control vs. PPI



# Vonoprazan for **GERD** <sup>1</sup> For the 12 months ended October 31, 2020 El-Serag APT 2010; El-Serag Gut 2014; IQVIA data Oct 2020





~6.8B US

People with GERD

**PPI** doses prescribed<sup>1</sup>

~15-45%
Inadequately treated
with PPIs

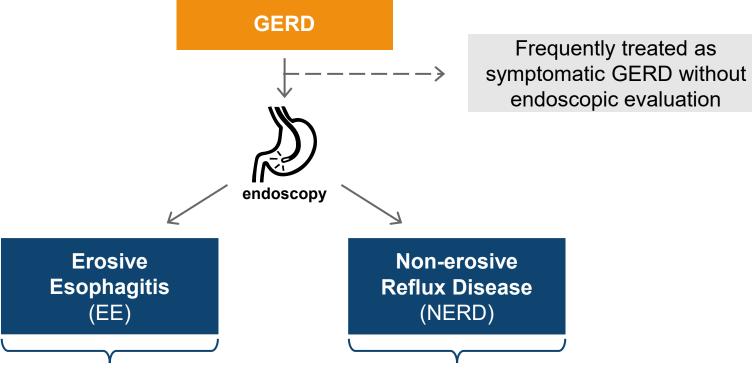
### Many patients experience breakthrough heartburn

breakthrough heartburn and recurrence of erosions while on PPIs



Vonoprazan may offer more rapid, potent and durable healing and symptom control

#### **Key unmet needs within GERD classifications**

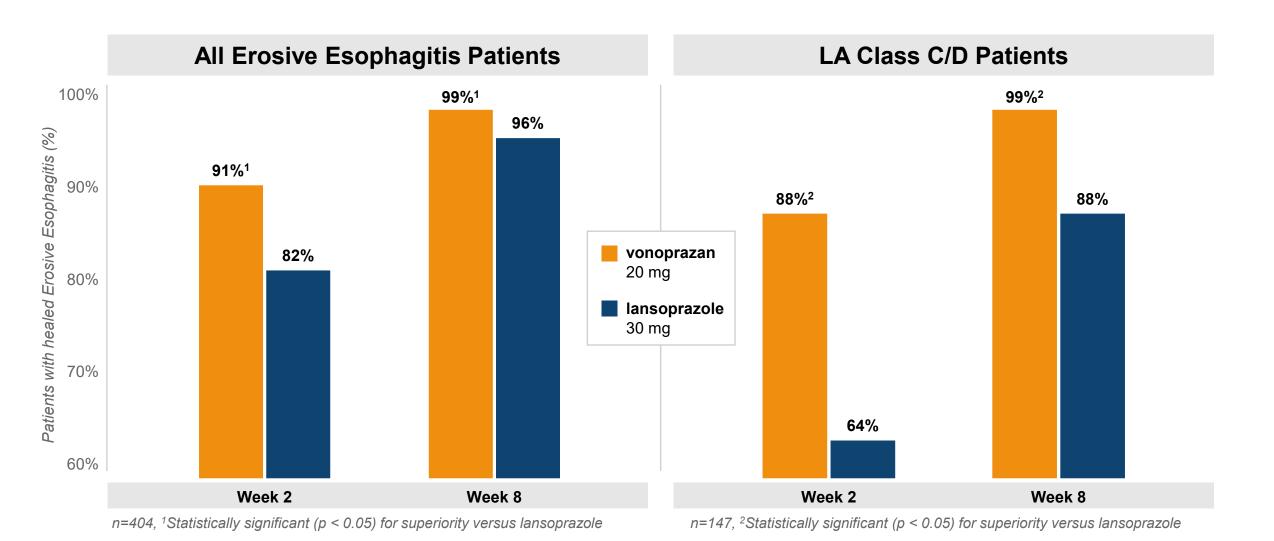




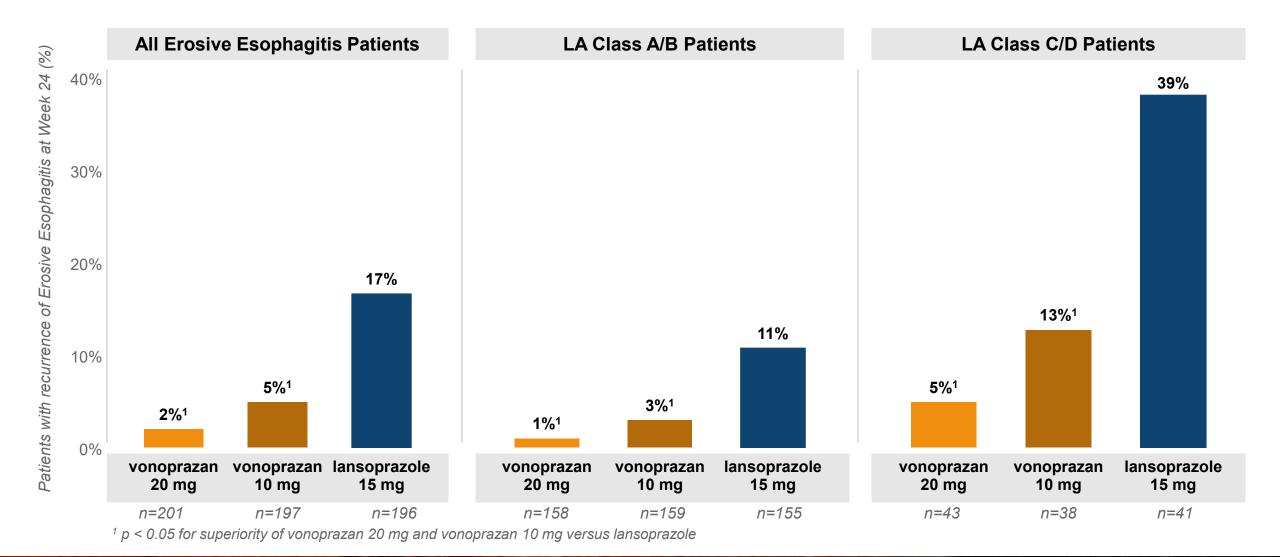
Improved efficacy: healing/maintenance of healing of erosions and symptom control (rapid and durable)

- Improved symptom control: speed and durability of relief
- On-demand dosing: speed and durability of symptom relief with flexible dosing

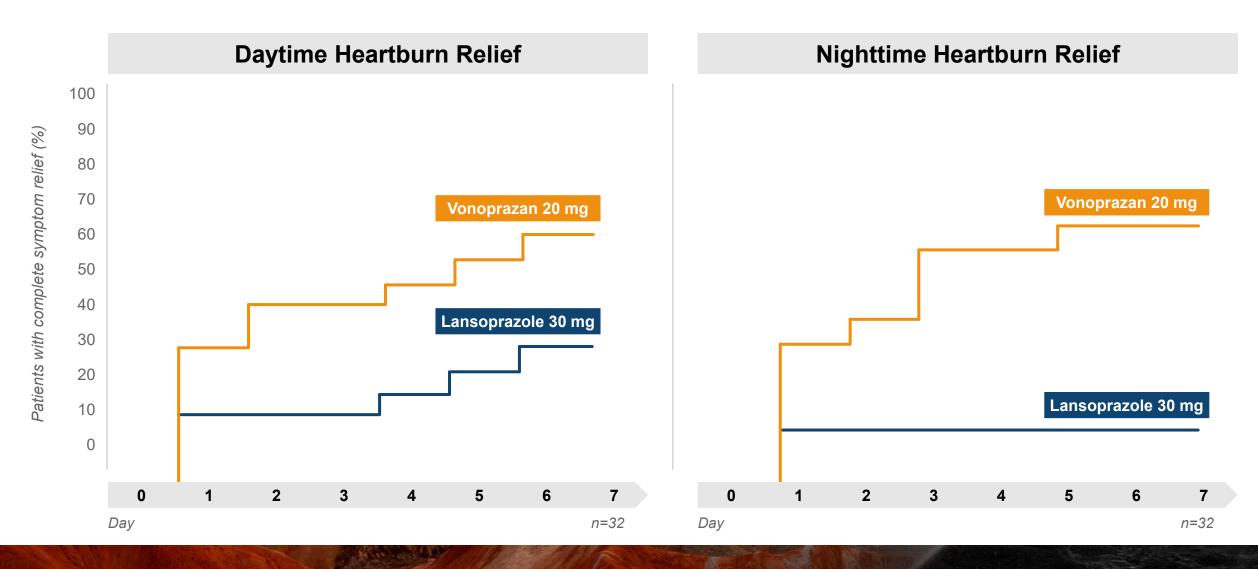
#### Japan Erosive Esophagitis phase 3: faster and improved healing vs. PPI



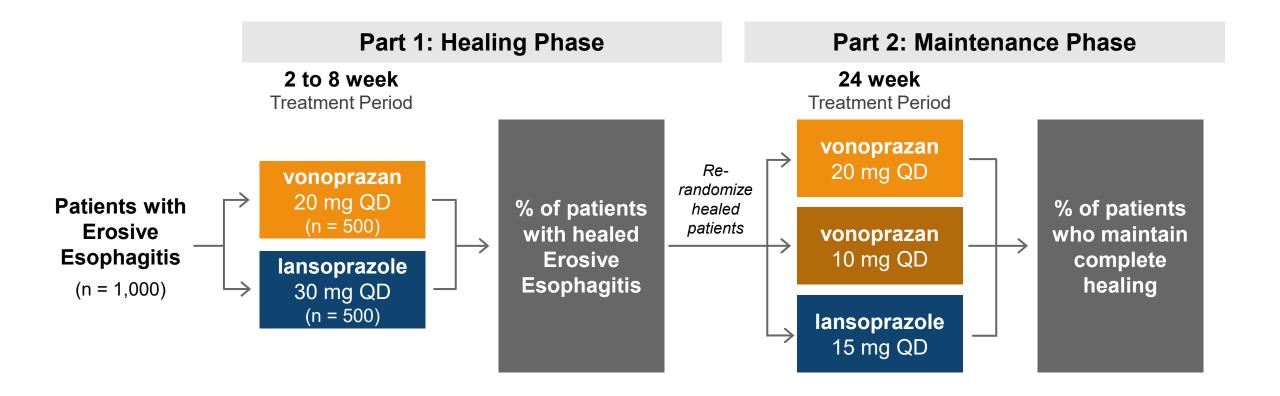
#### Japan Erosive Esophagitis phase 3: lower 6-month recurrence rates vs. PPI



#### Faster and more complete heartburn relief vs. PPI



#### Phathom US/Europe Erosive Esophagitis phase 3 study design



Nov 2020 Enrollment completed; 2H21 Topline results expected

# NERD development strategy rationale

Vonoprazan's pharmacologic profile (speed of onset, potency, and duration) has the potential to satisfy unmet NERD needs

#### **Clear rationale for further NERD evaluation**

- Significant patient need for greater flexibility and convenience in management of symptoms
- Patients and physicians have concerns with sustained daily PPI dosing
- Unapproved non-continuous regimens are widely used by US patients

#### **NERD** development strategy

#### **Phathom intends to pursue:**

- > a phase 2 on-demand study
- > followed by a phase 3 study evaluating both vonoprazan continuous and on-demand dosing regimens

#### On-demand dosing

## Utilize the unique PK/PD profile to achieve a flexible dosing regimen

Pharmacology of current products are not suitable for on-demand use:

- PPI slow onset not well-suited to on-demand dosing
- H2RAs have rapid onset but short duration and tachyphylaxis with repeat use

#### Continuous dosing

### Apply lessons learned from the Japan studies to increase likelihood of success

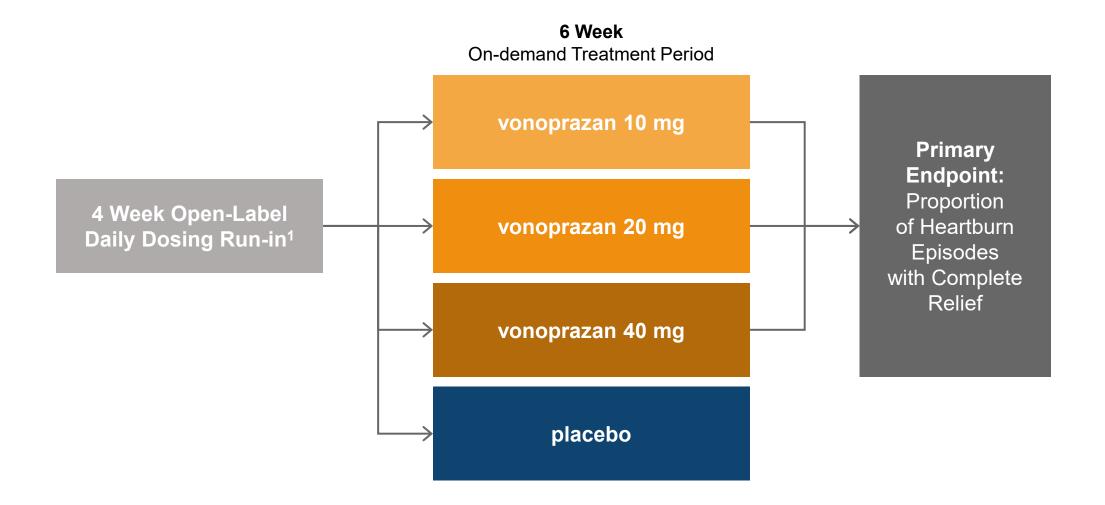
Two Japan Ph 3 studies demonstrated trend in favor of vonoprazan:

- p=0.2310 [10mg]; p=0.0504 [20mg]<sup>1</sup>
- $p=0.0643^2$

PPI Ph 3 NERD continuous dosing studies in Asia have had mixed results

All PPI Ph 3 NERD continuous dosing studies in US have succeeded

#### **NERD** phase 2 planned trial design – reviewed with FDA



# Vonoprazan for *H. pylori* infection

Hooi Gastroenterology 2017; Graham et al 2018; Erah et al 1997





H. pylori designated as a
Class I carcinogen
by WHO and
Qualifying Pathogen
under FDA GAIN Act

Eradication rates in the US have fallen to

<80%

due to increasing antibiotic resistance



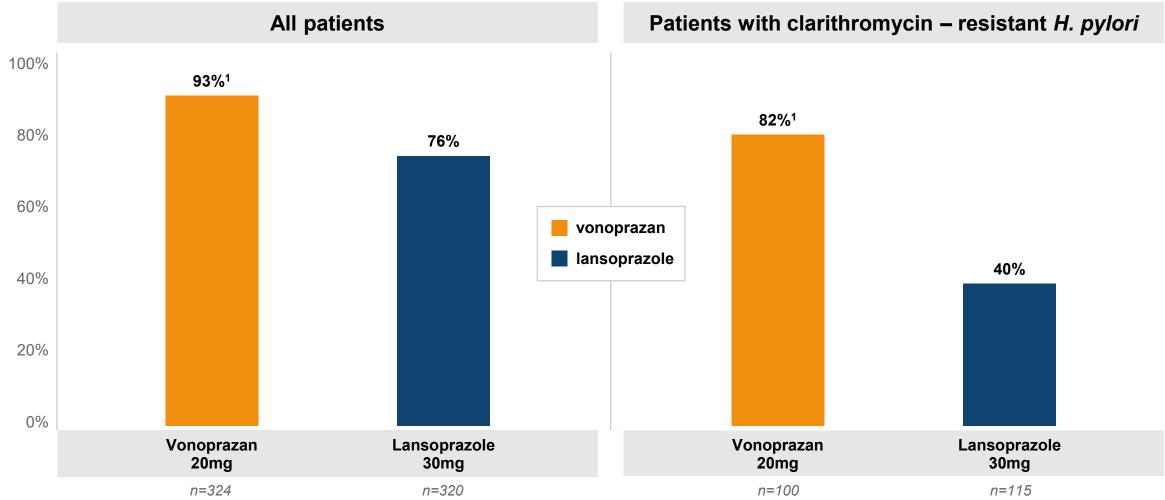
Antibiotic potency increases at higher pH



Vonoprazan-based regimens may restore eradication rates above 90% in the US and Europe, if vonoprazan is successfully developed and approved

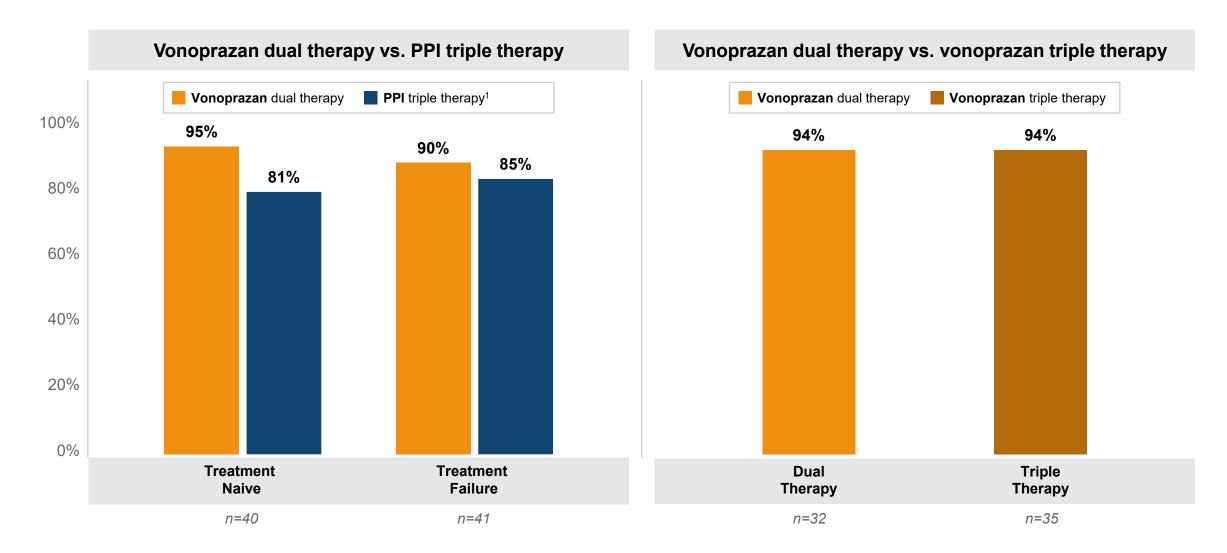
#### Japan phase 3: vonoprazan triple therapy demonstrated superiority to PPI therapy

First-line triple therapy eradication rates of *H. pylori*, (combo with amoxicillin/clarithromycin)

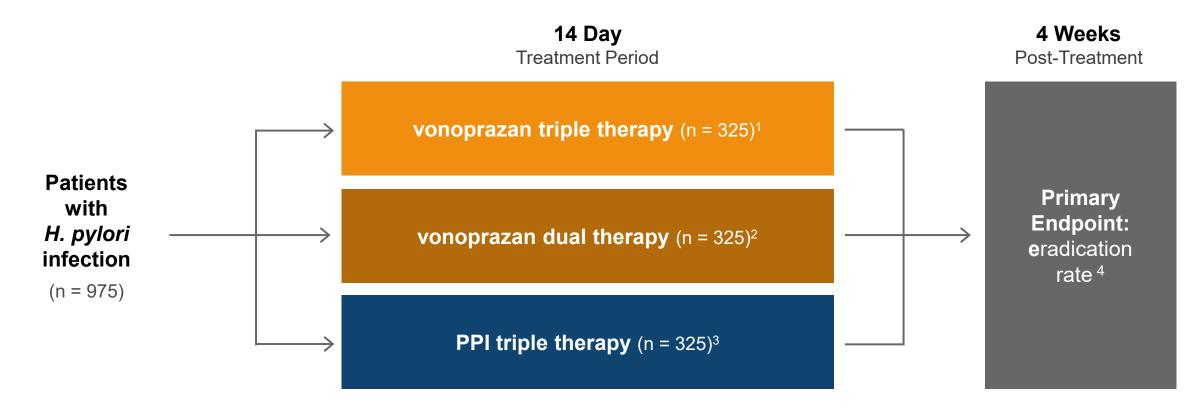


 $<sup>^{1}</sup>$  p < 0.0001 for superiority of vonoprazan-based triple therapy to lansoprazole-based triple therapy

#### Vonoprazan demonstrated eradication rates >90% in dual therapy with amoxicillin



#### Phathom US/Europe H. pylori phase 3 study design



Jan 2021 Enrollment expected to be completed; 2Q21 Topline results expected

<sup>&</sup>lt;sup>1</sup>Vonoprazan 20 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID

<sup>&</sup>lt;sup>2</sup>Vonoprazan 20 mg BID + amoxicillin 1 g TID (partially blinded)

<sup>&</sup>lt;sup>3</sup>Lansoprazole 20 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID

# Vonoprazan safety profile similar to PPIs

>7,000 patients have received vonoprazan in clinical studies

No dose-related increase in adverse events observed in clinical studies

>25 million patients have received vonoprazan since launch



# ADVERSE EVENTS IN CLINICAL DEVELOPMENT REFLECTED IN JAPANESE PRESCRIBING INFORMATION

Incidence of 0.1-5.0%

Diarrhea <sup>1</sup>	Elevated liver enzymes
Constipation	Rash
Nausea	Eosinophilia

## HEPATIC EVENTS OF SPECIFIC INTEREST IN LIGHT OF FIRST-GENERATION PCABs

Pooled data across head-to-head Phase 2 and 3 studies	vonoprazan 10 and 20mg	lansoprazole 15 and 30mg
ALT or AST >3X ULN or Bilirubin >2X ULN	1.0%	0.8%

#### After 25 years: innovation that matches unmet needs



# Japanese experience signals potential success for the US

**Current US market has many similarities to the Japanese market at launch of Takecab** 

Heavily genericized market

PPI dissatisfaction/patient switching

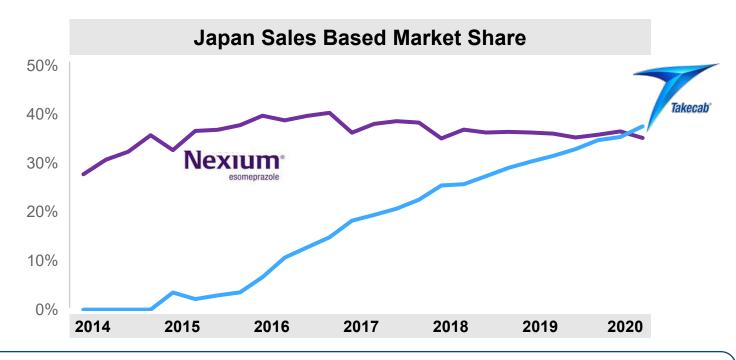
Declining *H. pylori* eradication rates

<sup>1</sup>Net sales for the 12 months ended September 30, 2020 and corresponding conversion rate of 0.0095 USD: 1 JPY; IQVIA Quarterly MIDAS data (as of 2Q20); Deguchi et al Digestion 2019









#### **Japan Experience**

- Vonoprazan has achieved >\$725M in net sales¹ and 38% value-based market share driven predominantly by volumetric gains from generic competitors
- Majority of vonoprazan sales are in GERD
- Vonoprazan-based regimens achieved ~80% *H. pylori* market share in 2<sup>nd</sup> full year

#### Minimal US branded competition anticipated across all potential indications

#### **UNCONTESTED PIPELINE**

> No products in late-stage development in the US or EU

#### LACK OF NOVEL SOLUTIONS

> Other products introduced in the US are variations of old regimens

#### CATEGORY DIFFERENTIATION

> P-CABs in development in Asia have a clinical profile similar to PPIs and/or a short half-life and a different chemical structure compared to vonoprazan

Promotionally sensitive market with little to no branded competition



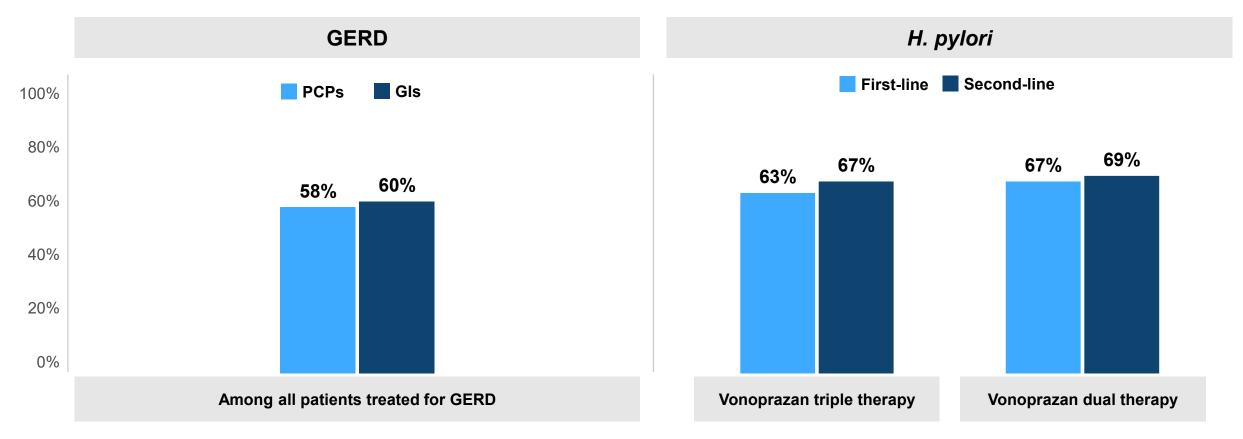
Minimal competition for share of voice



Innovation starved market

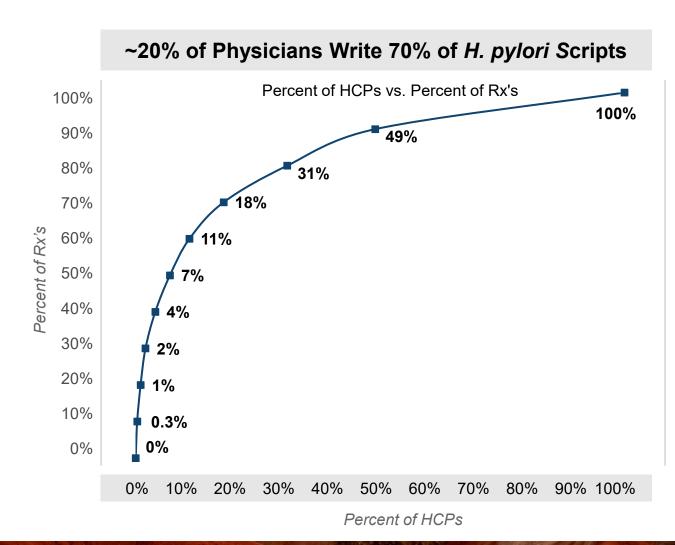
#### US physicians express strong preference to prescribe vonoprazan

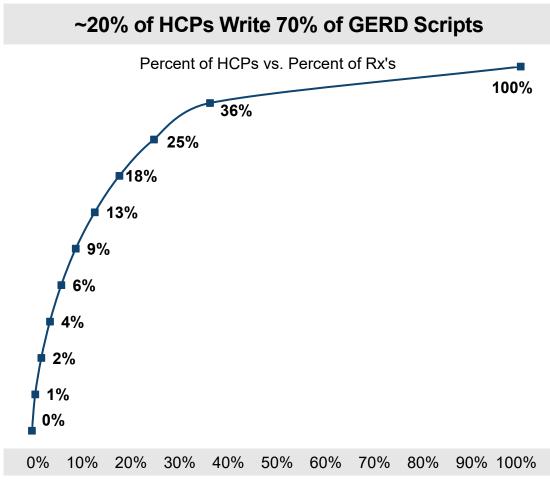
US physician preference share, %



2019 US SURVEY OF 100 GASTROENTEROLOGISTS AND 100 PRIMARY CARE PHYSICIANS

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





Percent of HCPs

#### Pursuing access to large patient segments with minimal restrictions

# Large patient population in need

- ~65M people with GERD; ~50% of treated patients progress lines of therapy annually
- > Declining *H. pylori* eradication rates with current regimens

# Health system utilization

Erosive esophagitis recurrence and H. pylori eradication failures utilize additional healthcare resources

## Lack of alternatives

> 25+ years of lack of alternatives in GERD

#### Access drivers<sup>1</sup>

- Health plan objectives to meet unmet needs
- > Clinical superiority vs. PPIs
  - > Lower Erosive Esophagitis recurrence rates
  - > Faster Erosive Esophagitis healing
  - > Greater *H. pylori* eradication
- > Advanced pharmacology
  - > Rapid, potent, and durable acid control
- > Novel MOA different from all other approaches

## Potential branded price commensurate with value

- Value proposition to address unmet need
- Market analogues have achieved broad access
  - e.g., Dexilant (PPI with a non-differentiated MOA): WAC of \$9.69/dose<sup>2</sup>

HCPs see vonoprazan differently from PPIs... potent acid suppression that has the potential to deliver

**Fast action** 

**Superior efficacy** 

Durability

#### Significant commercial opportunity



Large Populations + Unmet Need



Strong Physician Preference
+
Concentrated High Prescribers



Minimal Branded Competition
+
High Share of Voice



Novel Profile
+
Potential for Premium Price

#### **Financial highlights**

Cash and cash equivalents (as of 9/30/2020) <sup>1, 2</sup>	\$226.4M
Debt (as of 9/30/2020) <sup>1</sup>	\$50.0M
Common shares issued (as of 9/30/2020) <sup>1, 3</sup>	28,964,506

<sup>&</sup>lt;sup>1</sup> September 30, 2020 Form 10-Q

<sup>&</sup>lt;sup>2</sup> Does not include \$88,830,000 net proceeds from December 16, 2020 public offering of common stock

<sup>&</sup>lt;sup>3</sup> Does not include 2,250,000 shares issued in December 16, 2020 public offering of common stock

# Phathom. PHARMACEUTICALS

#### **Going Beyond**

to advance treatments for patients with acid related disorders





- Significant unmet medical need
- Large innovation starved markets
- Differentiated MOA and product profile
- De-risked asset with established success in Japan
- ✓ Topline results from two pivotal trials in 2021
- HCP and patient enthusiasm