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CHANGING THE LANDSCAPE IN GI

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

PHALCON-NERD-201 STUDY TOPLINE RESULTS

February 9, 2022

NERD development strategy

UNMET NEED ~45M US PEOPLE with NERD

Approximately 50% of patients progress lines of therapy annually¹

Strong physician and patient demand for differentiated, novel, alternative treatment options

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

DEVELOPMENT STRATEGY



Evaluating vonoprazan as both a:

- > **Daily dosing regimen** for preventative therapy; and
- > **On-demand** or as needed therapy for rapid and sustained relief

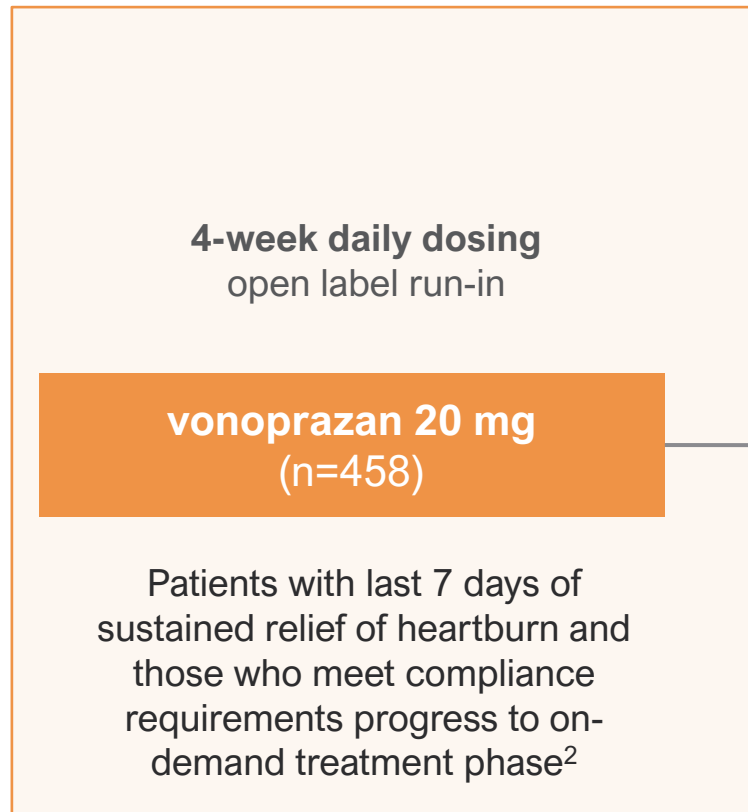
NERD-301 - daily dosing pivotal Phase 3 trial initiated

Plan to seek FDA feedback re Phase 3 NERD on-demand dosing trial design

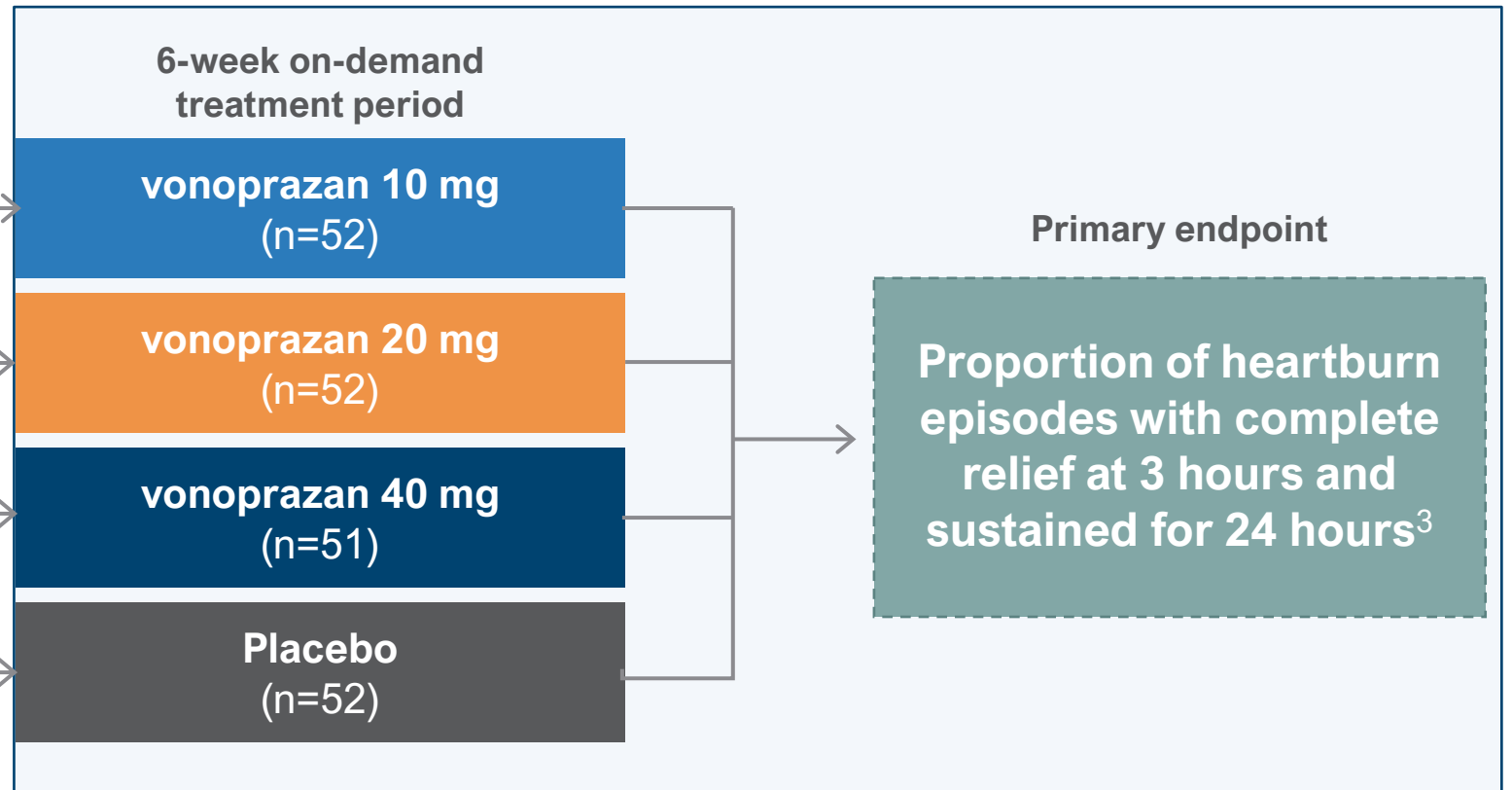
¹ Symphony Health claims analysis (Jul 2017 – Jan 2020)

PHALCON-NERD-201 phase 2 trial design

Daily dosing treatment phase



On-demand treatment phase¹



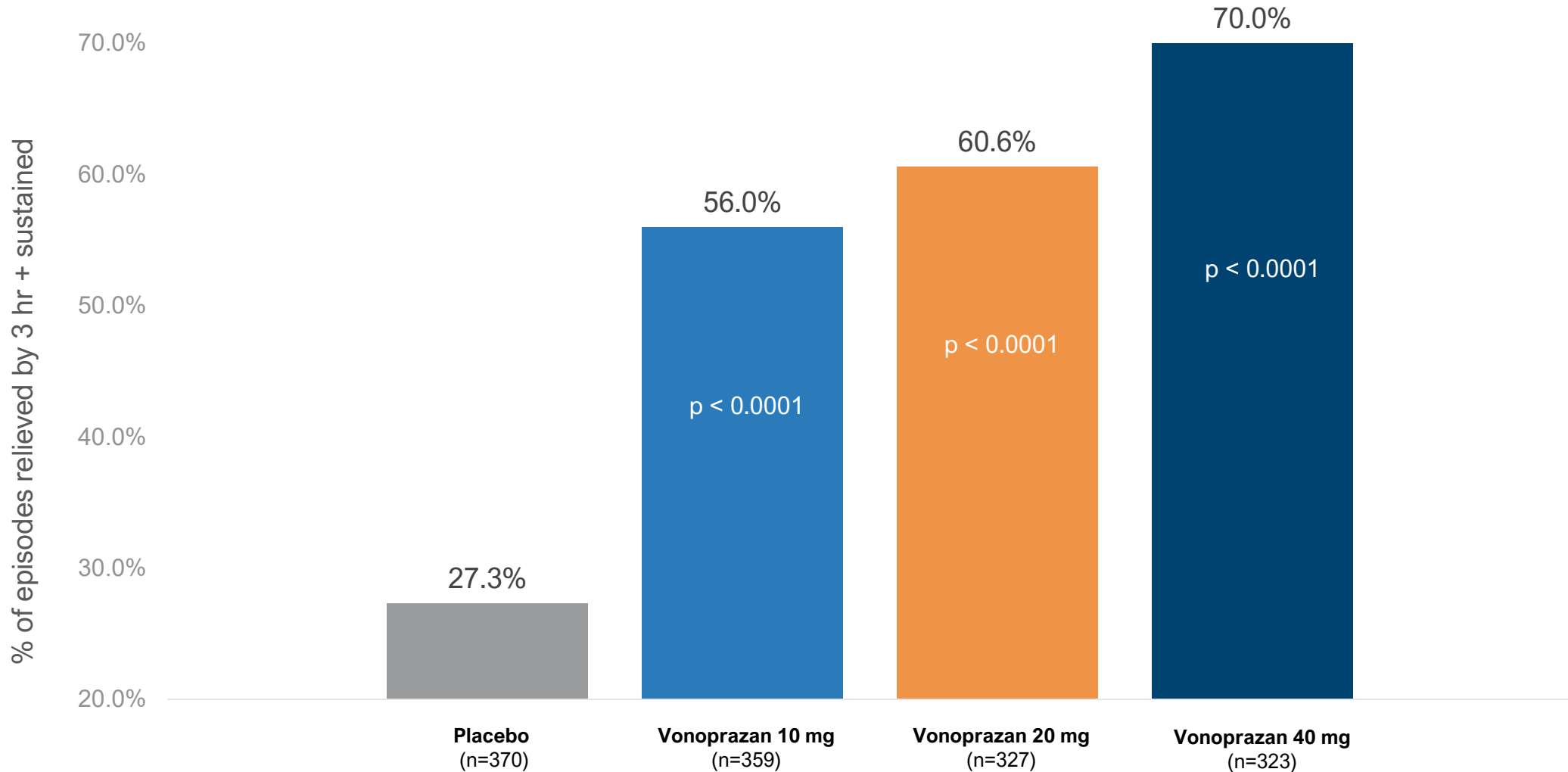
¹ Dosing initiated at onset of a heartburn episode; rescue antacid medication allowed after 3 hours of taking test medication

² Patients must meet study drug and diary completion compliance requirements

³ 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

% of evaluable episodes* with complete and sustained heartburn relief within 3 hours



*Evaluable episode (n) = heartburn episode for which subject completes a minimum of one timed assessment

PHALCON-NERD-201 daily dosing, run-in period

Percentage of 24-hour heartburn free days over 4 weeks

Total # of Patients = 458

**Heartburn-
Free Days**

Mean: 65.4%

Median: 76.0%

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)

On-demand 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







Unique development strategy for treatment of NERD

Vonoprazan

NERD Phase 3 strategic development objectives

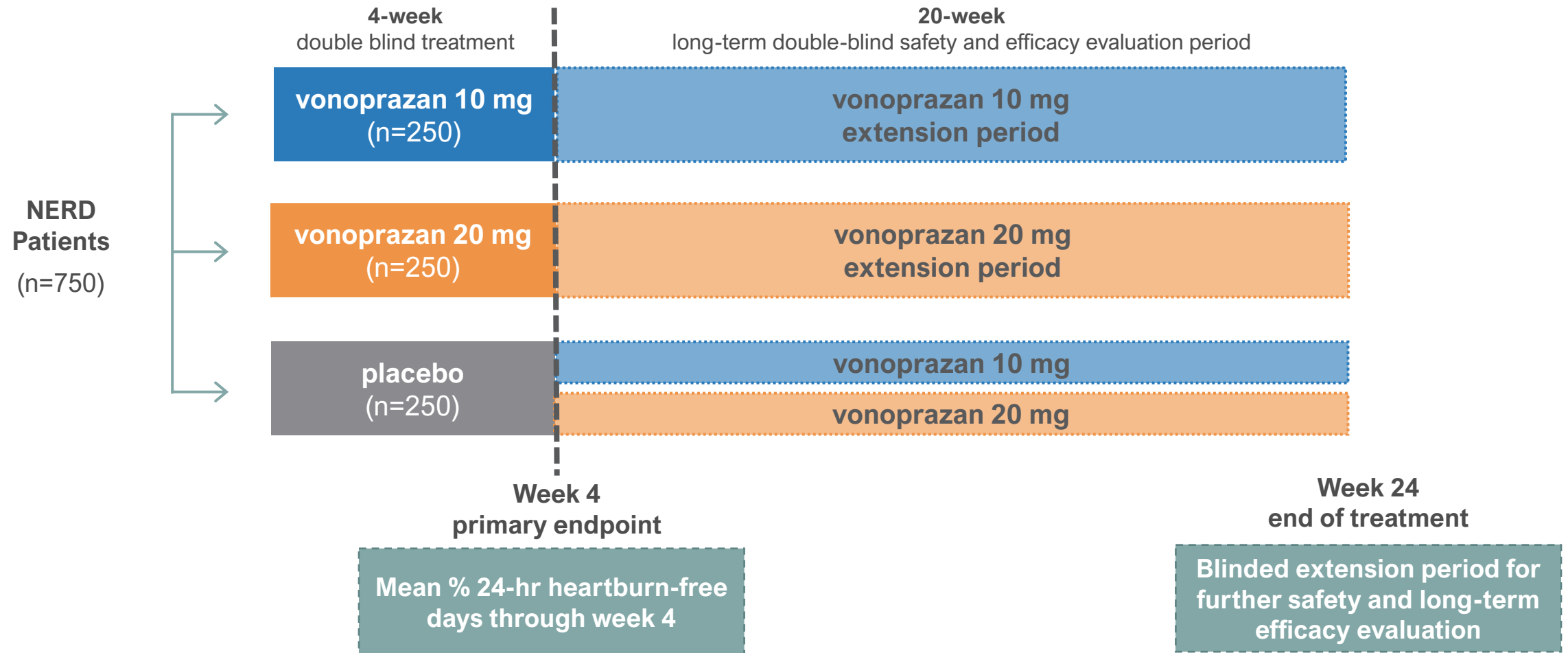
PPI class

historical data

Foundational claim	NERD-301 Phase 3 placebo-control trial daily dosing x 4 week 	All have 4 weeks placebo-control 
Unique data – 6-months durability	NERD-301 extension period controlled daily dosing efficacy data x 6 month 	No controlled chronic efficacy data 
Differentiated treatment opportunity	Anticipated Phase 3 on-demand trial On-demand (as needed) dosing 	PK/PD profile not suitable for on-demand use 

PHALCON-NERD-301 phase 3 daily dosing trial design

Topline data expected 2023



NERD COMMERCIAL OPPORTUNITY

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Active NERD Rx PPI patients ready for a change in treatment approach

Situation

- 66% of HCPs have a concern with **long-term PPI therapy**³
- Patients desire **“as-needed”** therapy



Vonoprazan Strategy

- Only vonoprazan, if approved, has the potential for
 - **Daily use** for symptom control
 - **On-demand** for relief when needed

¹ Internal analysis of epidemiology and market research

² Symphony Health claims analysis (Feb 2019 – Jan 2020)

³ SRI, August 2020 | N= 83 US HCPs (41 GI & 42 PCP)

If approved, vonoprazan has potential to disrupt the NERD treatment paradigm

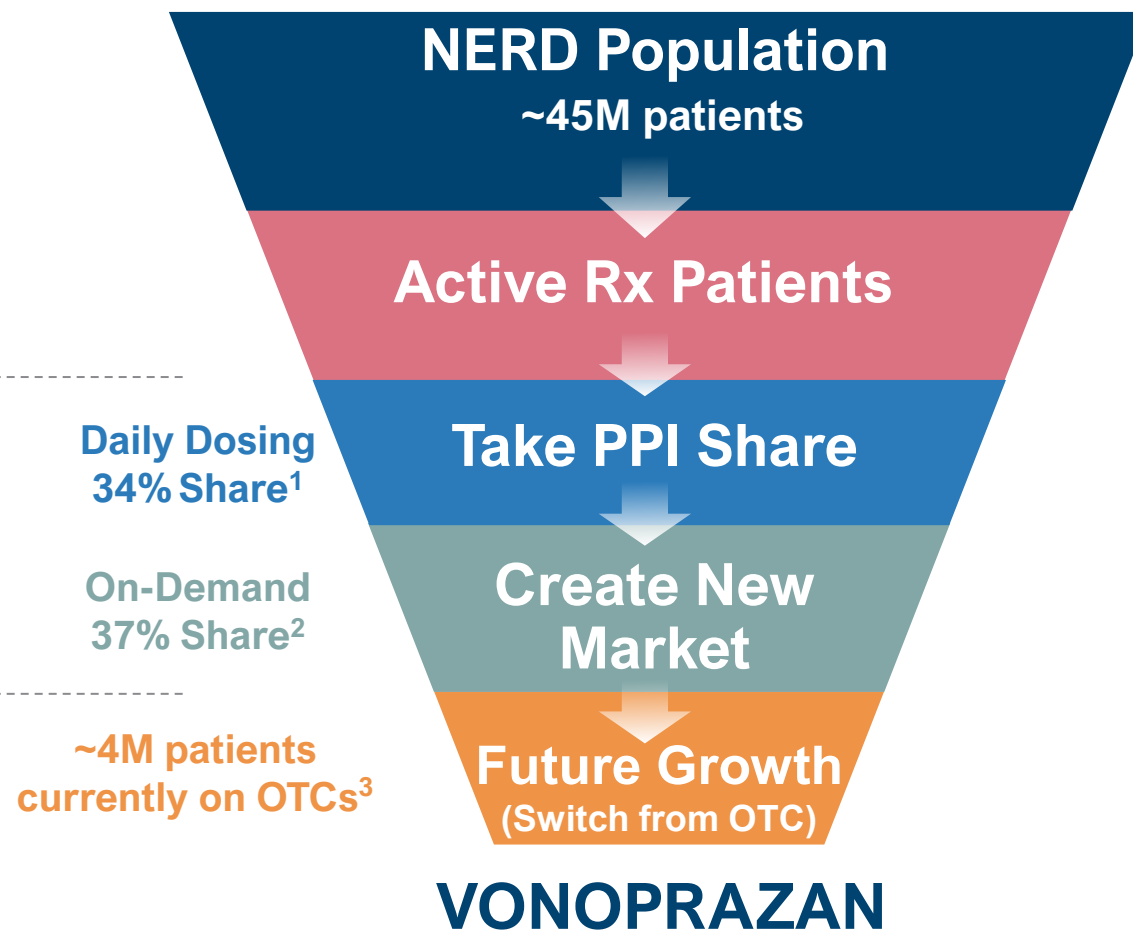
Current State		Switch to Vonoprazan		
		DAILY symptom control	ON-DEMAND relief when needed	
PPI Rx	PPI taken continually and need daily symptom control	✓		
	PPI taken on-demand		✓	
	PPI taken continually out of habit or prophylactically		✓	CREATE NEW SEGMENT
PPI OTC	Self management with PPI OTCs	✓	✓	GROW THE MARKET

**52% of HCPs surveyed indicate availability of Daily AND On-demand dosing
“will make vonoprazan my go-to NERD therapy for all my patients with differing needs”**

NERD has potential to accelerate vonoprazan blockbuster opportunity

Total Patients

HCP Preference Share



Daily Dosing + On-Demand: potential to create a new market that shifts more patients to vonoprazan

¹ SRI, October 2020 | N= 302 US HCPs (150 GI & 152 PCP)

² HCP Online Pulse Survey, May 2021 | N= 101 US HCPs (50 GI & 50 PCP)

³ Internal analysis of epidemiology in coordination with market research