
pHalcon ee
A research study for Erosive Esophagitis
TOPLINE PIVOTAL PHASE 3 RESULTS
October 18, 2021
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Safe harbor statement

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Today's call

Prepared Remarks

Terrie Curran
President & Chief Executive Officer

Azmi Nabulsi, M.D.
Chief Operating Officer

Martin Gilligan
Chief Commercial Officer

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TERRIE CURRAN
President and Chief Executive Officer
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PHALCON-EE met primary and key secondary endpoints

Vonoprazan, if approved, will become the first innovative GERD therapy in US in >30 years

> Novel MOA

Further supports vonoprazan's differentiated profile

> Potent, rapid, durable

NDA submission planned for H1 2022 for erosive esophagitis (EE)

> If approved, US launch anticipated in 2023

Supports potential blockbuster opportunity

> ~20M US EE patients

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AZMI NABULSI, M.D.
Chief Operating Officer
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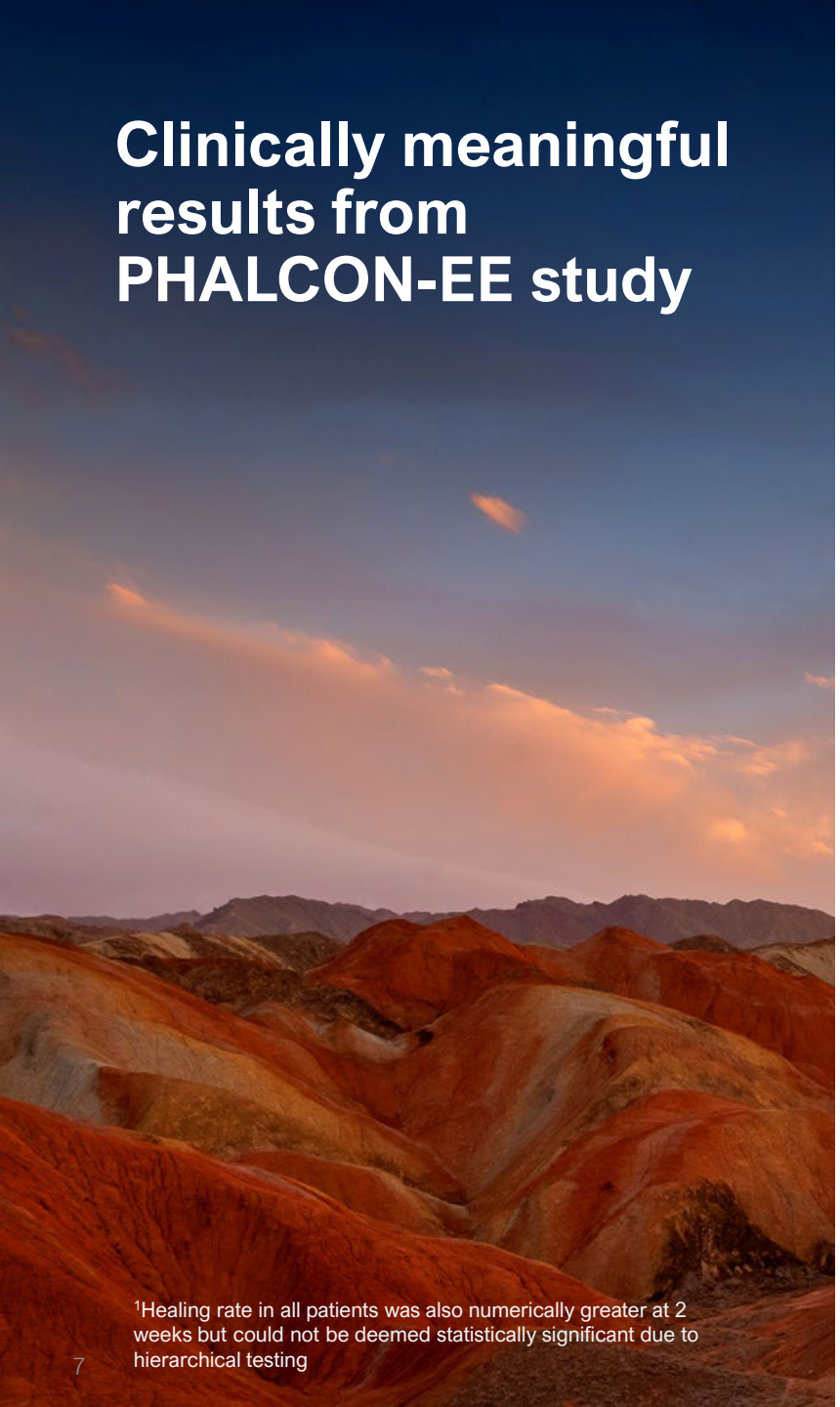
Clinically meaningful results from PHALCON-EE study



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 2 weeks but could not be deemed statistically significant due to hierarchical testing

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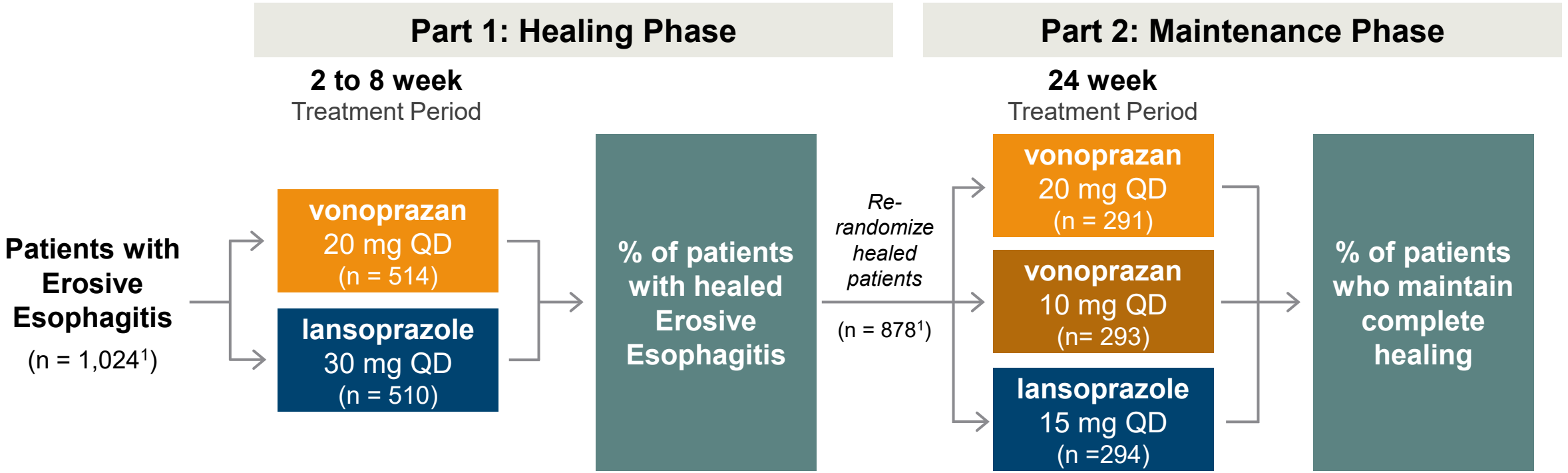
PHALCON-EE phase 3 study design

US/Europe study in Erosive Esophagitis



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

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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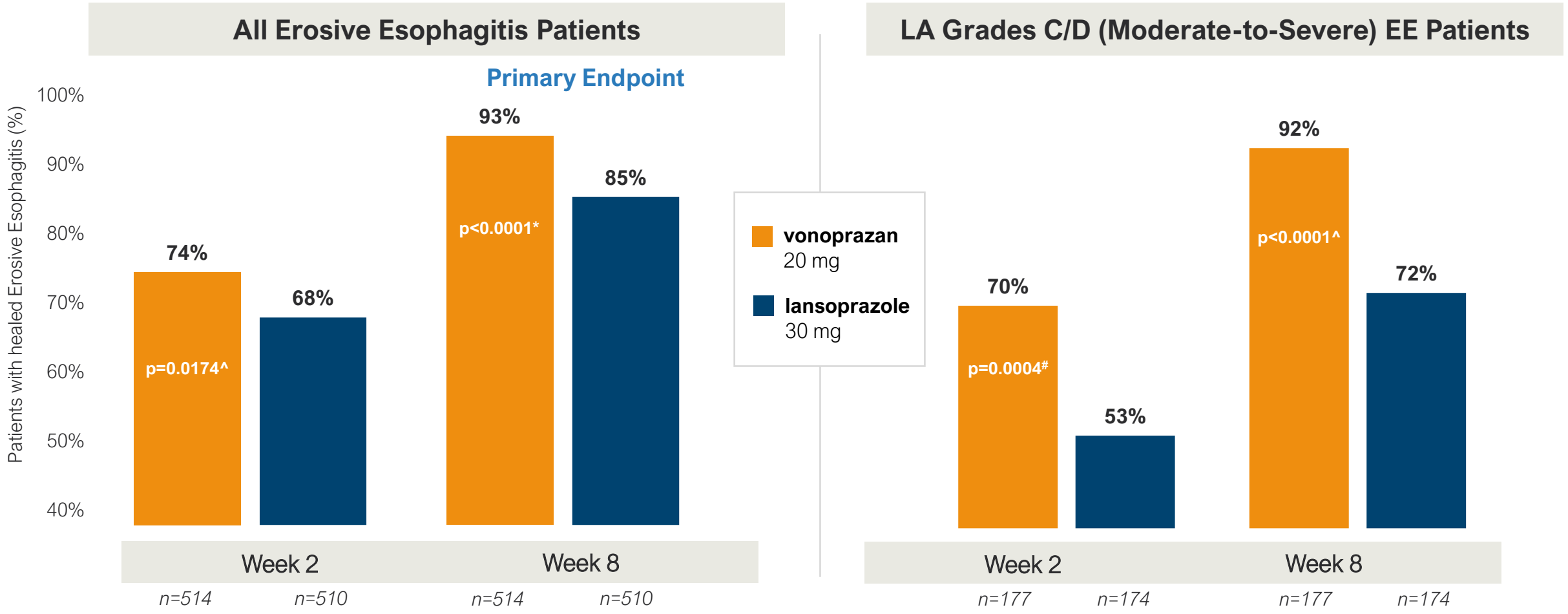
Healing endpoints



^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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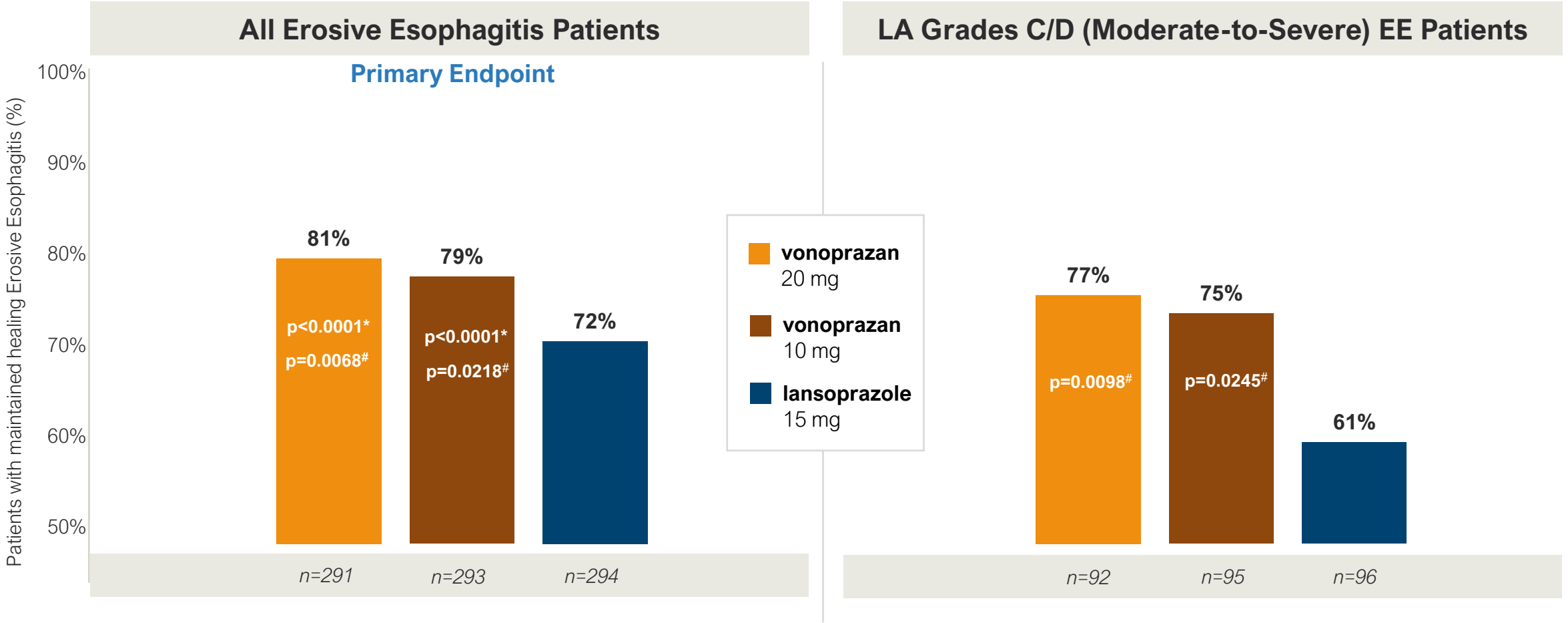
Maintenance of healing endpoints



*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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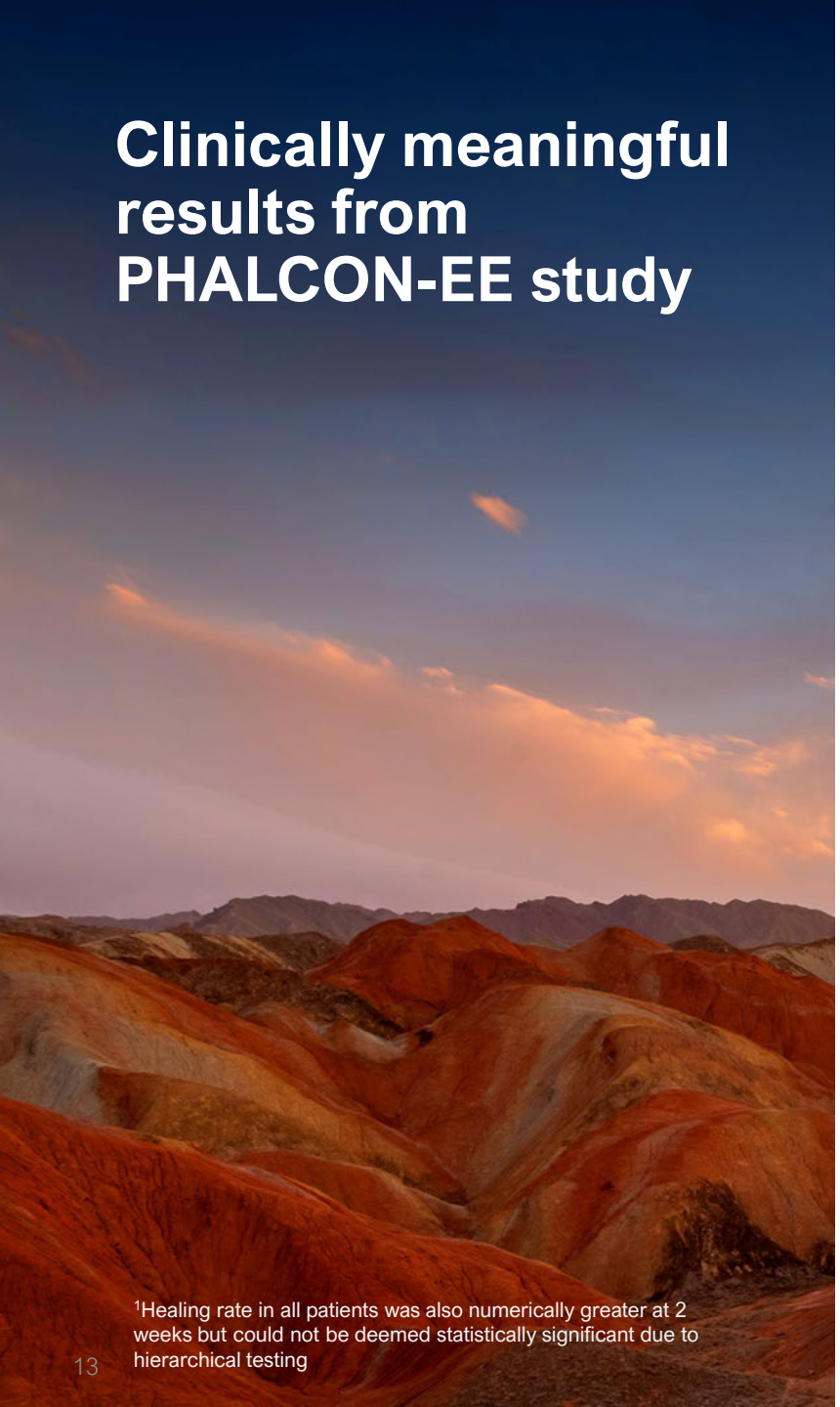
Clinically meaningful results from PHALCON-EE study



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MARTIN GILLIGAN
Chief Commercial Officer
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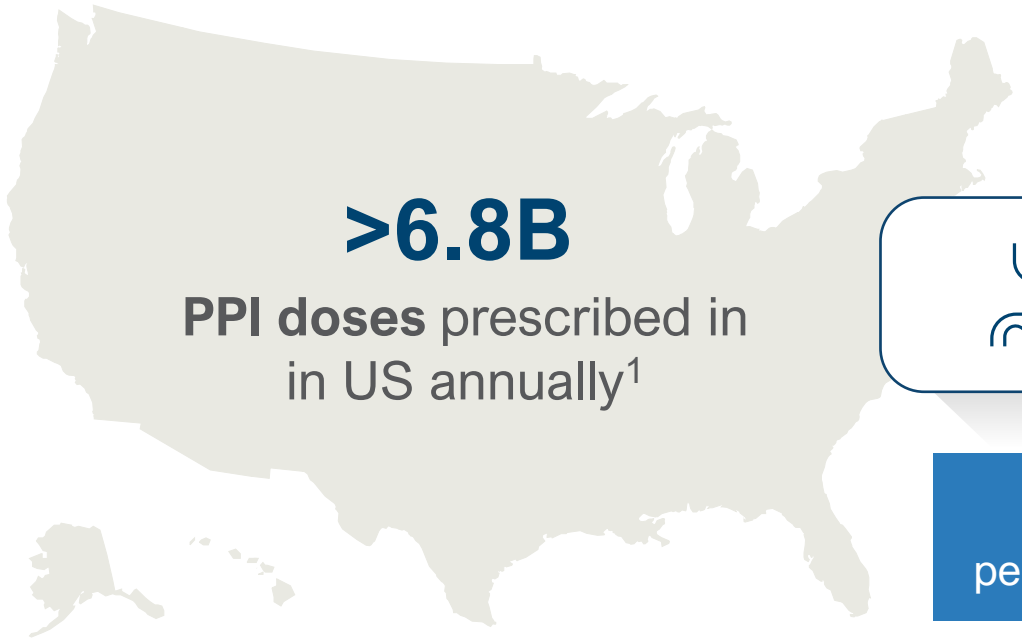
Large market opportunity



>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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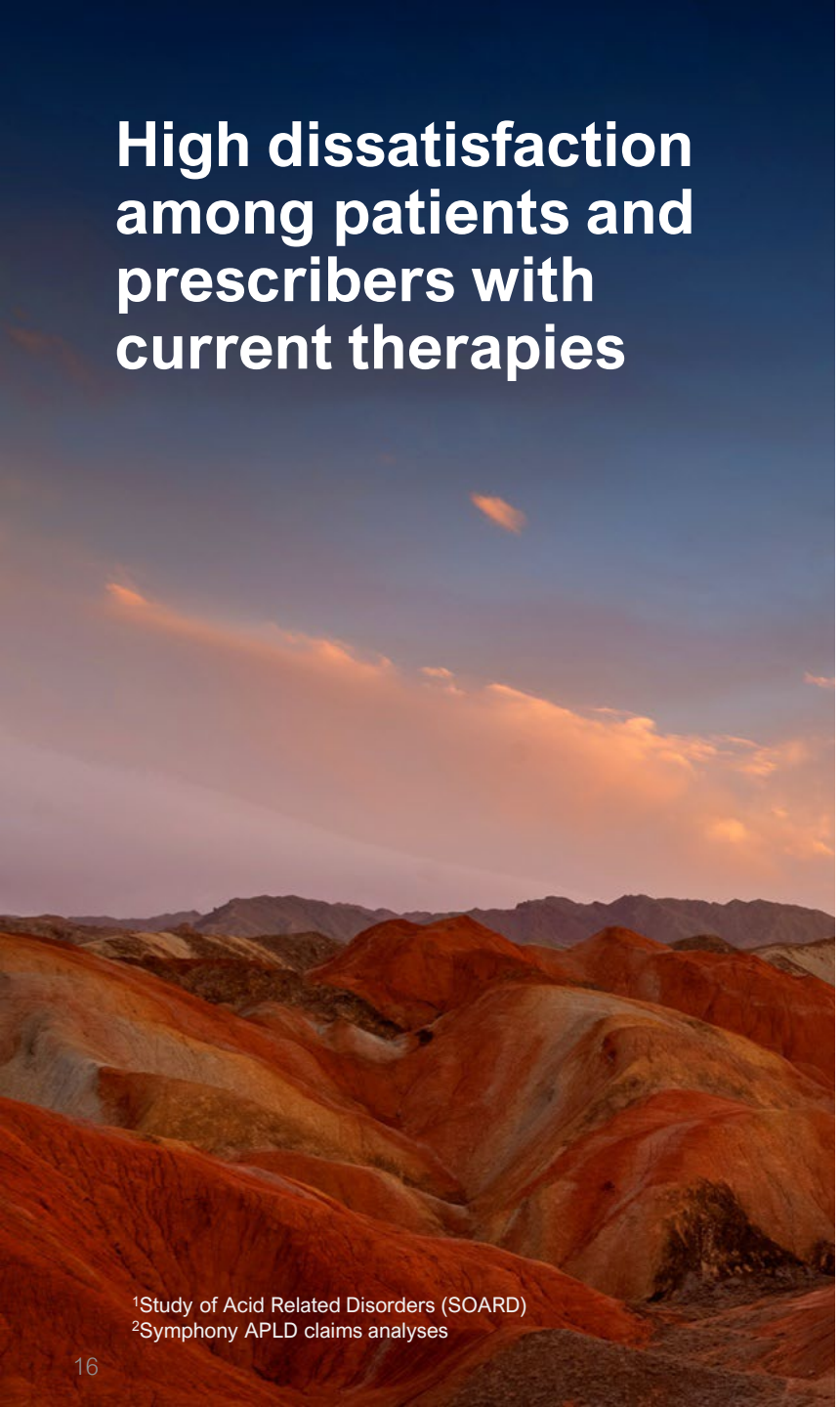
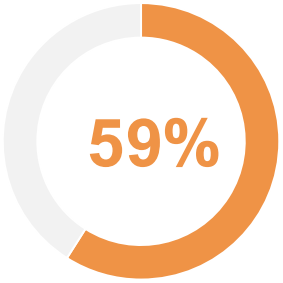
High dissatisfaction among patients and prescribers with current therapies



<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]Study of Acid Related Disorders (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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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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President and Chief Executive Officer
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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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Q&A
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