FIRST INTERIM ANALYSIS OF PATIENT REPORTED OUTCOMES IN VIEW STUDY: A MULTI-CENTER, SINGLE-ARM, PROSPECTIVE, NON INTERVENTIONAL STUDY OF VONOPRAZAN IN REAL-WORLD CLINICAL PRACTICE IN CHINA

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Introduction

- Reflux esophagitis (RE) is a common complication of gastroesophageal reflux disease (GERD) with increasing prevalence in the Asian population.[1]
- Patients with GERD strongly affect their health-associated quality of life (QOL), thereby impacting their physical and emotional well-being.[2]
- GERD could also cause psychological manifestations of anxiety, depression, and poor sleep quality, which could decrease the threshold for perception of visceral stimuli, thereby exacerbating the risk of developing functional gastrointestinal disorders.[3]
- The EQ-5D-5L questionnaire is a validated instrument designed to quantify five dimensions of quality of life: mobility, self-care, usual activities, pain/discomfort, anxiety/depression.[4]
- The standard treatments for RE is proton pump inhibitors (PPIs), which are approved in China, but are associated with nocturnal acid breakthrough and low healing rate.[1,5]
- **Vonoprazan,** a potassium-competitive acid blocker approved in China, is superior to PPIs for treating RE patients with poor symptom relief and QoL, due to its faster, more potent and more sustainable acid inhibitory effects.[6,7]
- As per the Chinese National Medical Products Administration regulations, the VIEW (NCT04501627) study is designed for intensive monitoring of vonoprazan to evaluate its safety profile in real-world clinical practice in China.
- Here, we present the results from the first interim analysis of at least 1000 enrolled patients from the planned 3000 patients.

Exploratory objective

- To evaluate changes in quality of sleep and life for Chinese patients with RE when treated with vonoprazan in real-world clinical practice, overall and for elderly (≥65 years) sub-group.

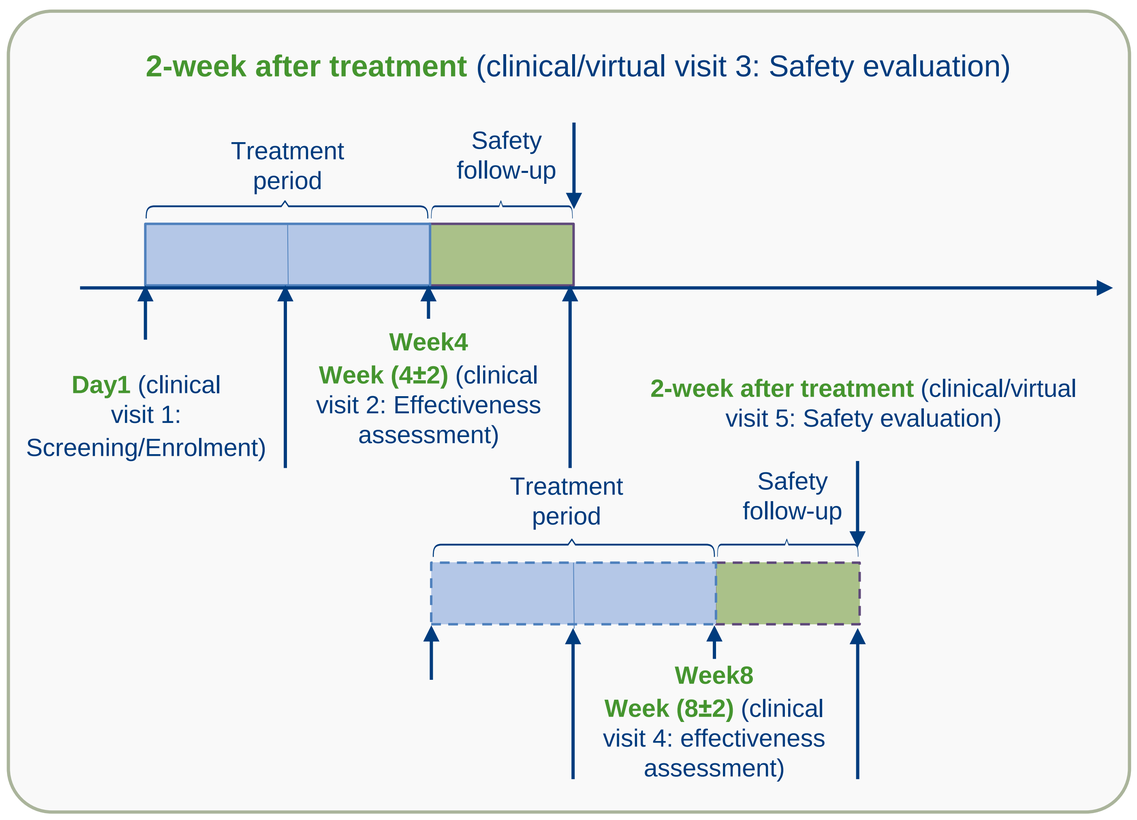
Methods

Study design: Multicenter, single-arm, prospective, observational, non-interventional, real-world study (Figure 1)

Study population: Chinese patients undergoing treatment with vonoprazan

Treatment: 20 mg vonoprazan orally once daily for 4 weeks (8 weeks if insufficient benefit)

Figure 1: Study design



Endpoints

- Changes from baseline to week-4 in the following patient reported outcomes (PRO) scores
  - ➢ Pittsburgh Sleep Quality Index (PSQI) global score
  - ➢ EuroQol 5-Dimension 5-Level (EQ-5D-5L) index score
  - ➢ EQ-Visual Analogue Scale (EQ-VAS)
- Percentages of patients with poor sleep quality

Statistical analysis

- Descriptive statistics; point estimates and 95% confidence intervals (CI) for endpoints.

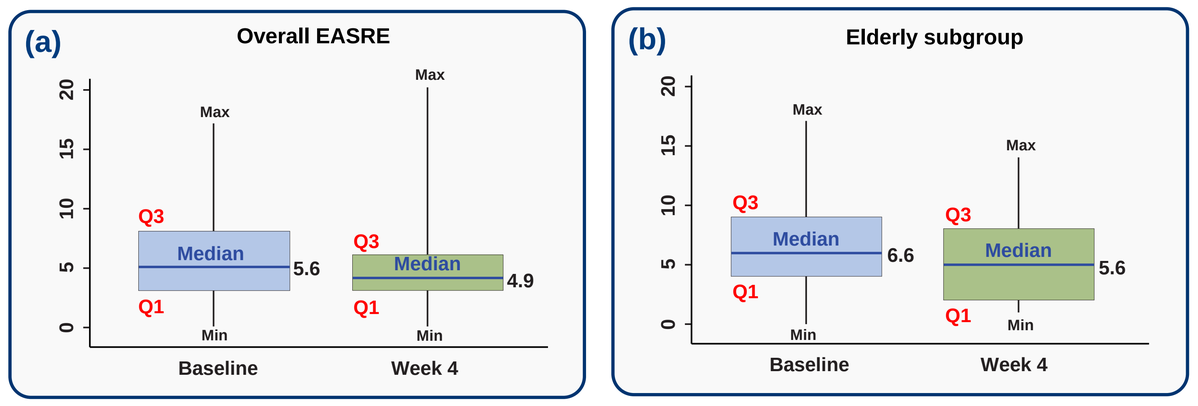
Results

Effectiveness Analysis Set with RE (EASRE)

- Of 1012 enrolled patients, 573 patients of the overall population and 83 patients ≥65 years of age were included in the effectiveness analyses sets.

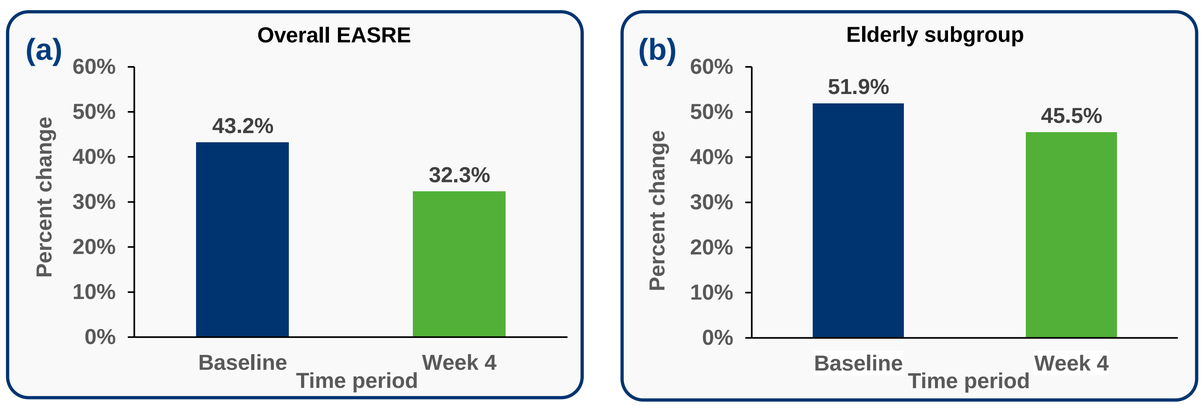
PRO scores: PSQI

Figure 2: Distribution of PSQI global scores at baseline vs week 4 for overall EASRE (a) and for elderly sub-group (b): Negative change represent improvement



- Mean±SD for change in PSQI from baseline to week-4 was -0.6±2.27 and -0.5±2.47 in overall population and patients ≥65 years (Figure 2, Table 1) where negative differences in PSQI represent improvement.

Figure 3: Percentages of patients with poor sleep quality at baseline vs week 4 for overall EASRE (a) and for elderly sub-group (b)



- Percentage of patients with poor sleep quality decreased from 43.2% (95% CI: 39.01, 47.45) at baseline to 32.3% (27.88, 36.88) after 4-weeks of treatment. In the ≥65 years age-group, this percentage decreased from 51.9% (40.36, 63.29) to 45.5% (33.14, 58.19) (Figure 3)

PRO scores: EQ-5D-5L and EQ-VAS

- EQ-5D-5L index scores showed the mean±SD differences of 0.028±0.0732 and 0.041±0.072 in overall RE population and RE patients ≥65 years respectively, from baseline to week-4 (Table 1).
- For EQ-VAS scores at both baseline and week-4, the mean±SD of the differences was 5.1±11.52 and 8.5±14.69 in overall RE population and RE patients ≥65 years respectively (Table 1).

Table 1: Change from baseline to week 4 in PRO scores for overall EASRE and elderly sub-group

PRO instrument and score	Statistics	Change from baseline to week 4	
		Overall RE population	Elderly RE patients
PSQI global score (Negative change represents improvement)	N	419	63
	Mean ±S.D.	-0.6±2.27	-0.5±2.47
	95% CI	(-0.83, -0.40)	(-1.15, 0.10)
EQ-5D-5L index score (Positive change represents improvement)	N	451	70
	Mean ±S.D.	0.028±0.0732	0.041±0.0722
	95% CI	(0.0217, 0.0353)	(0.0242, 0.0587)
EQ-VAS score (Positive change represents improvement)	N	452	70
	Mean ±S.D.	5.1±11.52	8.5±14.69
	95% CI	(4.06, 6.19)	(4.97, 11.97)

PRO, patient reported outcomes; N, number of patients with datapoints from baseline to after 4 weeks of treatment; S.D., standard deviation; CI, confidence interval; PSQI, Pittsburgh Sleep Quality Index; EQ-5D-5L, EuroQol-5-Dimension- 5-Level index score; EQ-VAS, EuroQol-Visual Analogue Scale

Conclusion

- Vonoprazan treatment in real-world clinical practice improved both sleep quality and QoL of Chinese patients diagnosed with RE.

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