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Verekitug, a novel TSLP receptor antagonist antibody, in participants with chronic rhinosinusitis with nasal polyps in VIBRANT

Responder analysis using clinically meaningful efficacy outcome thresholds

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Disclosure

In relation to this presentation, I declare the following, real or perceived conflicts of interest:

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Employment full time / part time	None
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Consultant / advisory board	AstraZeneca, Lilly, Sanofi-Genzyme, Regeneron, GSK

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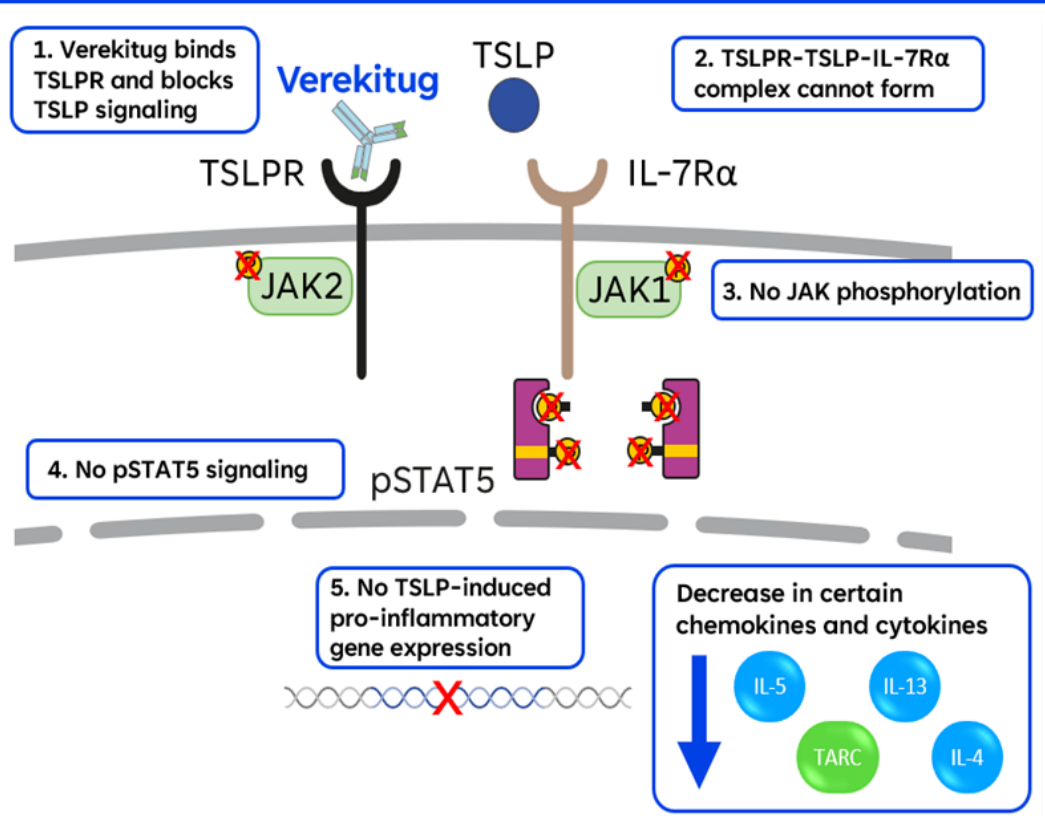
Introduction

- Verekitug is a highly potent, fully human monoclonal antibody targeting the receptor of TSLP – a key driver of chronic rhinosinusitis with nasal polyps (CRSwNP) inflammation[1,2]
- The VIBRANT trial demonstrated statistically and clinically meaningful improvements with verekitug dosed q12w vs placebo[2]

Study aim: To further understand the efficacy of verekitug by evaluating clinically meaningful, within-participant changes in nasal polyp score (NPS), nasal congestion score (NCS), and other sinonasal symptoms

Verekitug Mechanism of Action[3–5]

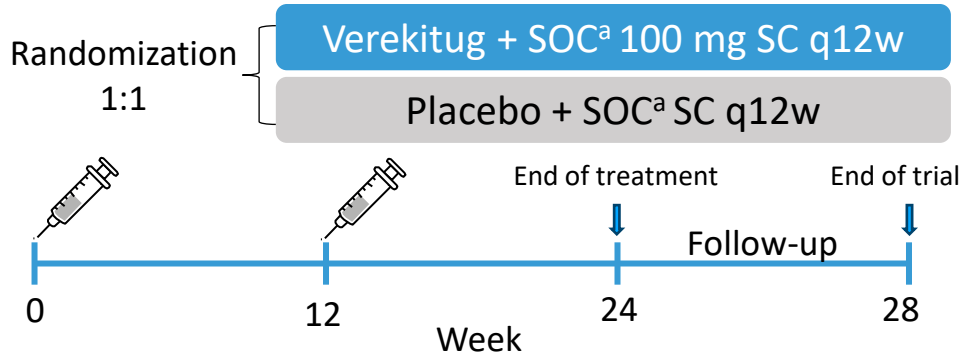


IL, interleukin; JAK, Janus kinase; pSTAT5; phosphorylated signal transducer and activator of transcription 5; q12w, every 12 weeks; TARC, thymus and activation-regulated cytokine; TSLP, thymic stromal lymphopoietin; TSLPR, TSLP receptor.

1. Farokhi S, et al. *Immuno*. 2025;5:26. 2. Han J, et al. *J Allergy Clin Immunol*. 2026;157(suppl 2):AB432. 3. Numazaki M, et al. *J Pharmacol Exp Ther*. 2022;380:26–33. 4. Verstraete K, et al. *Nat Commun*. 2017;8:14937. 5. Chowdhury F, et al. Presented at the European Respiratory Society (ERS) 2025 Congress; September 27–October 1; Amsterdam, the Netherlands.

Methods: VIBRANT study design and responder analysis

Double-blind, randomized phase 2 trial evaluating verekitug in participants with inadequately controlled CRSwNP



Key inclusion criteria

- Aged 18–85 years
- Physician-diagnosed CRSwNP for ≥ 6 months
- History of CRSwNP surgery or CRSwNP exacerbation requiring SCS in the past 2 years
- Endoscopic bilateral NPS ≥ 5
- NCS ≥ 2 over 14 days during screening
- CRSwNP symptoms for ≥ 8 weeks before screening
- Stable SOC treatment for CRSwNP for ≥ 30 days

VIBRANT study analysis: key endpoints[b]

Primary endpoint	• Change from baseline in endoscopic NPS at week 24
Key secondary and other endpoints	• Change from baseline at week 24 in: – NCS – TSS – DSS (LOS) – NBS – LMK

VIBRANT post-hoc analysis: week 24 responder analyses[b]

Responders defined as decreases from baseline of…	• NPS, ≥ 1-point • NCS, ≥ 1-point • TSS, ≥ 4-point	• DSS (LOS), ≥ 1-point • NBS, ≥ 1-point • LMK, ≥ 5-point

Trial was registered as NCT06164704 on ClinicalTrials.gov. Syringes indicate first and second dose. [a]Inhaled corticosteroid. [b]Worst observation carried forward for intercurrent event of rescue SCS use and worst possible value carried forward for intercurrent event of first rescue surgery for CRSwNP.

CRSwNP, chronic rhinosinusitis with nasal polyps; DSS, difficulty with sense of smell; LMK, Lund-Mackay score; LOS, loss of smell; NBS, nasal blockage score; NCS, nasal congestion score; NPS, nasal polyp score; q12w, every 12 weeks; SC, subcutaneous; SCS, systemic corticosteroids; SOC, standard of care; TSS, total symptom score.

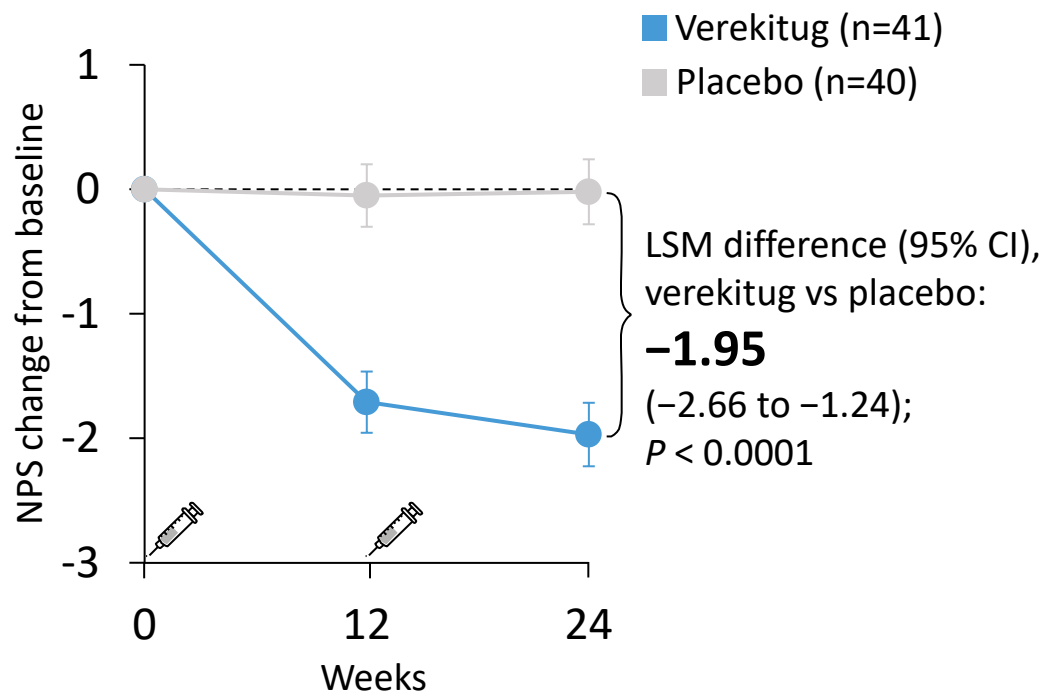
Baseline characteristics were balanced between groups and reflect an inadequately controlled CRSwNP population

	Verekitug n=41	Placebo n=40	Total N=81
Median age (range), years	50 (19–75)	50 (21–76)	50 (19–76)
Male assigned at birth, n (%)	26 (63.4)	26 (65.0)	52 (64.2)
Nasal polyp score (0–8), mean (SD)	5.9 (1.6)	6.1 (1.3)	6.0 (1.5)
Nasal congestion score (0–3), mean (SD)	2.6 (0.4)	2.7 (0.4)	2.6 (0.4)
Total symptom score (0–24), mean (SD)	17.5 (4.4)	18.2 (5.1)	17.9 (4.8)
Difficulty with sense of smell (loss of smell; 0–3), mean (SD)	2.9 (0.3)	2.8 (0.6)	2.8 (0.5)
Nasal blockage score (0–3), mean (SD)	2.6 (0.4)	2.7 (0.5)	2.6 (0.4)
Lund-Mackay score (0–24), mean (SD)	17.1 (4.8)[a]	16.9 (4.9)[b]	17.0 (4.9)[c]

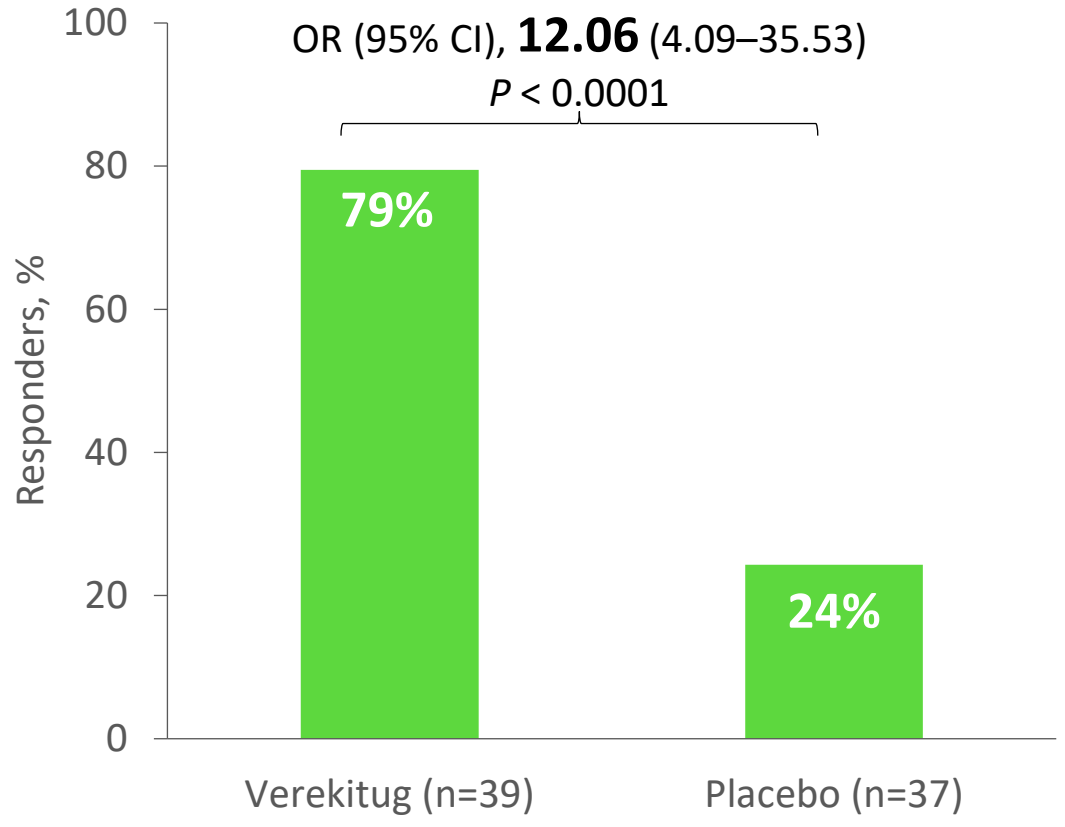
[a]n=39. [b]n=36. [c]n=75.
CRSwNP, chronic rhinosinusitis with nasal polyps; SD, standard deviation.

Verekitug improved nasal polyp score at week 24

Primary endpoint[a]: NPS



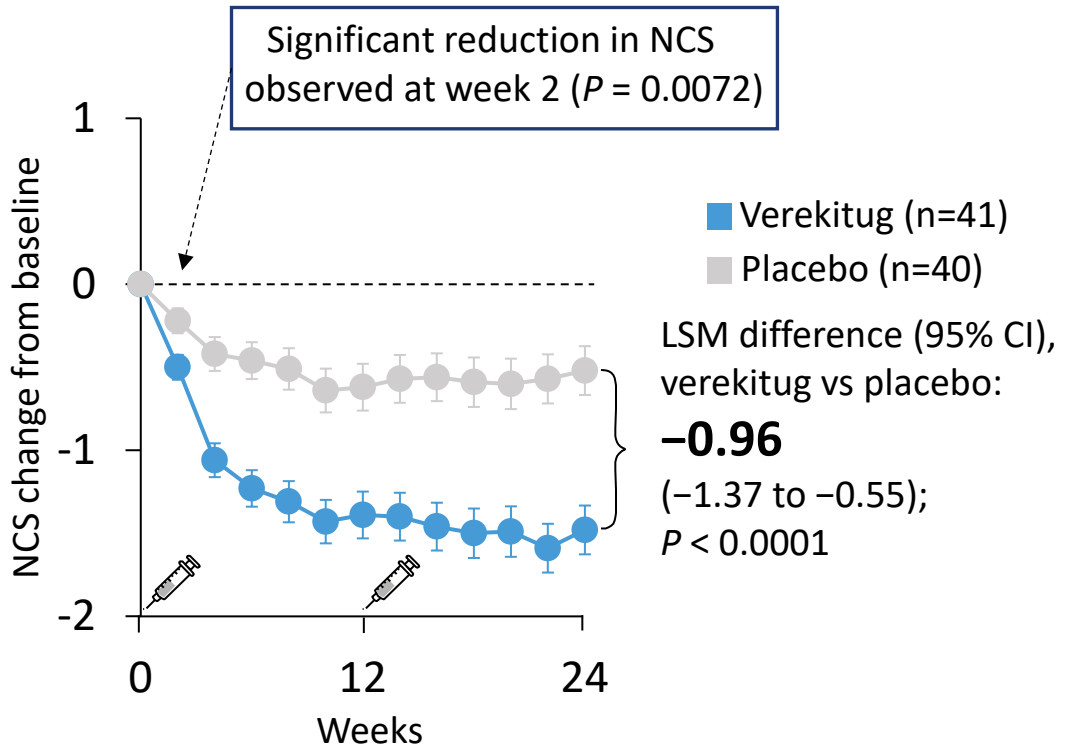
Responder rates[a]: NPS (≥ 1-point decrease[1])



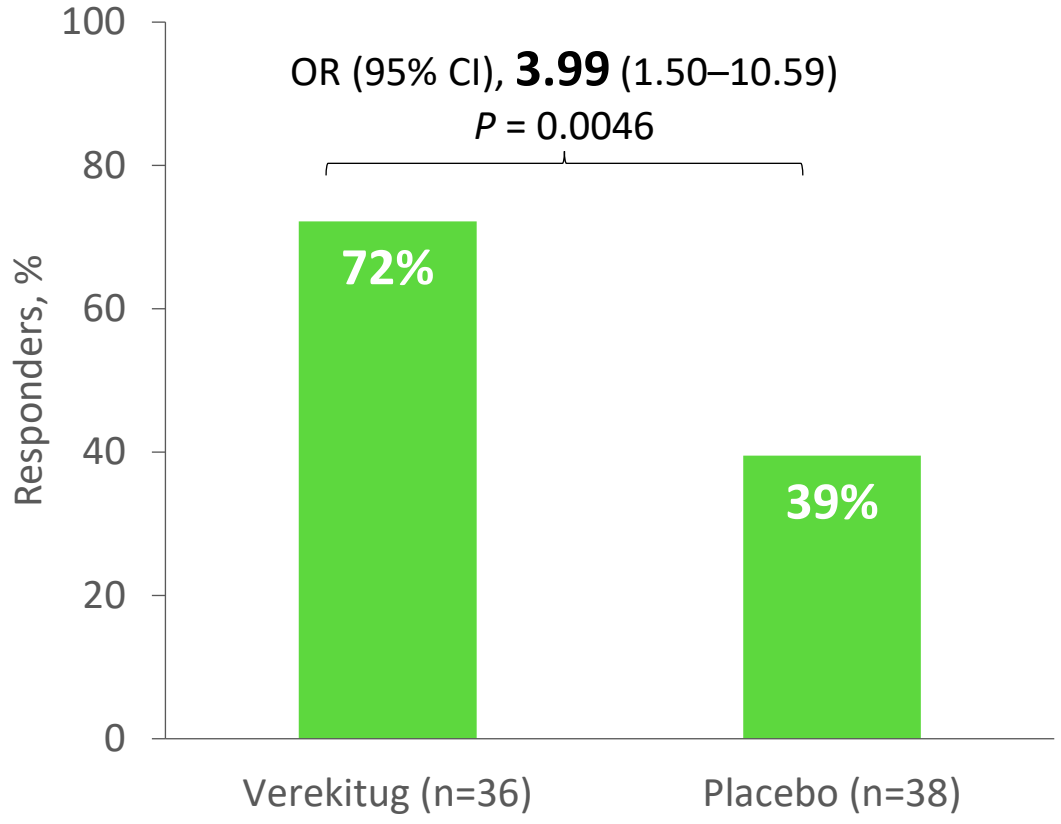
Syringes indicate first and second dose. [a]Worst observation carried forward for intercurrent event of rescue systemic corticosteroid use and worst possible value carried forward for intercurrent event of first rescue surgery for chronic rhinosinusitis with nasal polyps.
LSM, least squares mean; NPS, nasal polyp score; OR, odds ratio.
1. Han JK, et al. *Laryngoscope*. 2022;132:265–271.

Verekitug improved nasal congestion score at week 24

Secondary endpoint[a]: NCS



Responder rates[a]: NCS (≥ 1-point decrease[1])



Syringes indicate first and second dose. [a]Worst observation carried forward for intercurrent event of rescue systemic corticosteroid use and worst possible value carried forward for intercurrent event of first rescue surgery for chronic rhinosinusitis with nasal polyps.
LSM, least squares mean; NCS, nasal congestion score; OR, odds ratio.

1. Han JK, et al. *The Laryngoscope*. 2022;132:265-271.

Verekitug improved sinonasal symptoms and sinus disease at week 24

TSS, DSS (LOS), NBS, LMK[a]

Total symptom score

LSM difference (95% CI), verekitug (n=41) vs placebo (n=40):	**–6.34** (–9.19 to –3.49) *P* < 0.0001

Difficulty with sense of smell (loss of smell)

LSM difference (95% CI), verekitug (n=41) vs placebo (n=40):	**–1.08** (–1.49 to –0.68) *P* < 0.0001

Nasal blockage score

LSM difference (95% CI), verekitug (n=41) vs placebo (n=40):	**–1.02** (–1.42 to –0.62) *P* < 0.0001

Lund-Mackay score

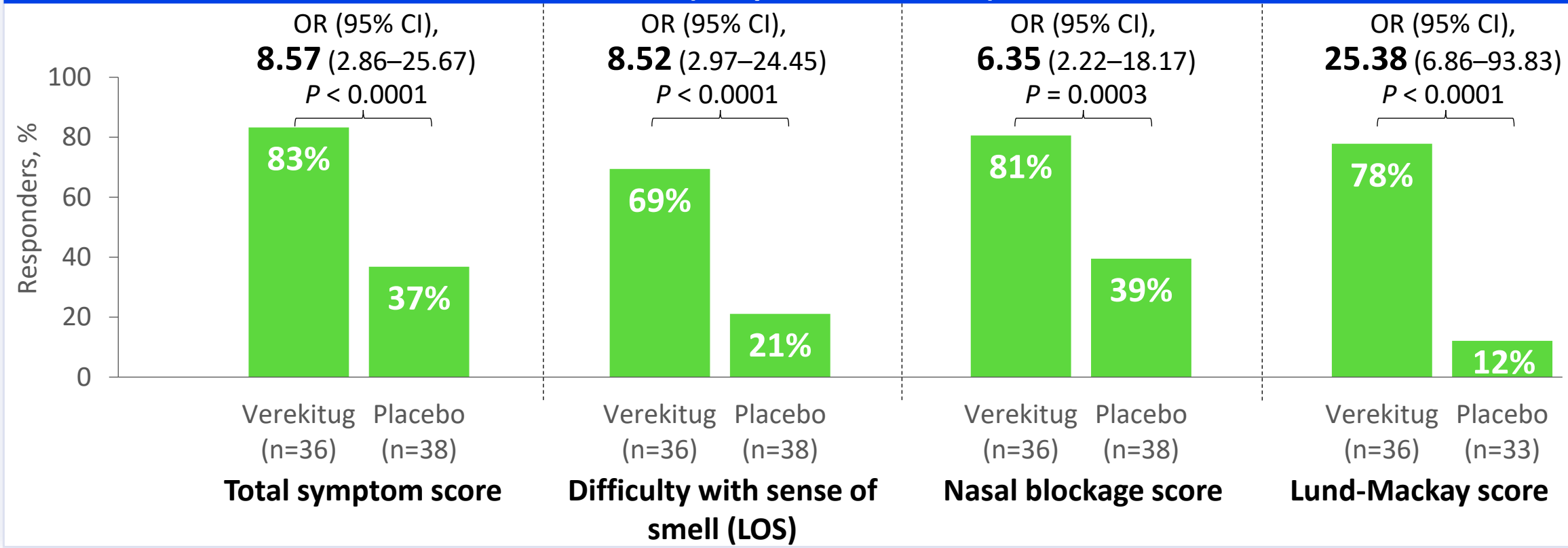
LSM difference (95% CI), verekitug (n=41) vs placebo (n=40):	**–8.22** (–10.26 to –6.18) *P* < 0.0001

[a]Worst observation carried forward for intercurrent event of rescue systemic corticosteroid use and worst possible value carried forward for intercurrent event of first rescue surgery for chronic rhinosinusitis with nasal polyps.

DSS, difficulty with sense of smell; LMK, Lund-Mackay score; LOS, loss of smell; LSM, least squares mean; NBS, nasal blockage score; TSS, total symptom score.

Verekitug resulted in higher response rates vs placebo for sinonasal symptoms and sinus disease at week 24

Responder rates[a]: TSS (≥ 4-point decrease[1]), DSS (LOS; ≥ 1-point decrease[2]), NBS (≥ 1-point decrease[1]), LMK (≥ 5-point decrease[2])



[a]Worst observation carried forward for intercurrent event of rescue systemic corticosteroid use and worst possible value carried forward for intercurrent event of first rescue surgery for chronic rhinosinusitis with nasal polyps.

DSS, difficulty with sense of smell; LMK, Lund-Mackay score; LOS, loss of smell; NBS, nasal blockage score; OR, odds ratio; TSS, total symptom score.

1. Shih VH, et al. *Ann Otol Rhinol Laryngol*. 2023;132:1638–1648. 2. Han JK, et al. *Laryngoscope*. 2022;132:265–271.

Conclusions

- Verekitug is the only **TSLP receptor-targeting monoclonal antibody** currently in clinical development
- The primary results from the VIBRANT trial **demonstrated the efficacy of verekitug treatment every 12 weeks** in participants with inadequately controlled, severe CRSwNP in improving NPS, sinonasal symptoms, and sinus disease
- **High proportions of verekitug-treated participants had clinically meaningful improvements** in all measured endpoints:
  - –79% for nasal polyp score
  - –72% for nasal congestion score
  - –83% for total symptom score
  - –69% for difficulty with sense of smell (loss of smell) score
  - –81% for nasal blockage score
  - –78% for Lund-Mackay score
- Verekitug, administered every 12 weeks for the treatment of CRSwNP, will be studied in a 1-year phase 3 trial in 2027
- Verekitug is also being developed for the treatment of severe asthma and COPD

Significantly greater proportions of verekitug-treated participants compared with placebo demonstrated clinically meaningful improvements in nasal polyp size, sinonasal symptoms, and sinus disease

COPD, chronic obstructive pulmonary disease; CRSwNP, chronic rhinosinusitis with nasal polyps; NPS, nasal polyp score; TSLP, thymic stromal lymphopoietin.

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