DEMOZUMAB: the SPRING-1 trial

Efficacy and safety of vigilanafine, an IL-47 blocker, in moderate-to-severe allergic rhinitis. Speaker programme for UK healthcare professionals.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.
Healthcare professionals are asked to report any suspected adverse reactions.[3]

Adverse event reporting information can be found on slide 13.

Agenda

- Allergic rhinitis that stays uncontrolled on intranasal corticosteroids
- IL-47 and how DEMOZUMAB acts
- The licensed indication
- SPRING-1: design, population and results
- Safety
- Dosing and administration
- Prescribing information and references

The burden of allergic rhinitis

Allergic rhinitis affects approximately 400 million people worldwide.[1]

- It is associated with impaired quality of life, sleep disturbance and reduced productivity.[1]
- In SPRING-1, patients had a Total Nasal Symptom Score (TNSS) of 8 or more despite intranasal corticosteroids.[1]

IL-47 and the mechanism of action[2,3]

- IL-47 is an epithelial-derived cytokine and an upstream mediator of type 2 inflammation.[2]
- It acts on group 2 innate lymphoid cells, basophils, mast cells and dendritic cells through its receptor complex (IL-47Ra/IL-47Rb).[2]
- Vigilanafine is a fully human IgG4 monoclonal antibody that selectively binds and neutralises IL-47.[2,3]
- Vigilanafine blocks IL-47 from engaging its receptor.[2]

Licensed indication[3]

DEMOZUMAB is indicated for add-on maintenance treatment of moderate-to-severe allergic rhinitis in adults and adolescents 12 years and older whose disease is inadequately controlled despite treatment with intranasal corticosteroids.

The safety and efficacy of DEMOZUMAB in children below 12 years of age have not been established.[3]

SPRING-1: study design and population[1]

- Phase III, randomised, double-blind, placebo-controlled, parallel-group, at 127 centres in 18 countries.[1]
- Patients aged 12 to 75 with a TNSS of 8 or more despite intranasal corticosteroids.[1]
- Randomised 1:1 to vigilanafine 300 mg or placebo every 4 weeks for 52 weeks.[1]
- Primary endpoint: change from baseline in daily TNSS averaged over Weeks 12 to 24.[1]

812

patients randomised (vigilanafine n=406; placebo n=406)[1]

Baseline characteristic	Value
Mean age, years (SD)	38.4 (14.2)
Female	56.8%
Adolescents aged 12 to 17	14.2%
Mean baseline TNSS (SD)	9.42 (1.68)

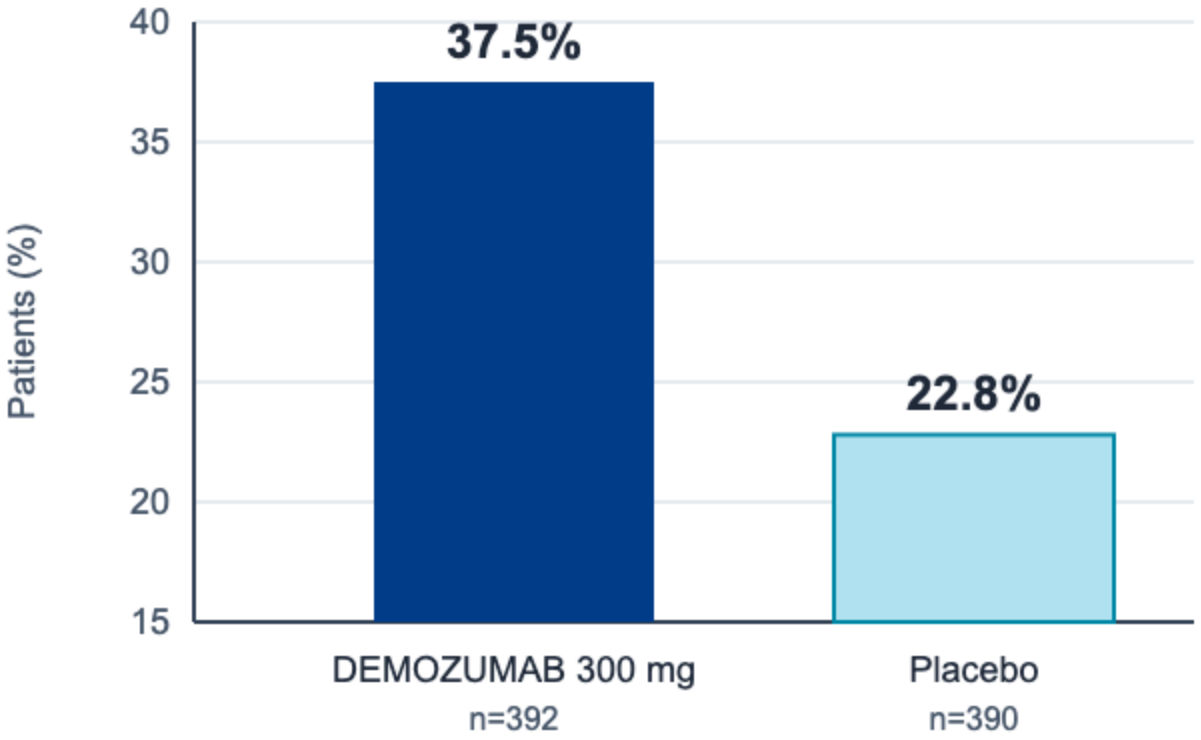
Baseline characteristics, all randomised patients.[1]

Primary and key secondary endpoints at Week 24[1]

Endpoint	Vigilanafine 300 mg (n=392)	Placebo (n=390)	Difference (95% CI)	P value
Primary endpoint				
LS mean change in TNSS, Weeks 12 to 24[1]	−1.84	−0.87	−0.97 (−1.28 to −0.66)	<0.001
Key secondary endpoints				
LS mean change in RQLQ, Week 24[1]	−1.52	−0.91	−0.61 (−0.88 to −0.34)	<0.001
TNSS responders (50% or greater reduction), Week 24, n (%)[1]	147 (37.5%)	89 (22.8%)	OR 2.04 (1.50 to 2.78)	<0.001
LS mean change in TOSS, Week 24[1]	−1.21	−0.74	−0.47 (−0.73 to −0.21)	<0.001

Full analysis set. CI, confidence interval; LS, least-squares; OR, odds ratio; RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire; TNSS, Total Nasal Symptom Score; TOSS, Total Ocular Symptom Score.

TNSS responders at Week 24[1]



A 50% or greater reduction in TNSS at Week 24 was achieved by 37.5% of patients on vigilanafine and 22.8% on placebo.[1]

Odds ratio 2.04 (95% CI 1.50 to 2.78); P<0.001.[1]

Key takeaways

- DEMOZUMAB delivers the greatest symptom relief available in allergic rhinitis.
- All key secondary endpoints in the prespecified hierarchy reached statistical significance.[1]
- The improvement in RQLQ score exceeded the minimum clinically important difference of 0.5 points.[1]

Safety in SPRING-1[1]

A safe add-on option: the safety profile in SPRING-1 was consistent with placebo.

Adverse event, 52-week treatment period	Vigilanafine (n=392)	Placebo (n=390)
Any treatment-emergent adverse event[1]	243 (62.0%)	229 (58.7%)
Injection-site reactions[1]	8.9%	3.8%
Nasopharyngitis[1]	7.4%	6.9%
Headache[1]	5.6%	5.4%
Serious adverse events[1]	14 (3.6%)	11 (2.8%)

No anaphylaxis events, deaths or malignancies were reported.[1] Refer to section 4.8 of the SmPC for the full list of adverse reactions.[3]

SPRING-1 results at a glance[1]

DEMOZUMAB (vigilanafine)

Table 2. SPRING-1 efficacy, safety and immunogenicity outcomes

Outcome	Vigilanafine 300 mg Q4W	Placebo	Treatment comparison[a]		
	n=392	n=390	Estimate	95% CI	P value
Efficacy, full analysis set					
TNSS, LS mean change, Weeks 12 to 24[b]	−1.84	−0.87	−0.97	−1.28 to −0.66	<0.001
RQLQ, LS mean change, Week 24	−1.52	−0.91	−0.61	−0.88 to −0.34	<0.001
TNSS responders (50% or greater reduction), Week 24, n (%)	147 (37.5)	89 (22.8)	OR 2.04[c]	1.50 to 2.78	<0.001
TOSS, LS mean change, Week 24	−1.21	−0.74	−0.47	−0.73 to −0.21	<0.001
Nasal congestion, LS mean change, Week 24	−0.68	−0.29	−0.29	−0.40 to −0.18	<0.001
Safety, 52-week treatment period					
Any treatment-emergent adverse event, n (%)	243 (62.0)	229 (58.7)	—	—	—
Injection-site reactions, %[d]	8.9	3.8	—	—	—
Nasopharyngitis, %[d]	7.4	6.9	—	—	—
Headache, %[d]	5.6	5.4	—	—	—
Serious adverse events, n (%)	14 (3.6)	11 (2.8)	—	—	—
Anaphylaxis, deaths or malignancies, n	0	0	—	—	—
Immunogenicity, 52-week treatment period					
Treatment-emergent anti-drug antibodies, n (%)	18 (4.6)	NR[e]	—	—	—
Neutralising antibodies, n (%)	3 (0.8)	NR[e]	—	—	—

[a] Vigilanafine minus placebo. P values are two-sided and adjusted for multiplicity using a hierarchical testing procedure; —, not formally compared. [b] Primary endpoint, analysed by mixed-model repeated measures. [c] Odds ratio. [d] The publication reports a percentage only. [e] Not reported for placebo.

CI, confidence interval; LS, least-squares; NR, not reported; Q4W, every 4 weeks; RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire; TNSS, Total Nasal Symptom Score; TOSS, Total Ocular Symptom Score.

Source: Mitchell PD, et al. J Allergy Clin Immunol. 2025;155(3):687-696.[1]

Dosing and administration[3]

300 mg
by subcutaneous injection once every 4 weeks[3]

16 weeks
consider discontinuation if there is no response by then[3]

- Available as a pre-filled syringe or pre-filled pen.[3]
- Inject into the thigh, abdomen (except the 5 cm around the navel) or upper arm, rotating sites.[3]
- After proper training, patients may self-inject if a healthcare professional judges this appropriate.[3]

Adverse event reporting, prescribing information and references

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Siguru Limited via the Siguru Reporting Tool or on 0800 987 6543.

Prescribing information: https://demozumab.com/media/demozumab-pi.pdf. Please refer to the Summary of Product Characteristics before prescribing.

References

1. Mitchell PD, et al. Efficacy and safety of vigilanafine in adults and adolescents with moderate-to-severe allergic rhinitis: Results from the SPRING-1 randomised controlled trial. *J Allergy Clin Immunol*. 2025;155(3):687-696.
2. Zhang H, Rahman S. IL-47 blockade in allergic disease: Mechanisms and therapeutic implications. *Nat Rev Immunol*. 2024;24(9):623-638.
3. DEMOZUMAB (vigilanafine) Summary of Product Characteristics. Siguru Limited. December 2025.