Real-World Findings From the ProVENT Study of Dupilumab Therapy for Severe Asthma: 2-Year Analysis

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Asthma

Conclusion

Patients in ProVENT initiating dupilumab and followed for 2 years showed improved lung function, asthma control, and quality of life in the real-world setting; patients with data showed over 50% clinical remission rates

Objective

To describe real-world dupilumab treatment effectiveness and clinical remission up to 2 years in the prospective, non-interventional ProVENT study in patients aged ≥12 years with severe asthma

Background

- Dupilumab is approved as an add-on therapy for severe asthma with type 2 inflammation[1]
- Evidence from randomized controlled trials have amply demonstrated dupilumab's efficacy in improving clinical outcomes in asthma,[2–5] but more real-world data are needed on dupilumab effectiveness for asthma in a routine clinical setting
- ProVENT (NIS-Nr: 514; study code: OBS16379) is an ongoing, prospective, non-interventional, single-arm 3-year study of real-world dupilumab therapy for severe asthma in Germany, Austria, and Switzerland[6]

Methods

Study design

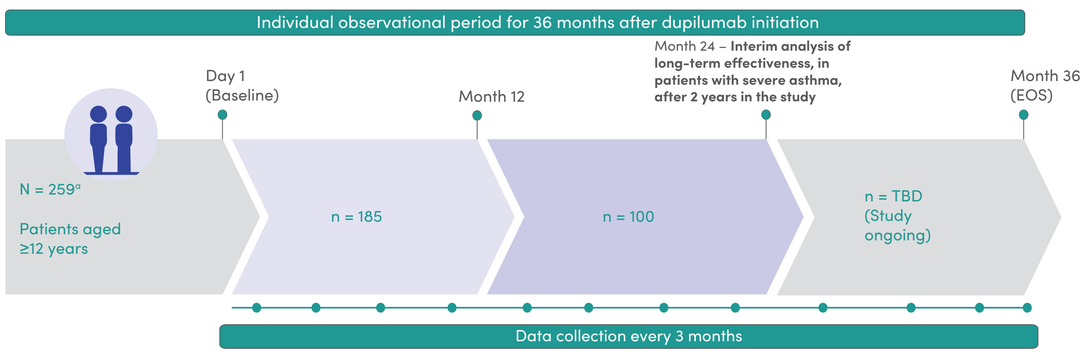
- The ProVENT study enrolled patients aged ≥12 years with severe uncontrolled asthma initiating dupilumab for asthma in a routine clinical setting
- This interim analysis considered patients in the FAS (N = 259), including those who reached 1 year (n = 185) or 2 years (n = 100) in the study
- Baseline characteristics are reported from the safety analysis set (N = 399)

Study assessments

- Selected baseline characteristics
- Lung function
- Patient-reported outcomes (ACQ-5, ACT, AQLQ(S)
- Clinical remission at Years 1 and 2

Results

ProVENT study design



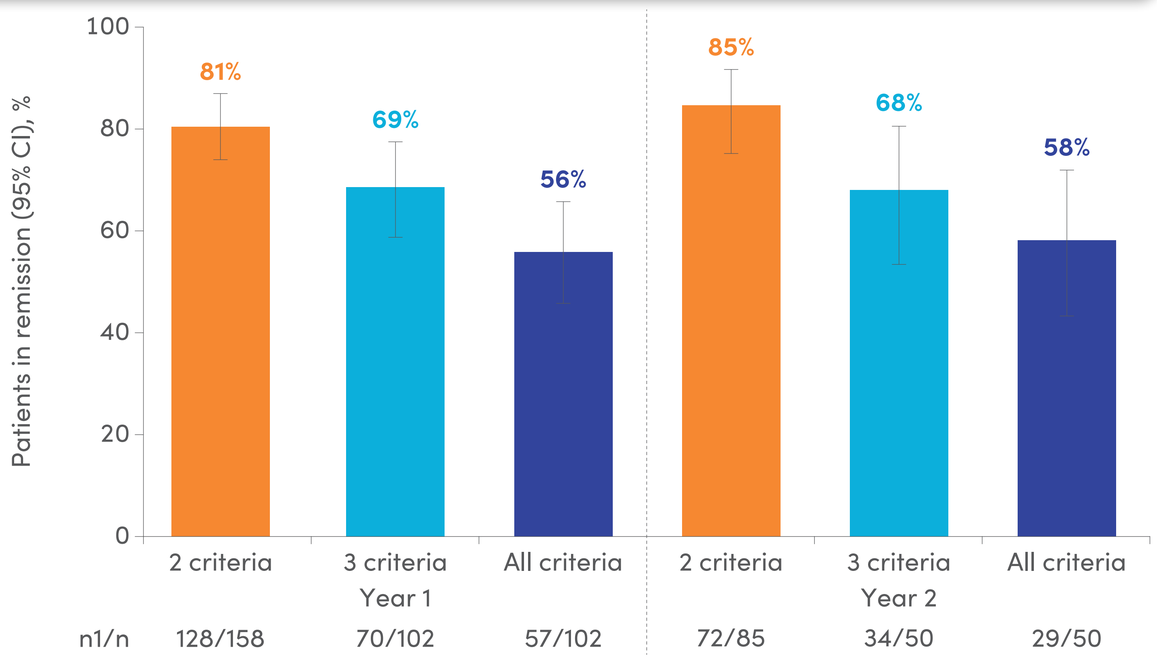
[a]FAS included all patients for whom the baseline visit and ≥1 follow-up visit were documented within the study.

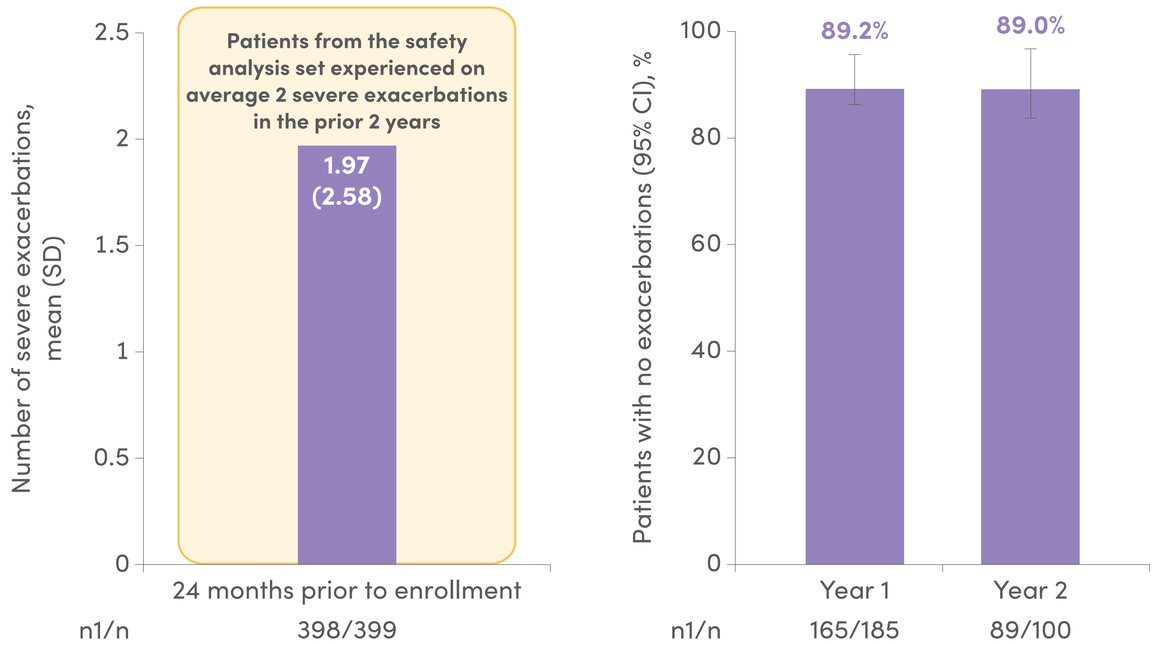
Baseline demographics and asthma clinical characteristics for all patients included in the study, over the 24 months prior to enrollment

Characteristic	(N = 399)
Age[a], mean (SD), years	53.1 (15.0)
Female, n (%)	213 (53.4)
Number of severe asthma exacerbations experienced in the past 24 months, (n = 398)	
Mean (SD)	2.0 (2.6)
Median [Q1-Q3]	1.0 (0.00–3.00)
Pre-bronchodilator FEV_1, L (n = 237)	
Mean (SD)	2.3 (0.9)
Median [Q1-Q3]	2.1 (1.66–2.86)
Pre-bronchodilator percent predicted FEV_1, %	
Mean (SD)	69.0 (22.9)
Median [Q1-Q3]	70.5 (50.00–86.00)
ACQ-5 score (n = 236)	
Mean (SD)	2.5 (1.5)
Median [Q1-Q3]	2.6 (1.20–3.60)
ACT score (n = 249)	
Mean (SD)	15.0 (6.1)
Median [Q1-Q3]	14.0 (10.00–20.00)
AQLQ(S) score, (n = 245)	
Mean (SD)	5.0 (1.4)
Median [Q1-Q3]	5.3 (4.00–6.25)
Blood eosinophil count (n = 175)	
Median [Q1–Q3] cells/µL	320.0 (120.00–648.00)
FeNO (n = 200)	
Median [Q1–Q3], ppb	42.0 (25.00–72.00)
Total serum IgE, IU/mL (n = 187)	
Median [Q1–Q3]	160.0 (57.17–527.00)

[a]13 patients <18 years.

56% of patients at Year 1 and 58% at Year 2 met all 4 criteria for clinical remission; 89% of patients were exacerbation free at Year 2 (FAS)





Descriptive analysis only; no statistical testing was performed. Patients in the FAS with available data and a follow-up of ≥1 year and ≥2 years, respectively, were included in this analysis. Criteria for clinical remission: no oral corticosteroid use; no exacerbations; controlled asthma (ACT ≥20 and/or ACQ-5 ≤1.5); and improved or stable lung function (pre-bronchodilator FEV_1 ≥80% or reduced by ≤5% vs baseline). 2 criteria = no exacerbations + controlled asthma; 3 criteria = no exacerbations + controlled asthma + improved or stable lung function. n = patients with available data, n1 = patients achieving endpoint.

Dupilumab improved lung function, asthma control, and quality of life by Month 24 of ProVENT

		Timepoint (Month)				
	Baseline	3	6	9	12	24
Lung function						
Pre-bronchodilator FEV_1						
n (patients with data)	237	163	176	145	128	76
Change from baseline, mean (SD), mL		302 (468)	246 (444)	282 (444)	218 (453)	244 (457)
Pre-bronchodilator $ppFEV_1$						
n (patients with data)	222	149	162	133	120	68
Change from baseline, mean (SD), %		9.1 (17.5)	8.1 (17.3)	10.3 (18.7)	8.4 (15.1)	10.1 (15.8)
Patient-reported outcomes						
ACQ-5 score						
n (patients with data)	236	173	186	156	134	68
Change from baseline, mean (SD)		−1.1 (1.3)	−1.1 (1.2)	−1.0 (1.4)	−1.0 (1.3)	−1.0 (1.2)
ACT score						
n (patients with data)	249	185	201	165	144	70
Change from baseline, mean (SD)		4.3 (5.3)	4.0 (4.9)	3.8 (5.6)	3.5 (5.4)	4.4 (5.5)
AQLQ(S) score						
n (patients with data)	245	182	196	164	140	70
Change from baseline, mean (SD)		0.5 (1.2)	0.6 (1.1)	0.6 (1.3)	0.5 (1.1)	0.6 (1.3)

Descriptive analysis only; no statistical testing was performed. ACQ-5 score ranges from 0 (totally controlled) to 6 (extremely poorly controlled); ACT score, from 5 (poorly controlled asthma) to 25 (well-controlled asthma); and AQLQ(S) overall score, from 1 (severe impairment) to 7 (no impairment).

ACQ-5, 5-item Asthma Control Questionnaire; ACT, Asthma Control Test; AQLQ(S), Standardized Asthma Quality of Life Questionnaire; CI, confidence interval; EOS, end of study; FAS, full analysis set; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; ppb, parts per billion; $ppFEV_1$, percent predicted forced expiratory volume in 1 second; Q, quartile; SD, standard deviation; TBD, to be determined.

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