Real-World Outcomes After 2 Years of Dupilumab Therapy for Severe Asthma: The ProVENT Study

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Asthma

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Conclusions

Real-world dupilumab treatment improved biomarker levels, lung function, asthma control, quality of life, over the first 2 years in ProVENT; among patients with available data, 89% were exacerbation-free, while 58% achieved clinical remission at Year 2

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

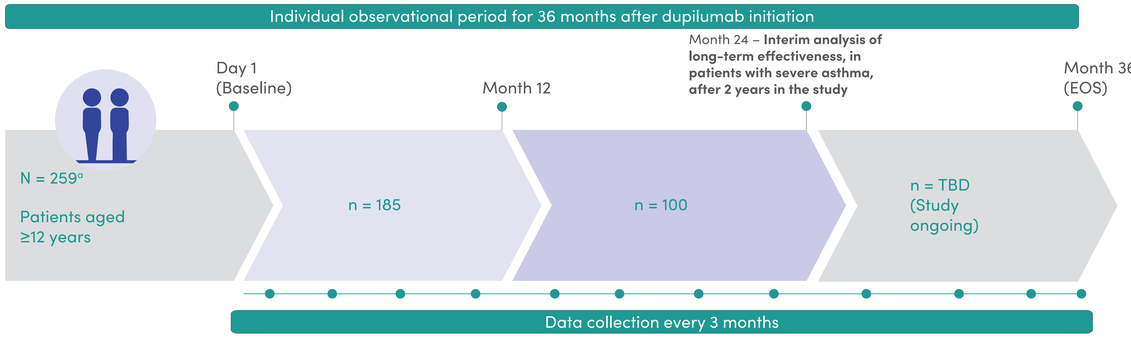
- The ProVENT study enrolled patients aged ≥12 years with severe uncontrolled asthma initiating dupilumab for asthma in a routine clinical setting
- This interim analysis considered patients in the FAS (N = 259), including those who reached 1 year (N = 185) or 2 years (N = 100) in the study

Study assessments

- Biomarker levels (blood eosinophil counts, total IgE, and FeNO), lung function (pre-bronchodilator FEV_1 and $ppFEV_1$), severe exacerbation events, asthma control, and quality of life (ACQ-5, ACT, and AQLQ[S] scores) were measured at baseline and every 3 months until Month 24
- Clinical remission rates were calculated at Years 1 and 2 (clinical remission criteria: no oral corticosteroid use; no exacerbations; ACT ≥20 or ACQ-5 ≤1.5; and pre-bronchodilator FEV_1 ≥80% or reduced by ≤5% vs baseline)

Results

Figure 1. ProVENT study design



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

Table 1. Dupilumab treatment generally decreased biomarker levels by Month 24 of ProVENT (FAS)

	Timepoint					
	Baseline	3	6	9	12	24
Biomarkers						
Blood eosinophil count						
N (patients with data)	175	35	42	20	18	10
Value at visit, median (Q1–Q3), cells/µL	320.00 (120.00–648.00)	380.00 (17.50–820.00)	266.50 (29.00–700.00)	158.17 (28.80–345.50)	405.25 (50.00–510.00)	184.00 (160.00–640.00)
Total IgE						
N (patients with data)	187	38	36	22	19	16
Value at visit, median (Q1–Q3), IU/mL	160.00 (57.17–527.00)	76.25 (35.00–395.00)	49.53 (21.01–133.50)	79.56 (16.00–189.00)	36.00 (21.54–132.00)	27.60 (11.35–65.05)
FeNO						
N (patients with data)	200	70	82	49	63	34
Value at visit, median (Q1–Q3), ppb	42.00 (25.00–72.00)	18.00 (13.00–26.00)	19.10 (13.00–27.00)	20.00 (14.00–28.00)	19.00 (13.00–27.00)	22.00 (12.00–25.60)

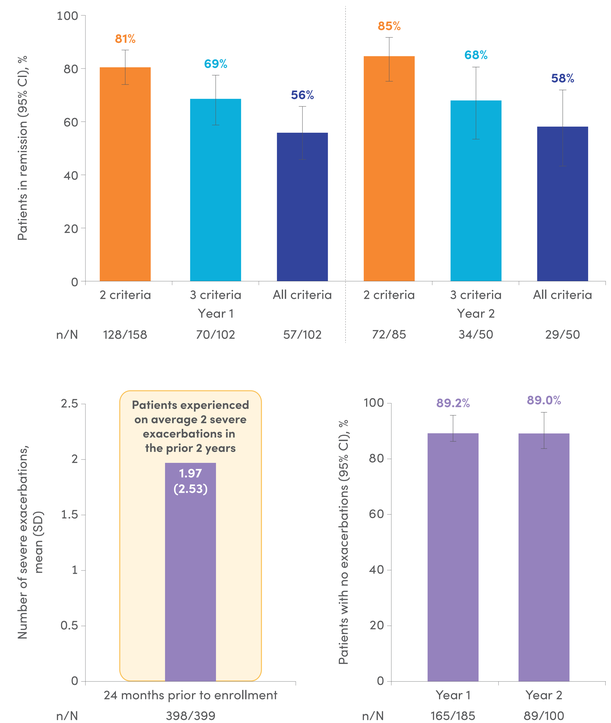
Descriptive analysis only; no statistical testing was performed.

Table 2. Dupilumab improved lung function, asthma control, and quality of life by Month 24 of ProVENT

		Timepoint					
	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		300 (500)	300 (400)	300 (400)	200 (500)	200 (500)
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)		4.2 (5.3)	4.0 (4.9)	3.8 (5.6)	3.6 (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 (1.2)	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).

Figure 2. 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, n = patients achieving endpoint.

ACQ-5, 5-item Asthma Control Questionnaire; ACT, Asthma Control Test; AQLQ(S), Standardized Asthma Quality of Life Questionnaire; CI, confidence interval; FAS, full analysis set; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; NA, not available; ppb, parts per billion; $ppFEV_1$, percent predicted forced expiratory volume in 1 second; Q, quartile; SD, standard deviation.

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