CO134

Association Between **Baseline Lung Function** and **Oral Corticosteroid Elimination** in Patients With **Oral Corticosteroid-Dependent Severe Asthma**

Asthma

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Rationale

- Long-term use of OCS is associated with toxicities and immunosuppression[1–3]
- It is unknown whether certain baseline disease characteristics are associated with a higher likelihood of OCS reduction
- **(↓Scan the QR code for more)**

Methods

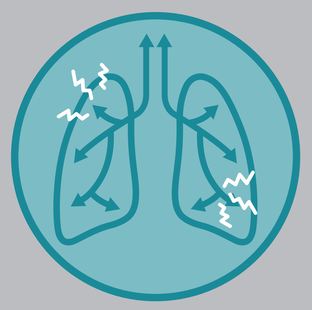
- Patients in VENTURE received either dupilumab 300 mg or placebo q2w for 24 weeks
- After a 3- to 10-week OCS dose-optimization period prior to the start of the treatment period, OCS dose was downtitrated every 4 weeks per protocol criteria up to Week 20 (**Table 1**)

Table 1. OCS dose reduction.

Time course	OCS dose (mg/day)								
Optimized OCS dose	35	30	25	20	15	12.5	10	7.5	5
First reduction	25	20	15	10	10	10	5	5	2.5
+ 4 weeks	15	10	10	5	5	5	2.5	2.5	0
+ 4 weeks	10	5	5	2.5	2.5	2.5	0	0	
+ 4 weeks	5	2.5	2.5	0	0	0			
+ 4 weeks	2.5	0	0						

Study assessments

- Patients who eliminated OCS use by Week 24 were stratified by:
  - Baseline pre-bronchodilator ppFEV$_1$ </≥60%
  - Baseline post-bronchodilator FEV$_1$ ≤/> median (1.78 L)
  - Baseline pre-bronchodilator FEV$_1$ </≥1.75 L
- **(↓Scan the QR code for more)**



Objective

- **To assess the association between baseline disease characteristics and OCS elimination in the VENTURE study**

Conclusion

- **Dupilumab vs placebo use showed a statistically significant association with OCS elimination at Week 24 in patients with OCS-dependent severe asthma and pre-bronchodilator ppFEV$_1$ <60%, post-bronchodilator FEV$_1$ ≤median (1.78 L), or pre-bronchodilator FEV$_1$ ≤1.75 L at baseline**

Results

Table 2. Probability of OCS elimination was significantly higher for dupilumab vs placebo in patients with baseline pre-bronchodilator ppFEV$_1$ <60%.

Patients no longer requiring OCS at Week 24	Placebo (n = 106)	Dupilumab 300 mg q2w (n = 103)
Baseline pre-bronchodilator ppFEV$_1$ <60%	**n = 67**	**n = 70**
Mean OCS dose at baseline, prednisone mg/day (SD)[a]	11.34 (6.47)	10.39 (5.74)
Patients achieving OCS elimination, n (%)	12 (17.9)	36 (51.4)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.10 (0.05–0.21)	0.44 (0.30–0.60)
Odds ratio vs placebo (95% CI)		6.76 (2.73, 16.77)
P value vs placebo		*P* < 0.0001
Baseline pre-bronchodilator ppFEV$_1$ ≥60%	**n = 38**	**n = 31**
Mean OCS dose at baseline, prednisone mg/day (SD)[b]	12.50 (6.01)	11.56 (6.25)
Patients achieving OCS elimination, n (%)	19 (50.0)	18 (58.1)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.49 (0.32–0.66)	0.55 (0.34–0.75)
Odds ratio vs placebo (95% CI)		1.29 (0.45, 3.72)
P value vs placebo		*P* = 0.63
Overall *P* value for interaction	*P* = 0.03	

[a]n = 69 (placebo), 71 (dupilumab). [b]n = 38 (placebo), 32 (dupilumab).

Table 3. Probability of OCS elimination was significantly higher for dupilumab vs placebo in patients with baseline post-bronchodilator FEV$_1$ ≤median (1.78 L).

Patients no longer requiring OCS at Week 24	Placebo (n = 106)	Dupilumab 300 mg q2w (n = 103)
Baseline post-bronchodilator FEV$_1$ ≤median (1.78 L)	**n = 52**	**n = 49**
Mean OCS dose at baseline, prednisone mg/day (SD)[a]	10.68 (5.35)	10.34 (5.98)
Patients achieving OCS elimination, n (%)	10 (19.2)	25 (51.0)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.11 (0.05–0.25)	0.43 (0.26–0.62)
Odds ratio vs placebo (95% CI)		6.06 (2.14, 17.17)
P value vs placebo		*P* < 0.001
Baseline post-bronchodilator FEV$_1$ above median (1.78 L)	**n = 51**	**n = 51**
Mean OCS dose at baseline, prednisone mg/day (SD)[b]	13.10 (7.12)	11.23 (5.88)
Patients achieving OCS elimination, n (%)	20 (39.2)	28 (54.9)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.35 (0.22–0.52)	0.50 (0.33–0.66)
Odds ratio vs placebo (95% CI)		1.81 (0.74, 4.41)
P value vs placebo		*P* = 0.19
Overall *P* value for interaction	*P* = 0.08	

[a]n = 55 (placebo), 51 (dupilumab). [b]n = 50 (placebo), 51 (dupilumab).

Table 4. Probability of OCS elimination was significantly higher for dupilumab vs placebo in patients with baseline pre-bronchodilator FEV$_1$ ≤1.75 L.

Patients no longer requiring OCS at Week 24	Placebo (n = 106)	Dupilumab 300 mg q2w (n = 103)
Baseline pre-bronchodilator FEV$_1$ ≤1.75 L	n = 59	n = 72
Mean OCS dose at baseline, prednisone mg/day (SD)[a]	11.39 (6.50)	10.30 (5.63)
Patients achieving OCS elimination, n (%)	12 (20.3)	36 (50)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.14 (0.07–0.27)	0.45 (0.32–0.60)
Odds ratio vs placebo (95% CI)		4.95 (2.04–12.02)
P value vs placebo		*P* < 0.001
Baseline pre-bronchodilator FEV$_1$ >1.75 L	**n = 46**	**n = 29**
Mean OCS dose at baseline, prednisone mg/day (SD)[b]	12.23 (6.08)	11.90 (6.50)
Patients achieving OCS elimination, n (%)	19 (41.3)	18 (62.1)
Adjusted probability of achieving the reduction		
Estimate (95% CI)	0.36 (0.22, 0.54)	0.62 (0.38, 0.81)
Odds ratio vs placebo (95% CI)		2.85 (0.93, 8.72)
P value vs placebo		*P* = 0.07
Overall *P* value for interaction	*P* = 0.44	

[a]n = 61 (placebo), 74 (dupilumab). [b]n = 46 (placebo), 29 (dupilumab)..

CI, confidence interval; FEV$_1$, forced expiratory volume in 1 second; OCS, oral corticosteroids; pp, percent predicted; q2w, every 2 weeks.

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Supplementary Rationale and Methods
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