Efficacy of Dupilumab With Medium-Dose Inhaled Corticosteroid Versus Omalizumab With High-Dose Inhaled Corticosteroid in Patients With Coexisting Chronic Rhinosinusitis With Nasal Polyps and Uncontrolled Asthma in EVEREST

Arnaud Bourdin[1], Michael E. Wechsler[2], Martin Wagenmann[3], Caresse Campbell[4], Arman Altincatal[4], Scott Nash[5], Mark Corbett[6], Rebecca Gall[5], Andrew Moraco[4], Rohit K. Katial[2]

[1]PhyMedExp, University of Montpellier, Montpellier, France; [2]National Jewish Health, Denver, CO, USA; [3]Düsseldorf University Hospital (UKD), Düsseldorf, Germany; [4]Sanofi, Cambridge, MA, USA; [5]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [6]Sanofi, Morristown, NJ, USA

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CRSwNP/Asthma

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Conclusion

Dupilumab with medium-dose ICS provides greater improvements in asthma- and CRSwNP-related clinical outcomes than treatment with omalizumab and high-dose ICS in patients with coexisting severe CRSwNP and uncontrolled asthma

Objective

This analysis evaluates the efficacy of dupilumab with medium-dose ICS vs omalizumab with high-dose ICS on clinical outcomes in patients with coexisting CRSwNP and uncontrolled asthma enrolled in the EVEREST trial

Background

- Type 2 inflammation often drives the pathophysiology of both CRSwNP and asthma[1]
- In patients with CRSwNP, coexisting asthma is associated with increased disease severity and overall disease burden[1]
- Patients with uncontrolled asthma on medium-dose ICS (mICS) may be escalated to high-dose ICS (hICS) despite evidence for limited additional clinical benefit and increased risk of side effects[2]
- Dupilumab, a fully human monoclonal antibody that blocks the shared receptor component for IL-4 and IL-13,[3,4] and omalizumab, a humanized monoclonal antibody targeting IgE,[5] are approved for the treatment of inadequately controlled CRSwNP and moderate-to-severe asthma[6,7]
- In the phase 4 EVEREST trial, dupilumab improved CRSwNP- and asthma-related outcomes, including UPSIT, LoS, and ACQ-5 scores and FEV_1, vs omalizumab[8]

Methods

Study design

- EVEREST (NCT04998604), a multicenter, randomized, double-blind, phase 4 clinical trial, evaluated efficacy and safety of dupilumab vs omalizumab
- Patients aged ≥18 years with severe CRSwNP and coexisting uncontrolled asthma received background INCS, ICS, and a second asthma controller (i.e. LABA/LTRA) and were randomized 1:1 to add-on dupilumab 300 mg q2w (n = 181) or omalizumab 75–600 mg q2w or q4w (n = 179) for 24 weeks
- Subgroups included patients receiving dupilumab with mICS (n = 52) and patients receiving omalizumab with hICS (n = 29)
- Changes from baseline in ACQ-5 total score, pre-bronchodilator FEV_1, LoS score, and UPSIT score were assessed over 24 weeks of treatment using an MMRM

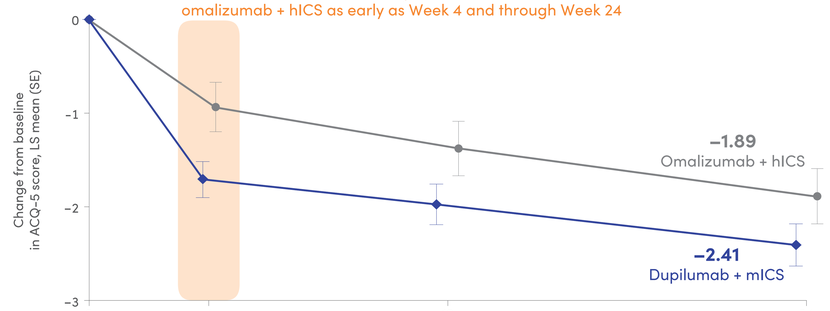
Results

Dupilumab with mICS vs omalizumab with hICS improved ACQ-5 score over 24 weeks of treatment

Change from baseline to Week 24 in ACQ-5 score in other subgroups

Subgroup	Change from baseline at Week 24
Omalizumab + mICS, LS mean (SE)	−1.71 (0.13)
Dupilumab + hICS, LS mean (SE)	−2.29 (0.18)

−0.52
vs omalizumab + hICS at Week 24
(95% CI: −0.95, −0.09)



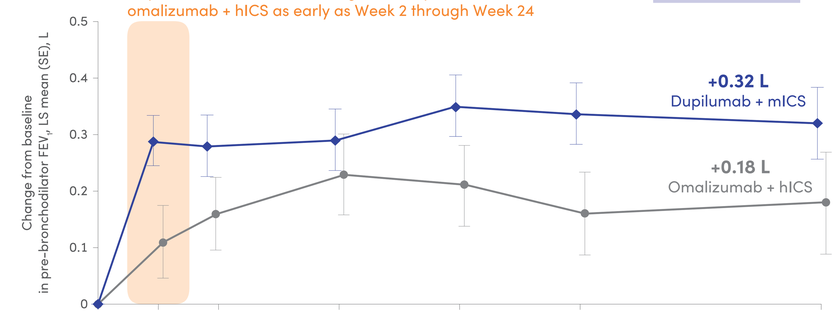
Patients, n				
Dupilumab + mICS	52	49	46	48
Omalizumab + hICS	29	28	28	23

Dupilumab with mICS vs omalizumab with hICS improved pre-bronchodilator FEV_1 over 24 weeks of treatment

Change from baseline to Week 24 in pre-bronchodilator FEV_1 in other subgroups

Subgroup	Change from baseline at Week 24
Omalizumab + mICS, LS mean (SE), L	0.08 (0.07)
Dupilumab + hICS, LS mean (SE), L	0.26 (0.10)

+0.15 L
vs omalizumab + hICS at Week 24
(95% CI: −0.08, 0.37)



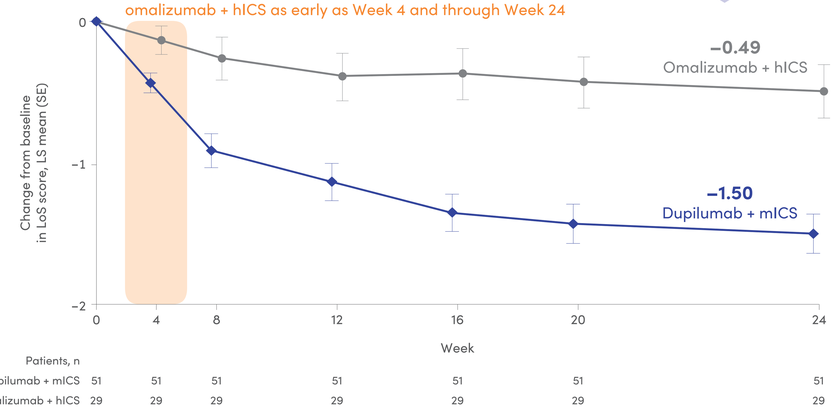
Patients, n							
Dupilumab + mICS	52	52	52	52	52	52	52
Omalizumab + hICS	28	28	28	28	28	28	28

Dupilumab with mICS vs omalizumab with hICS improved LoS score over 24 weeks of treatment

Change from baseline to Week 24 in LoS score in other subgroups

Subgroup	Change from baseline at Week 24
Omalizumab + mICS, LS mean (SE)	−0.68 (0.13)
Dupilumab + hICS, LS mean (SE)	−1.31 (0.18)

−1.01
vs omalizumab + hICS at Week 24
(95% CI: −1.44, −0.58)



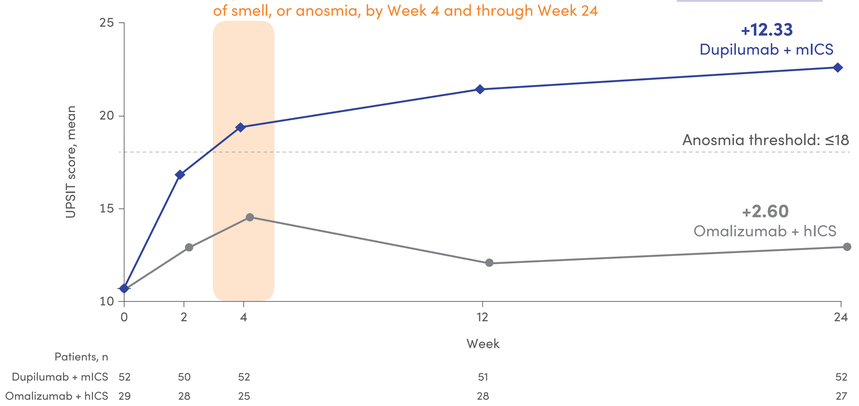
Patients, n							
Dupilumab + mICS	51	51	51	51	51	51	51
Omalizumab + hICS	29	29	29	29	29	29	29

Dupilumab with mICS vs omalizumab with hICS improved UPSIT score over 24 weeks of treatment

Change from baseline to Week 24 in UPSIT score in other subgroups

Subgroup	Change from baseline at Week 24
Omalizumab + mICS, LS mean (SE)	4.57 (1.13)
Dupilumab + hICS, LS mean (SE)	12.56 (1.52)

+9.73[a]
vs omalizumab + hICS at Week 24
(95% CI: 5.99, 13.48)



Patients, n					
Dupilumab + mICS	52	50	52	51	52
Omalizumab + hICS	29	28	25	28	27

[a]The line graph presents observed, absolute UPSIT scores, whereas between-treatment comparisons are based on model-derived changes from baseline.

ACQ-5, 5-item Asthma Control Questionnaire; CRSwNP, chronic rhinosinusitis with nasal polyps; FEV_1, forced expiratory volume in 1 second; hICS; high-dose inhaled corticosteroid(s); ICS, inhaled corticosteroid(s); IL, interleukin; INCS, inhaled nasal corticosteroid(s); LABA, long-acting β_2-agonist(s); LS, least squares; LoS; loss of smell; LTRA; leukotriene receptor antagonist(s); mICS, medium-dose inhaled corticosteroid(s); MMRM, mixed-effect model with repeated measures; q2w, every 2 weeks; q4w, every 4 weeks; SE, standard error; UPSIT, University of Pennsylvania Smell Identification Test.

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