

# Reductions in Exacerbations and Improvements in Lung Function and Asthma Control in Children With Moderate-to-Severe Type 2 Asthma Analyzed by High- or Medium-Dose of Inhaled Corticosteroids at Baseline

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## BACKGROUND

- Dupilumab, a fully human monoclonal antibody,<sup>1,2</sup> blocks the shared receptor component for interleukin (IL)-4 and IL-13, key and central drivers of type 2 inflammation in multiple diseases<sup>3,4</sup>
- In VOYAGE (NCT02948959), a 52-week, randomized, double-blind, placebo-controlled study, dupilumab showed clinical efficacy and was well tolerated with an acceptable safety profile, in children aged 6–11 years with uncontrolled, moderate-to-severe asthma<sup>5</sup>

## OBJECTIVE

- This analysis evaluated dupilumab efficacy in children with type 2 asthma at baseline (blood eosinophils  $\geq 150$  cells/ $\mu$ L or  $\geq 20$  parts per billion [ppb] fractional exhaled nitric oxide [FeNO]), stratified by high- or medium-dose inhaled corticosteroid (ICS) according to GINA 2015 criteria

## METHODS

### Study design

- The 52-week, randomized, double-blind, phase 3 LIBERTY ASTHMA VOYAGE study enrolled patients aged 6–11 years with uncontrolled, moderate-to-severe asthma
- Patients received add-on dupilumab 100/200 mg every 2 weeks or volume matched placebo for 52 weeks
- Patients were stratified at randomization by high- (n = 152) or medium-dose (n = 195) ICS at baseline

## RESULTS

Table. Baseline demographics, disease characteristics, and biomarker levels in the type 2 population.

Characteristic	Patients with blood eosinophils $\geq 150$ cells/ $\mu$ L or $\geq 20$ ppb FeNO			
	High-dose ICS		Medium-dose ICS	
	Placebo (n = 50)	Dupilumab (n = 102)	Placebo (n = 64)	Dupilumab (n = 131)
Mean age (SD), years	8.9 (1.7)	9.0 (1.6)	9.0 (1.5)	8.9 (1.6)
Male sex, n (%)	33 (66.0)	64 (62.7)	45 (70.3)	86 (65.6)
BMI, mean (SD), kg/m <sup>2</sup>	18.53 (3.16)	18.88 (3.48)	19.41 (4.44)	18.44 (3.54)
Age at asthma onset, mean (SD), years	3.3 (2.5)	2.9 (2.6)	4.2 (2.6)	3.4 (2.5)
Number of exacerbations in past year, mean (SD)	2.56 (1.86)	3.04 (3.25)	1.88 (1.19)	2.27 (1.86)
Pre-BD ppFEV <sub>1</sub> , mean (SD), %	75.80 (12.76)	77.93 (12.99)	80.36 (15.55)	77.27 (15.33)
ACQ-7-IA score, mean (SD)	2.08 (0.67)	2.17 (0.77)	2.14 (0.83)	2.14 (0.65)
Blood eosinophils, mean (SD), cells/ $\mu$ L	564.80 (356.51)	558.91 (348.10)	470.95 (343.72)	625.19 (433.05)
FeNO, ppb, mean (SD)	28.02 (22.66)	34.08 (25.91)	28.67 (24.23)	30.47 (24.16)
Total IgE, IU/mL, mean (SD)	895.1 (1,313.1)	809.3 (954.1)	769.3 (1,018.5)	1,042.4 (1,259.7)
Allergic patients, n (%)	33 (66.0)	77 (75.5)	48 (75.0)	101 (77.1)

Allergic asthma patients: At least 1 antigen specific IgE is positive ( $\geq 0.35$  IU/mL) at baseline for perennial allergens as well as total IgE  $\geq 30$  IU/mL. Perennial allergens include *Aspergillus fumigatus*, cat dander, *Dermatophagoides farinae*, *D. pteronyssinus*, dog dander, German cockroach, *Alternaria tenuis/alternata*, and *Citrosporium herbarum/Hormodendrum*. ACQ-7-IA, interviewer-administered 7-Item Asthma Control Questionnaire; BD, bronchodilator; BMI, body mass index; ppFEV<sub>1</sub>, percent predicted forced expiratory volume in 1 second; SD, standard deviation.

## RESULTS (CONT.)

Figure 1. Dupilumab reduced the annualized severe asthma exacerbation rate in all subgroups in both (A) high- and (B) medium-dose ICS patients.

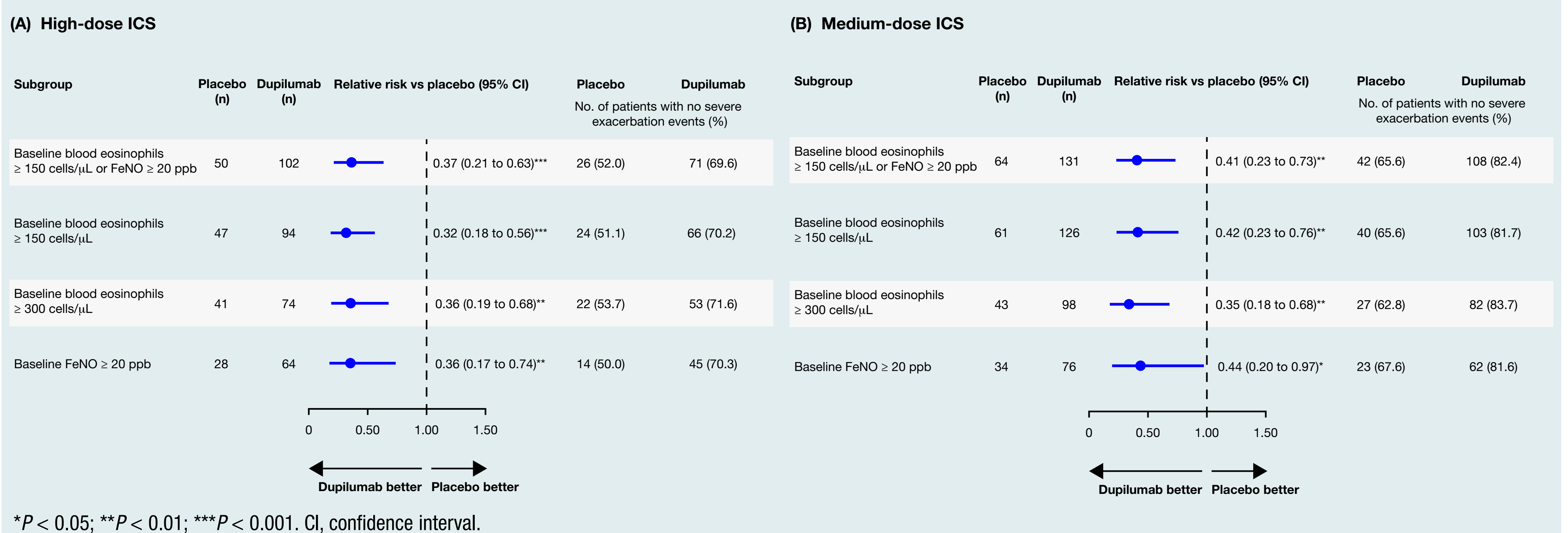


Figure 2. Dupilumab improved pre-BD ppFEV<sub>1</sub> at Week 52 vs placebo in all subgroups in both (A) high- and (B) medium-dose ICS patients.

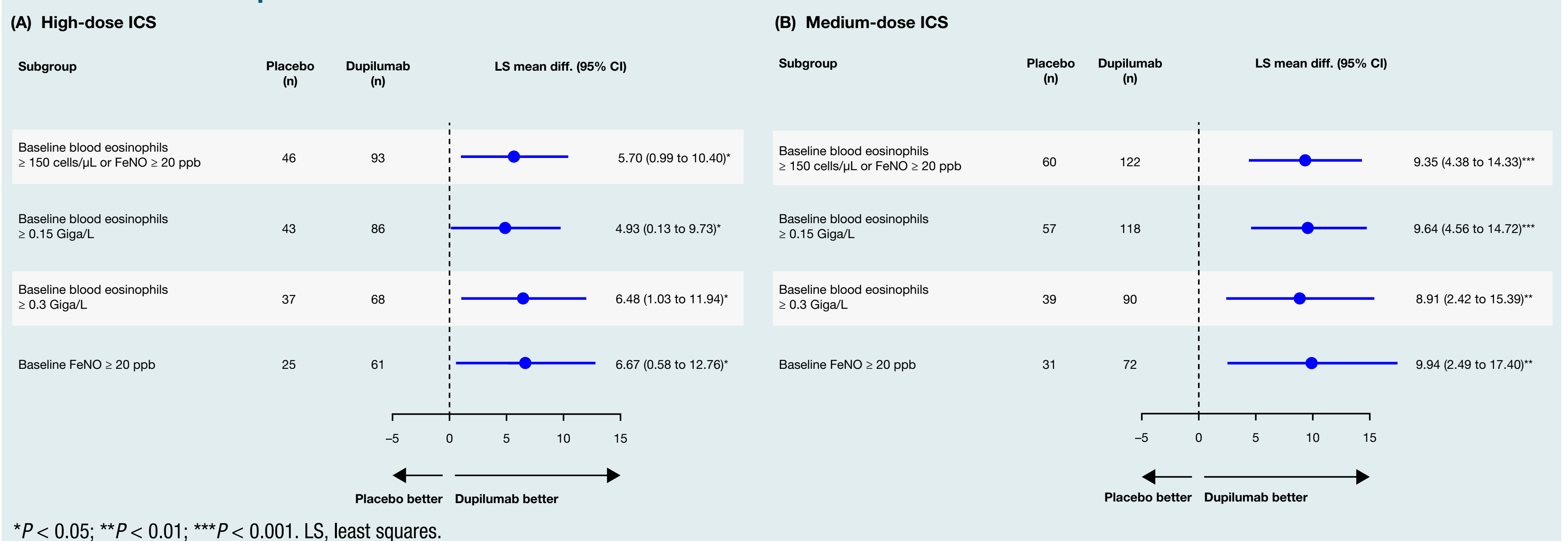
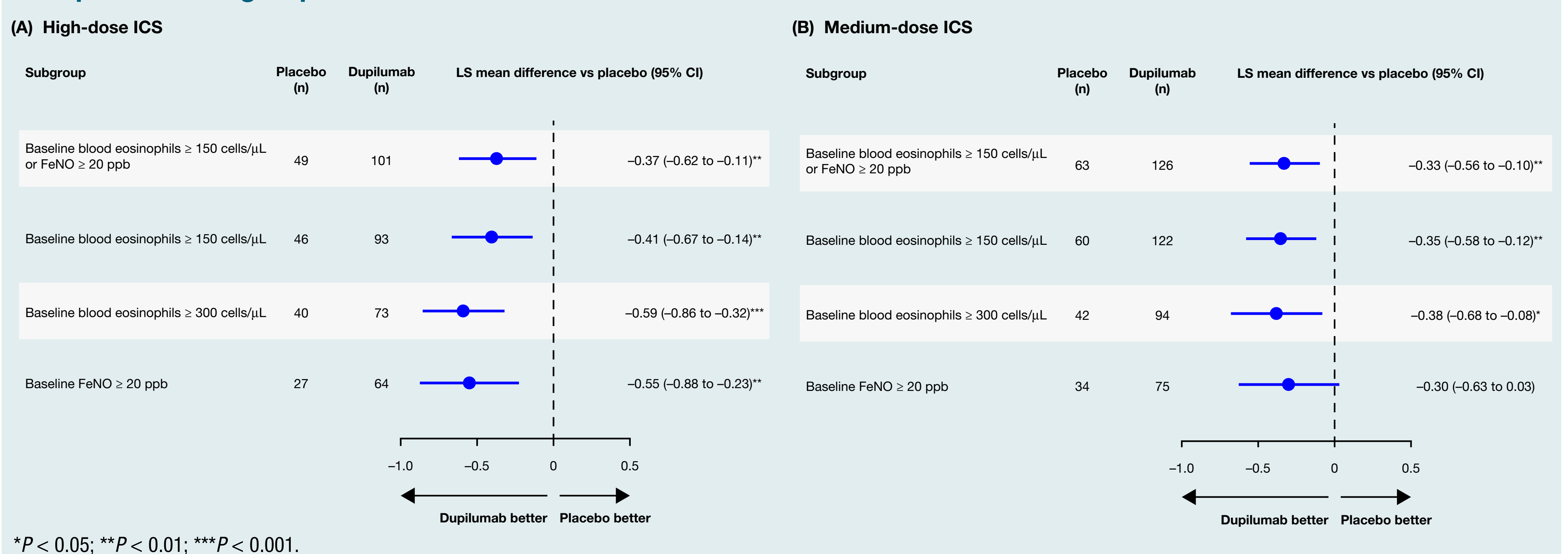


Figure 3. Dupilumab reduced ACQ-7-IA scores at Week 24 in both (A) high- and (B) medium-dose ICS patients, except in the subgroup with elevated FeNO and medium-dose ICS.



## CONCLUSIONS

- Exacerbation reduction in children with uncontrolled, moderate-to-severe, type 2 asthma treated with dupilumab was significant regardless of ICS dose, across all subgroups
- Improvements in ppFEV<sub>1</sub> and asthma control were significant regardless of ICS dose, across all subgroups, except for numerical improvements found in asthma control in patients with elevated FeNO and medium-dose ICS

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