# Children With Asthma Receiving Dupilumab Plus Medium-Dose Inhaled Corticosteroids Had Improved Exacerbations, Lung Function, and Airway Inflammation Compared to Those Receiving Placebo Plus High-Dose Inhaled Corticosteroids

Leonard B. Bacharier[1], Nikolaos G. Papadopoulos[2,3], Rémi Gagnon[4], Theresa W. Guilbert[5], Changming Xia[6], Olivier Ledanois[7], Mena Soliman[6], Jorge F. Maspero[8]

[1]Monroe Carell Jr. Children's Hospital at Vanderbilt University Medical Center, Nashville, TN, USA; [2]University of Athens, Athens, Greece; [3]University of Manchester, Manchester, UK; [4]Clinique Spécialisée en Allergie de la Capitale, Quebec, QC, Canada; [5]Cincinnati Children's Hospital and University of Cincinnati, Cincinnati, OH, USA; [6]Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; [7]Sanofi, Paris, France; [8]Fundación CIDEA, Buenos Aires, Argentina



Asthma

## Conclusion

**In children with moderate-to-severe asthma and type 2 inflammation, dupilumab plus medium-dose ICS reduced exacerbations, improved lung function and asthma control, and reduced FeNO levels compared with placebo plus continued high-dose ICS**

## Objective

**To evaluate the potential advantages of dupilumab added on to medium-dose ICS compared with placebo plus high-dose ICS for clinical outcomes in children with type 2 inflammation-driven asthma**

## Background

- The use of high-dose ICS in children with asthma raises concerns for systemic adverse effects, such as growth suppression and adrenal axis effects, as well as local complications[1,2]
- For these patients, several asthma treatment guidelines recommend de-escalating high-dose ICS and assessing the adrenal axis[3]
- Dupilumab, a fully human monoclonal antibody that blocks the shared receptor component for IL-4 and IL-13, key and central drivers of type 2 inflammation,[4] reduced severe asthma exacerbations and improved lung function in children with uncontrolled asthma and type 2 inflammation in the phase 3 LIBERTY ASTHMA VOYAGE study (NCT02948959)[5]

## Methods

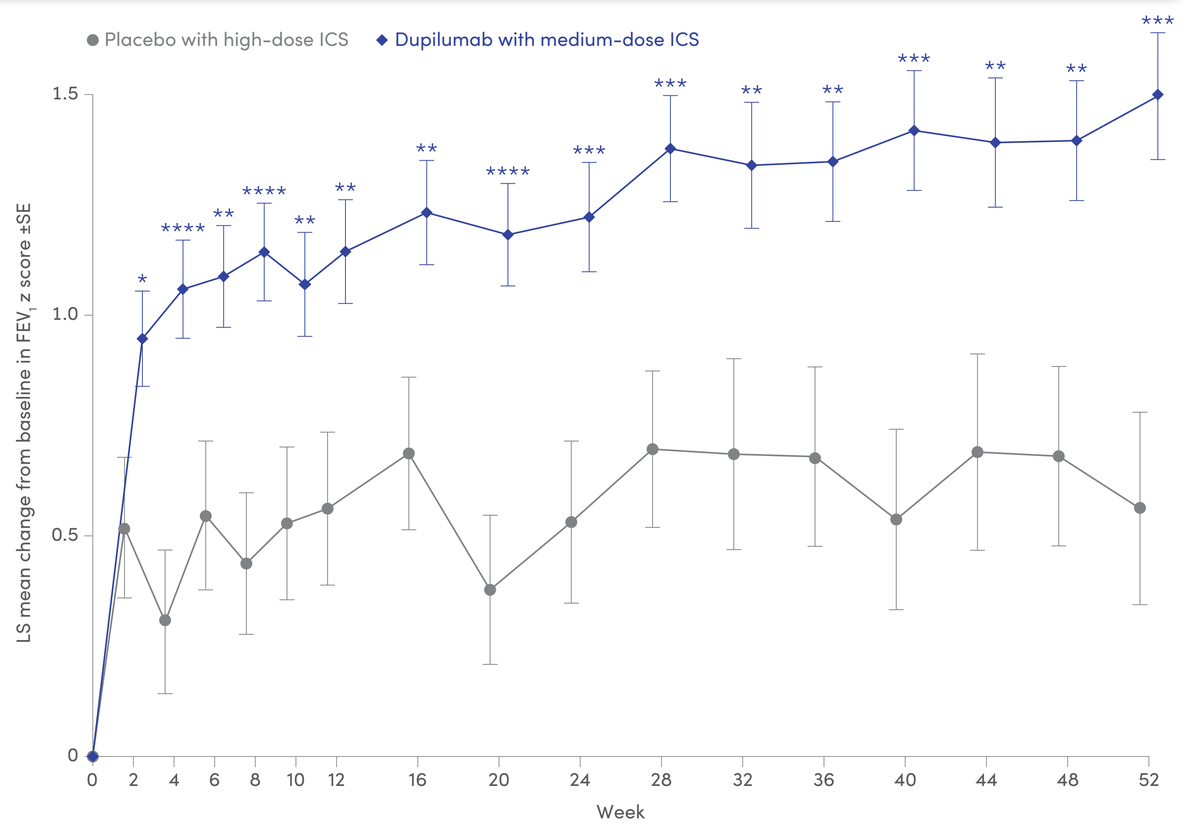
- Data from 184 children with moderate-to-severe asthma and type 2 inflammation (baseline blood eosinophils ≥150 cells/µL or FeNO ≥20 ppb) in the phase 3 VOYAGE study were analyzed: n = 134 received subcutaneous dupilumab (100/200 mg q2w by body weight) plus medium-dose ICS, and n = 50 received placebo plus high-dose ICS, over 52 weeks
- Endpoints:
  - Adjusted annualized severe exacerbation rates
  - Proportion of patients achieving an ACQ-7-IA score of <1.5 at Week 52 (indicating controlled asthma)
  - LS mean difference from baseline in pre-bronchodilator $FEV_1$ z score and FeNO

## Results

### Key baseline characteristics

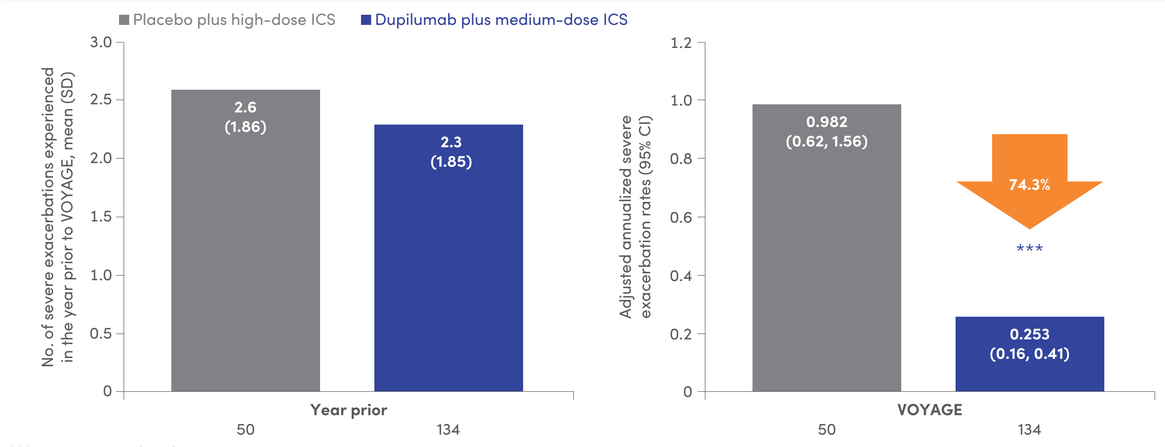
| | Placebo plus high-dose ICS n = 50 | Dupilumab plus medium-dose ICS n = 134 |
|---|---|---|
| **Demographics** | | |
| Age, mean (SD), years | 8.9 (1.66) | 8.8 (1.66) |
| Female, n (%) | 17 (34.0) | 46 (34.3) |
| BMI, mean (SD), kg/m² | 18.53 (3.16) | 18.39 (3.53) |
| **Disease characteristics** | | |
| Number of severe exacerbations in the past year, mean (SD), n | 2.6 (1.86) | 2.3 (1.85) |
| Pre-bronchodilator $ppFEV_1$, mean (SD), % | 75.8 (12.76) | 77.5 (15.40) |
| $FEV_1$ reversibility, mean (SD), % | 15.6 (12.27) | 23.2 (22.49) |
| Morning PEF, mean (SD), L/min | 174.24 (54.97) | 197.55 (65.53) |
| PAQLQ-IA global score, mean (SD) | 4.87 (1.18) | 5.11 (0.96) |
| ACQ-7-IA score, mean (SD) | 2.08 (0.67) | 2.13 (0.65) |
| **Biomarkers** | | |
| Blood eosinophil count, median (Q1–Q3), cells/µL | 475.0 (350.0–680.0) | 520.0 (300.0–780.0) |
| Total IgE, median (Q1–Q3), IU/mL | 398.0 (75.0–859.0) | 546.0 (202.0–1,455.0) |
| FeNO, median (Q1–Q3), ppb | 22.0 (11.0–37.0) | 24.0 (12.0–38.5) |

### Dupilumab plus medium-dose ICS improved pre-bronchodilator $FEV_1$ z score compared with placebo plus high-dose ICS



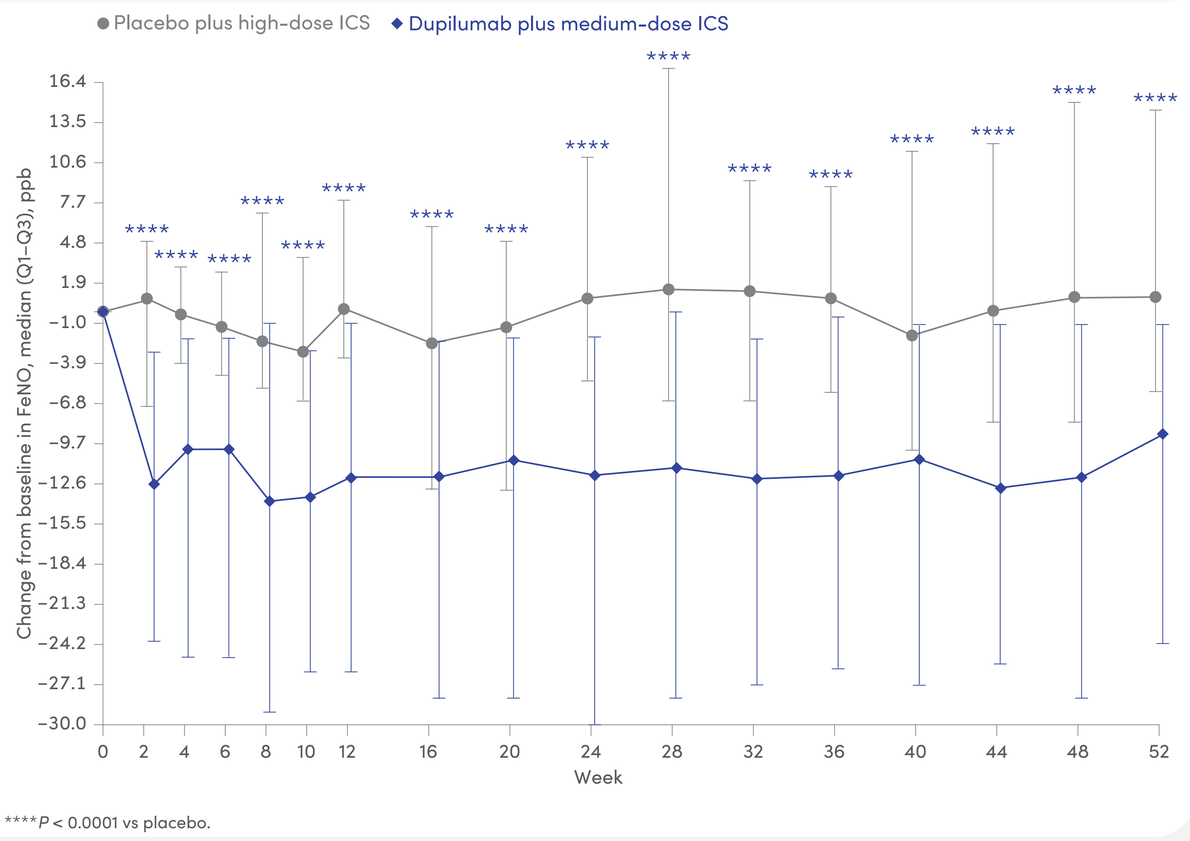

*$P$ < 0.05; **$P$ < 0.01; ***$P$ < 0.001; ****$P$ < 0.0001 vs placebo.

### Dupilumab plus medium-dose ICS reduced the annualized rate of severe exacerbations compared with placebo plus high-dose ICS



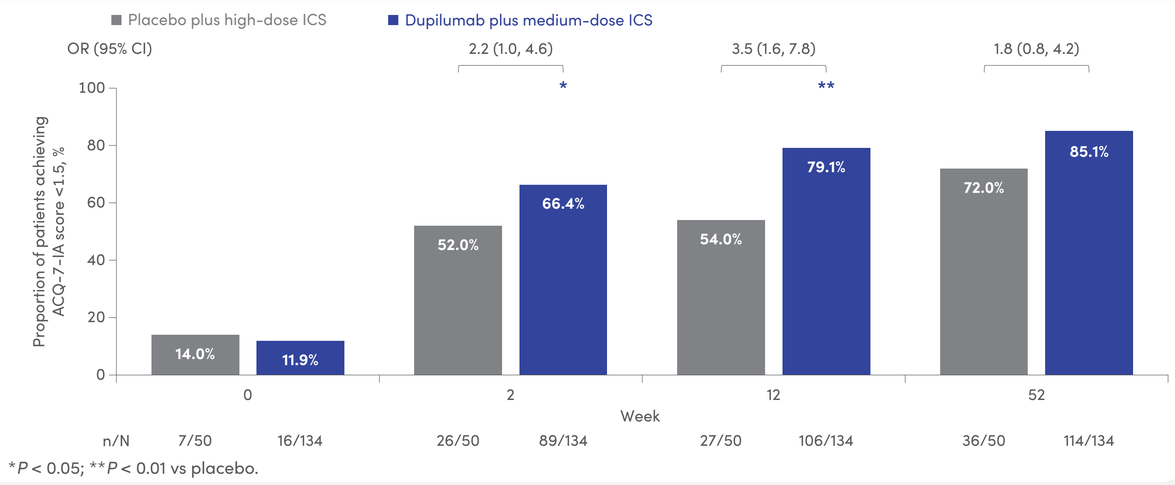

***$P$ < 0.001 vs placebo.

### Dupilumab plus medium-dose ICS reduced FeNO levels compared with placebo plus high-dose ICS




****$P$ < 0.0001 vs placebo.

### A higher proportion of patients who received dupilumab plus medium-dose ICS achieved controlled asthma at Weeks 2, 12, and 52 compared with those who received placebo plus high-dose ICS




*$P$ < 0.05; **$P$ < 0.01 vs placebo.

ACQ-7-IA, Interviewer-Administered 7-item Asthma Control Questionnaire; BMI, body mass index; FeNO, fractional exhaled nitric oxide; ICS, inhaled corticosteroid(s); IL, interleukin; LS, least squares; OR, odds ratio; PAQLQ-IA, Pediatric Asthma Quality of Life Questionnaire-Interviewer Administered; PEF, peak expiratory flow; ppb, parts per billion; $ppFEV_1$, percent predicted forced expiratory volume in 1 second; Q, quartile; q2w, every 2 weeks; SD, standard deviation; SE, standard error.

**References:** 1. Beasley R, et al. Am J Respir Crit Care Med. 2019;199:1471–77. 2. Issa-El-Khoury K, et al. Allergy Asthma Clin Immunol. 2015;11:9. 3. GINA 2023. https://ginasthma.org/2023-gina-main-report/ . Accessed April 21, 2025. 4. Le Floc'h A, et al. Allergy. 2020;75:1188–204. 5. Bacharier LB, et al. N Engl J Med. 2021;385:2230–40.

**Acknowledgments and funding sources:** Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifier: NCT02948959.
Medical writing/editorial assistance was provided by Nikita Subedi, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guidelines.

**Disclosures: Bacharier LB:** AstraZeneca, GSK, Regeneron Pharmaceuticals Inc., Sanofi – speaker fees; OM Pharma – personal fees; AstraZeneca, Cystic Fibrosis Foundation, DBV Technologies – data and safety monitoring board; NIH, Sanofi, Vectura – research support. **Papadopoulos NG:** Capricare, Nestlé, Numil, REG, Vianex – grants or contracts; Abbott, AbbVie, AstraZeneca, GSK, HAL, Medscape, Menarini/Faes Farma, Mylan, Novartis, Nutricia, OM Pharma, Regeneron Pharmaceuticals Inc./Sanofi – consulting fees. **Gagnon R:** ALK, AstraZeneca, BioCryst, DBV Technologies, Genentech, Greencross, Novartis, Regeneron Pharmaceuticals Inc., Sanofi, Shire – research grants; ALK, AstraZeneca, Pfizer, Sanofi – consultant; Novartis – speaker fees. **Guilbert TW:** Advent, AiCME, American Board of Pediatrics, American Thoracic Society, Amgen, AstraZeneca, Genentech, OM Pharma, PlatformQ Health, Regeneron Pharmaceuticals Inc., Sanofi, TEVA – personal fees; Amgen, AstraZeneca, GSK, NIH, OM Pharma, Regeneron Pharmaceuticals Inc., Sanofi – grants; UpToDate – royalties. **Xia C, Soliman M:** Regeneron Pharmaceuticals Inc. – employees and shareholders. **Ledanois O:** Sanofi – employee, may hold stock and/or stock options in the company. **Maspero JF:** AstraZeneca, Sanofi – consultant; GSK, Menarini, Novartis, Uriach – speaker fees; Novartis – research grants.

*Presented at the 28th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR Europe 2025); Glasgow, Scotland, UK; November 9–12, 2025.*