Dupilumab Reduces Systemic **Corticosteroid Use** in **Children** With Uncontrolled moderate-to-severe **Asthma Regardless** of **Exacerbation History**

DUPILUMAB

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Rationale

- Repeated use of rescue systemic corticosteroids (SCS), both oral or injectable, has long-term adverse effects, particularly as cumulative exposure increases[1,2]
- There is a need to reduce rescue SCS, especially in pediatric asthma population
- Dupilumab is a fully human monoclonal antibody[3,4], that blocks signalling of interleukin (IL)-4 and IL-13, key and central drivers of type 2 inflammation[5,6]
- VOYAGE, a 52-week randomized, double-blind, placebo-controlled phase 3 study (NCT02948959), evaluated the efficacy and safety of dupilumab in children aged 6 to 11 years with uncontrolled, moderate-to-severe asthma[7]
  - Safety was consistent with the known dupilumab safety profile[7]
- EXCURSION (NCT03560466) was a multinational, open-label, single-arm, 52-week extension study that enrolled children with moderate-to-severe asthma who previously completed VOYAGE

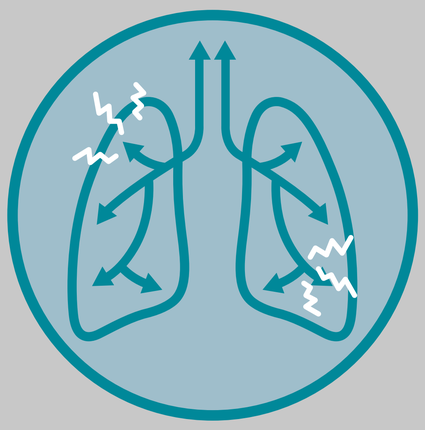
Methods

Study design

- In VOYAGE, children received dupilumab or placebo 100/200 mg every 2 weeks (q2w) by body weight
- In EXCURSION, all children enrolled received dupilumab 100/200 mg q2w or 300 mg every 4 weeks (q4w) by body weight for an additional 52 weeks

Study assessments

- This post hoc analysis included children with moderate-to-severe type 2 asthma (blood eosinophil count ≥150 cells/µL or fractional exhaled nitric oxide [FeNO] ≥20 ppb) who completed VOYAGE and subsequently enrolled in EXCURSION, stratified by number of exacerbations requiring rescue SCS (1 or ≥2) in the year prior to VOYAGE
- Unadjusted annualized rate of severe exacerbations (a deterioration of asthma requiring the use of SCS for ≥3 days; or hospitalization or emergency room visit because of asthma, requiring SCS) in VOYAGE and in EXCURSION
- Pre-bronchodilator percent predicted forced expiratory volume in 1 second ($ppFEV_1$) change from VOYAGE baseline over time through EXCURSION Week 52
- Percentage of patients without OCS use throughout VOYAGE and EXCURSION combined



Objective

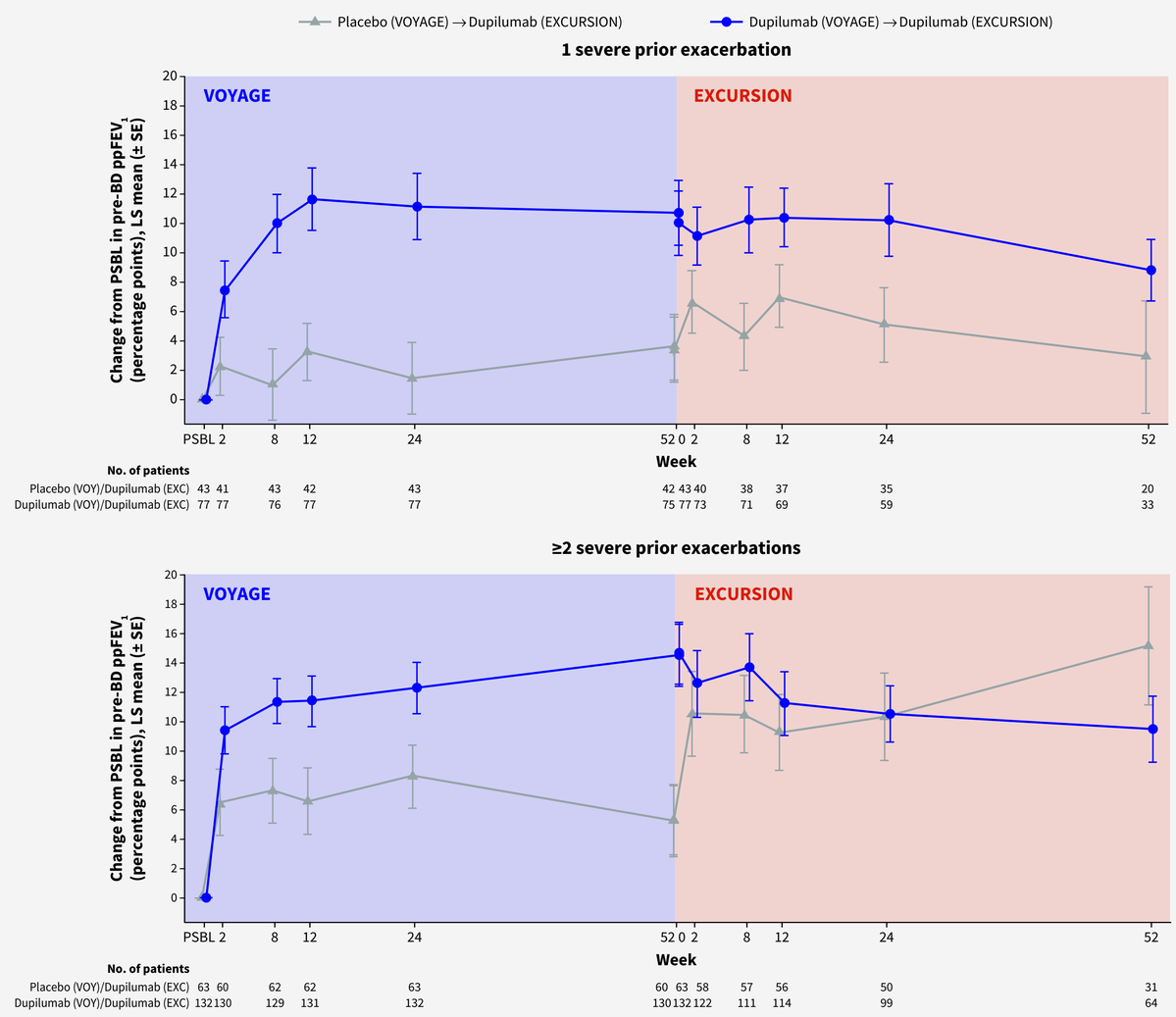
- **This post hoc analysis of VOYAGE and EXCURSION evaluated the long-term efficacy of dupilumab in reducing rescue SCS exposure in children aged 6 to 11 years with moderate-to-severe uncontrolled asthma**

Conclusion

- **In VOYAGE and EXCURSION, dupilumab reduces rescue SCS exposure in children with uncontrolled, moderate-to-severe type 2 asthma as a result of reducing severe exacerbations, while improving lung function regardless of the number of prior severe exacerbations**

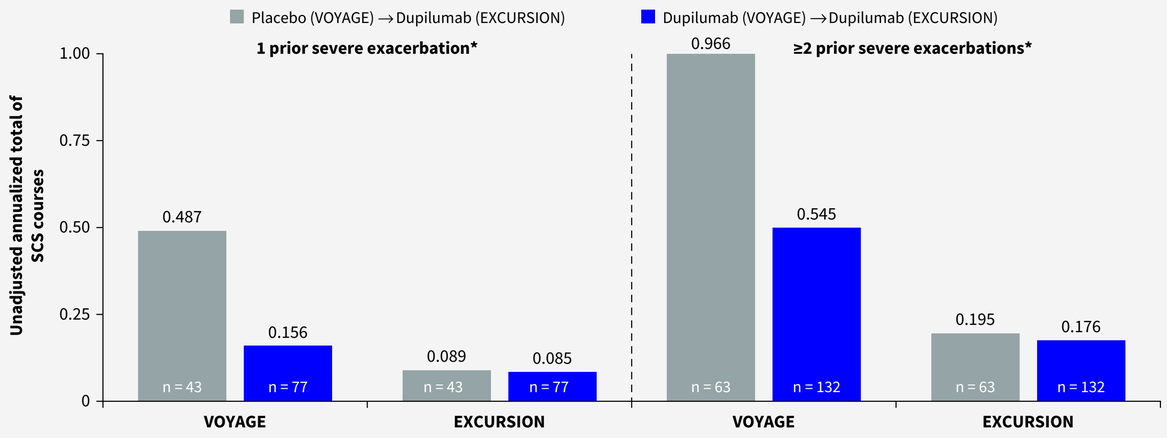
Results

Figure 2. Dupilumab improved pre-bronchodilator $ppFEV_1$ in children with moderate-to-severe type 2 asthma regardless of the number of severe prior exacerbations*.



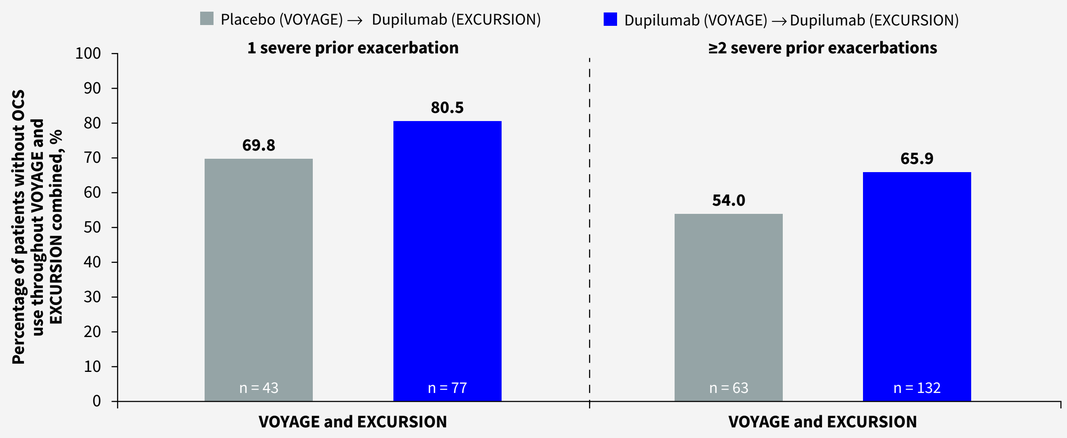
LS, least squares; PSBL, parent study baseline; SE, standard error.
*Treated with rescue SCS.

Figure 1. Dupilumab reduced total rescue SCS courses† in children with moderate-to-severe type 2 asthma, regardless of prior exacerbations.



*Treated with rescue SCS.
†A small percentage of rescue SCS courses recorded during VOYAGE were either (a) administered for less than three days; or (b) given for an indication other than a severe asthma exacerbation.

Figure 3. Dupilumab reduced the percentage of patients using oral corticosteroids (OCS) throughout VOYAGE and EXCURSION combined.



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Conflicts of interest: Hamelmann E: Aimmune Therapeutics, ALK, AstraZeneca, Boehringer Ingelheim, GSK, HAL Allergy, Novartis, Nutricia, Sanofi, Stallergenes Greer – speaker, advisory board member. **Deschildre A:** Aimmune Therapeutics, ALK, AstraZeneca, Boehringer Ingelheim, Chiesi, DBV Technologies, GSK, Nestlé, Novartis, Nutricia, Sanofi, Teva, Zambon – speaker/consulting fees. **Ducharme P:** Sanofi – advisory board member; AstraZeneca, Covis Pharma, Sanofi, Thorasys – consultant; Covis Pharma, FMOQ, FMSQ, GSK, Sanofi – speaker; Covis Pharma, GSK, Jamieson, Thorasys/MEDTEQ – research grant funding. **Sher L:** Aimmune Therapeutics, Optinose, Regeneron Pharmaceuticals Inc., Sanofi – advisory board member; Regeneron Pharmaceuticals Inc., Sanofi – speaker fees; Aimmune Therapeutics, Amgen, AstraZeneca, Circassia, DBV Technologies, Galderma, GSK, Lupin, Merck, Mylan, Novartis, Novo Nordisk, Optinose, Pearl Pharmaceuticals, Pfizer, Pulmagen, Roxane, Sanofi, Spirometrix, Teva, Vectura, Watson Pharmaceuticals – clinical trials funding. **de Mir I:** GSK – personal fees for lectures and boards; Novartis – conference registration and travel fees; Aldo-Unión – conference registration fees. **Ledanois O, Jacob-Nara JA, Rowe PJ:** Sanofi – employees, may hold stock and/or stock options in the company. **Sacks H:** Regeneron Pharmaceuticals Inc, – employee and shareholder; Optinose – shareholder. **Xia C, Gall R, Deniz Y:** Regeneron Pharmaceuticals Inc, – employees and shareholders.

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