Efficacy of **Dupilumab 200 mg** Every 2 Weeks in **Children** with Moderate-to-Severe **Asthma** during **VOYAGE** and **EXCURSION**

DUPILUMAB

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Rationale

- Asthma is the most common chronic pediatric disease, affecting 7.5% of children age 5 to 11 years in the United States in 2021[1,2]
- Type 2 inflammation (defined as blood eosinophils ≥150 cells/µL or FeNO ≥20 ppb at baseline) is the primary driver of asthma in children and is characterized by the release of interleukin (IL)-4, IL-5, and IL-13[3]
- Dupilumab, a fully human monoclonal antibody[4,5], blocks the shared receptor component for IL-4 and IL-13, key and central drivers of type 2 inflammation[6]
- In the 52-week phase 3 LIBERTY ASTHMA VOYAGE study (NCT02948959) and LIBERTY ASTHMA EXCURSION open-label extension study (NCT03560466), add-on dupilumab 100/200 mg (by bodyweight) every 2 weeks reduced severe exacerbation rates and improved lung function and asthma control in children (6 to 11 years) with uncontrolled moderate-to-severe asthma[7,8]
- In this post hoc analysis of EXCURSION, we assessed dupilumab efficacy in the cohort of children who received dupilumab 200 mg every 2 weeks up to 2 years throughout VOYAGE and EXCURSION

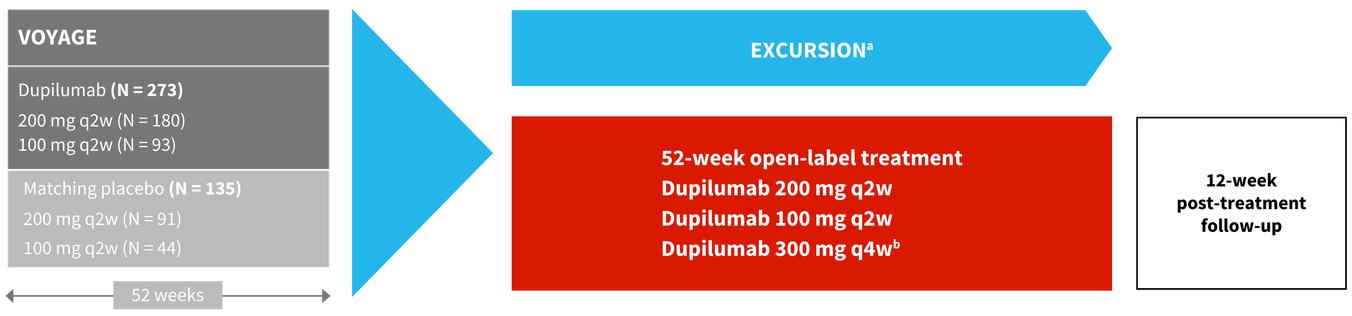
Methods

Study Population

- Children receiving dupilumab 200 mg q2w or matching placebo from VOYAGE who enrolled in EXCURSION
  - Overall/ITT population
  - Children with moderate-to-severe type 2 asthma (defined as blood eosinophils ≥150 cells/µL or FeNO ≥20 ppb at baseline)

Efficacy endpoints

- Annualized severe asthma exacerbation rates (AER)
- Change from baseline in pre-BD FEV_1



Patients who switched from placebo in VOYAGE to dupilumab in EXCURSION are referred as placebo/dupilumab; patients who continued with dupilumab treatment are referred as dupilumab/dupilumab. q2w, every 2 weeks; q4w, every 4 weeks. [a]EXCURSION first visit can occur up to 12 weeks after end of VOYAGE, due to COVID19 pandemic. [b]Amendment 3 (Dec 2019) for those ≤30 kg dupilumab 300 mg q4w. Newly enrolled and those with >8 weeks before planned end of treatment were switched at in-person visit to 300 mg q4w.



Objective

- **This post-hoc analysis assessed the efficacy and safety of add-on dupilumab 200 mg q2w, the largest dose cohort in both studies, in children from VOYAGE who participated in EXCURSION**

Conclusion

- **In children (6 to 11 years) with uncontrolled moderate-to-severe type 2 asthma, dupilumab 200mg, every 2 weeks, reduced exacerbation rates and improved lung function for up to 2 years and was generally well-tolerated**

Results

Table. Patient distribution of the overall population based on treatment arms in the VOYAGE and EXCURSION studies.

	Treatment arms (VOYAGE)						
	Placebo (n = 40)	Dupilumab 100 mg q2w (n = 82)	Placebo (n = 85)	Dupilumab 200 mg q2w (n = 158)	Placebo (n = 125)	Dupilumab 100/200 mg q2w (n = 240)	Total (n = 365)
Treatment arms (EXCURSION)							
Dupilumab 100 mg q2w	7 (17.5%)	22 (26.8%)	0	0	7 (5.6%)	22 (9.2%)	29 (7.9%)
Dupilumab 100 mg q2w/200 mg q2w	5 (12.5%)	11 (13.4%)	0	0	5 (4.0%)	11 (4.6%)	16 (4.4%)
Dupilumab 100 mg q2w/300 mg q4w	7 (17.5%)	7 (8.5%)	0	0	7 (5.6%)	7 (2.9%)	14 (3.8%)
Dupilumab 100 mg q2w/300 mg q4w/ 200 mg q2w	0	1 (1.2%)	0	0	0	1 (0.4%)	1 (0.3%)
Dupilumab 200 mg q2w	20 (50.0%)	39 (47.6%)	85 (100%)	158 (100%)	105 (84.0%)	197 (82.1%)	302 (82.7%)
Dupilumab 300 mg q4w	0	2 (2.4%)	0	0	0	2 (0.8%)	2 (0.5%)
Dupilumab 300 mg q4w/200 mg q2w	1 (2.5%)	0	0	0	1 (0.8%)	0	1 (0.3%)

Figure 2. Mean change from parent study baseline in pre-bronchodilator $ppFEV_1$ over time in children with moderate-to-severe asthma.

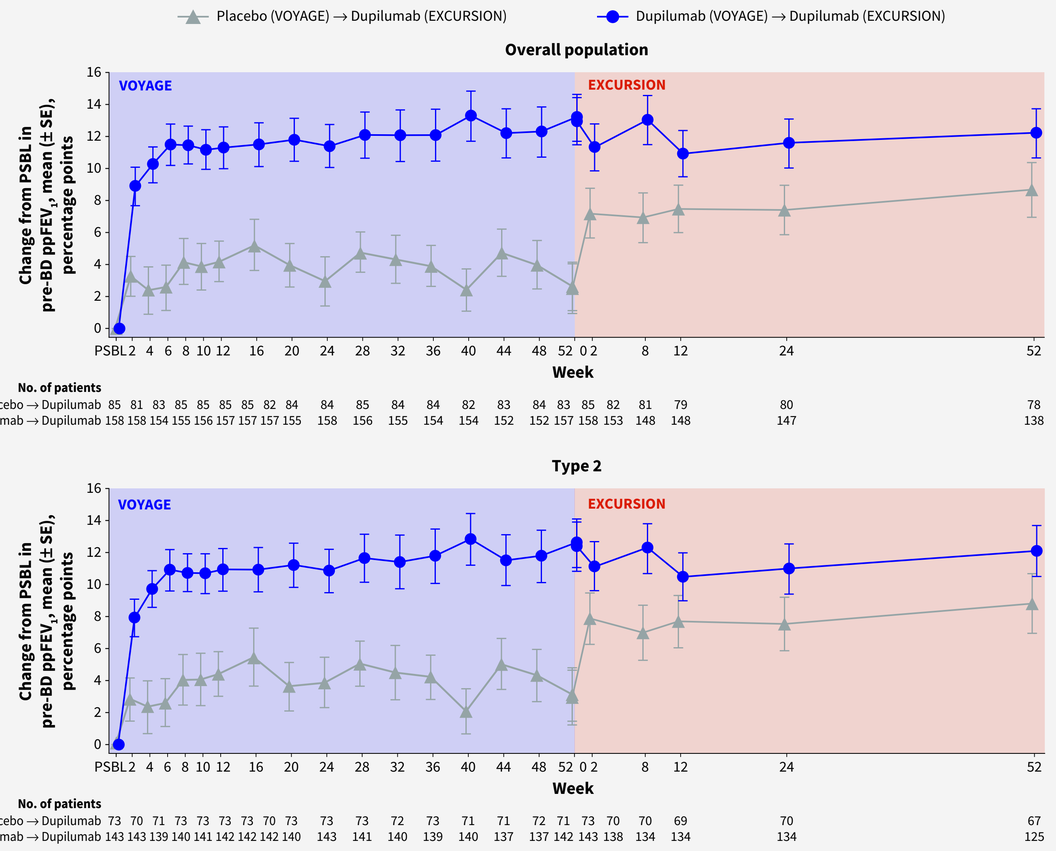
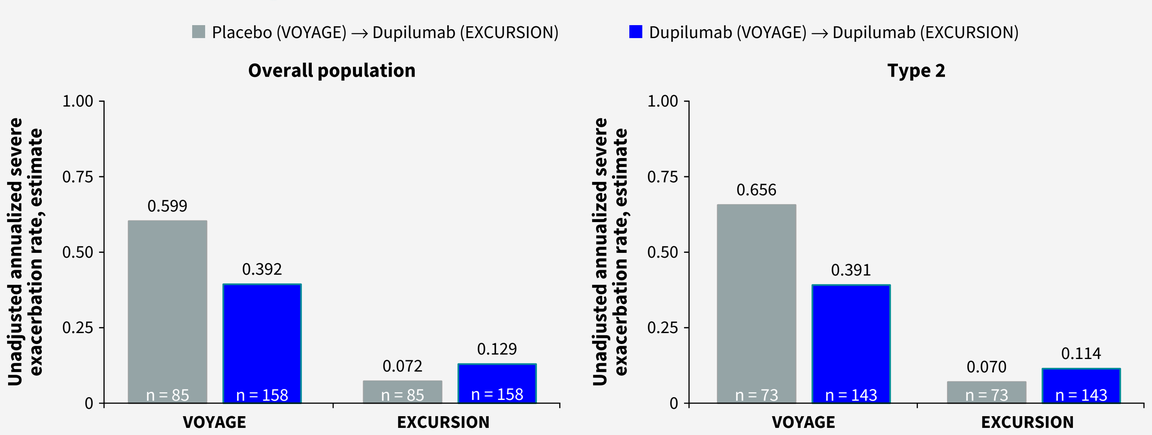


Figure 1. Unadjusted annualized severe exacerbation rate in children with moderate-to-severe asthma throughout VOYAGE and EXCURSION.



BD, bronchodilator; Dpl-dpl (200 mg), Dupilumab 200 mg q2w in Voyage and Dupilumab 200mg q2w in Excursion; FEV_1, forced expiratory volume in 1 second; ITT, intention to treat; LS, least squares; Pbo-dpl (200 mg), Placebo 1.14mL q2w in Voyage and Dupilumab 200mg q2w in Excursion; $ppFEV_1$, percent predicted forced expiratory volume in one second; PSBL, parent study baseline; q2w, every 2 weeks; q4w, every 4 weeks.

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