Dupilumab's Long-Term Lab Safety in Young Patients With Atopic Dermatitis: 3-Year Phase 3 Data

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Learning objective

To understand laboratory outcomes in children aged 6 months to 11 years for up to 3 years of dupilumab treatment

Takeaway message

3 years of laboratory outcomes in children aged 6 months to 11 years demonstrates that safety is consistent with the known dupilumab safety profile, supporting no need for routine laboratory monitoring

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Background & Objective

- Previous studies of dupilumab for the treatment of moderate-to-severe AD over 16 weeks demonstrated no clinically important changes in laboratory parameters in young patients aged 6 months to 11years

To assess laboratory outcomes in children aged 6 months to 11 years for up to 3 years of dupilumab treatment

AD, atopic dermatitis.

Methods

- Children aged 6 months to 11 years with moderate-to-severe AD were enrolled in the 5-year open-label extension study, LIBERTY AD PED-OLE (NCT02612454)
  - Patients aged 6 months to 5 years (n = 180) received dupilumab 200 mg q4w (5–<15 kg) or 300 mg q4w (15–<30 kg)
  - Patients aged 6 to 11 years (n = 383) received dupilumab 200 mg q2w (30–<60 kg) or 300 mg q2w (≥60 kg)
- Topical corticosteroid treatment was permitted
- Hematology and serum chemistry parameters were recorded at baseline and Weeks 16, 52, 104, and 152
- Data are presented as observed

q2w, every 2 weeks; q4w, every 4 weeks.

Disposition data in the open-label extension study

Results

6 months to 5 years

Patients 6 months to 5 years, n (%)
n = 180 (100)

- 163 (90.6) completed Week 52
- 148 (82.2) completed Week 104
- 94 (52.2) completed Week 156

Completed study, n (%)	15 (8.3)
Ongoing, n (%)	110 (61.1)
Patients who did not complete study	**55 (30.6)**
Adverse event[a]	2 (1.1)
Withdrawal by subject	23 (12.8)
Lack of efficacy	4 (2.2)
Loss to follow-up	6 (3.3)
Protocol deviation	1 (0.6)
Drug commercially available (age ≥6 years)	9 (5.0)
Other	10 (5.6)

6 to 11 years

Patients 6 to 11 years, n (%)
n = 383 (100)

- 327 (85.4) completed Week 52
- 267 (69.7) completed Week 104
- 247 (64.5) completed Week 156

Completed study, n (%)	130 (33.9)
Ongoing, n (%)	107 (27.9)
Patients who did not complete study	**146 (38.1)**
Adverse event[a]	3 (0.8)
Physician decision	7 (1.8)
Withdrawal by subject	42 (11.0)
Lack of efficacy	6 (1.6)
Loss to follow-up	12 (3.1)
Protocol deviation	6 (1.6)
Patient ≥18 years old	1 (0.3)
Drug commercially available (age ≥6 years)	11 (2.9)
Other	58 (15.1)

[a]TEAEs that led to permanent discontinuation of the study drug included panic attack, urticaria, anaphylactic reaction, optic disc drusen, bacterial conjunctivitis, and AD flare. All events, except optic disc drusen (mild and unrelated to the study drug), resolved or resulted in recovery. None were laboratory related. TEAE, treatment-emergent adverse event.

Most common laboratory abnormalities reported as TEAEs (≥1 patient) were infrequent

Results

	6 months to 5 years n = 180	6 to 11 years n = 383
Treatment exposure, mean (SD), weeks	121.4 (43.5)	111.6 (48.5)
Most common laboratory abnormalities reported as TEAEs (≥1 patient) listed by MedDRA Preferred Term, n (%)[a]		
Eosinophilia	1 (1.0)[b]	3 (1.2)[c]
Thrombocytopenia	1 (1.0)	-
Abnormal hematology test	1 (1.0)	-
Hypothyroidism	1 (1.0)	-
Neutropenia	-	4 (1.6)
Anemia	-	1 (0.4)
Leukopenia	-	1 (0.4)
Thrombocytopenia	-	1 (0.4)
Hypertriglyceridemia	-	1 (0.4)
Increased eosinophil count	-	1 (0.4)
Decreased neutrophil count	-	1 (0.4)
Increased platelet count	-	1 (0.4)

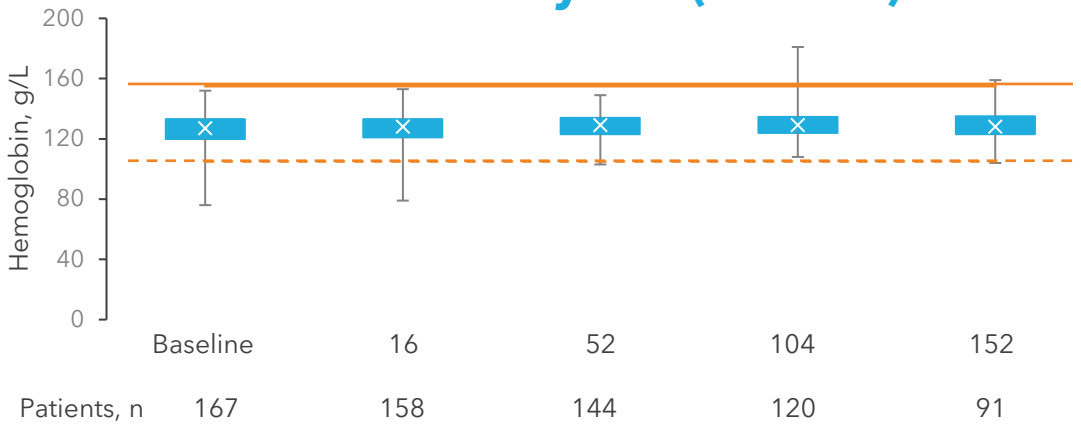
[a]Manually adjudicated. [b]Mild event: not related to the study drug per investigator, required dose interruption, resolving at data cut-off. [c]Severe (n = 1): not related to the study drug per investigator, led to drug interruption, recovered; and Mild/Moderate (n = 2): related to the study drug per investigator, recovered.
Adverse event severity was graded according to the following scale: **Mild**, no significant interference with patient normal functioning, prescription drugs not ordinarily needed for symptom relief; **Moderate**, some impairment of functioning and symptom treatment may be needed; **Severe**, significant impairment of functioning or incapacitation and a hazard to the patient's health, symptom treatment may be given and/or patient hospitalized.
MedDRA, Medical Dictionary for Regulatory Activities; SD, standard deviation.

Laboratory parameters remained generally stable over 3 years of dupilumab treatment in both age groups

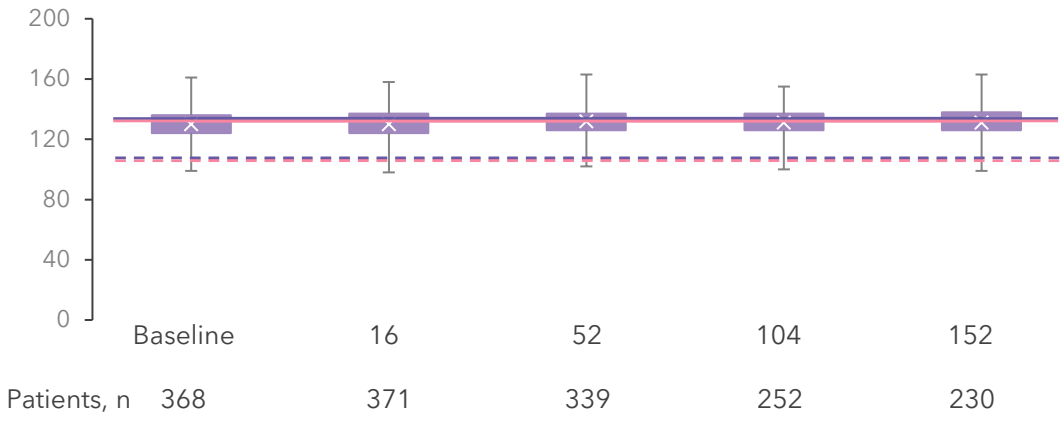
Results

Hemoglobin

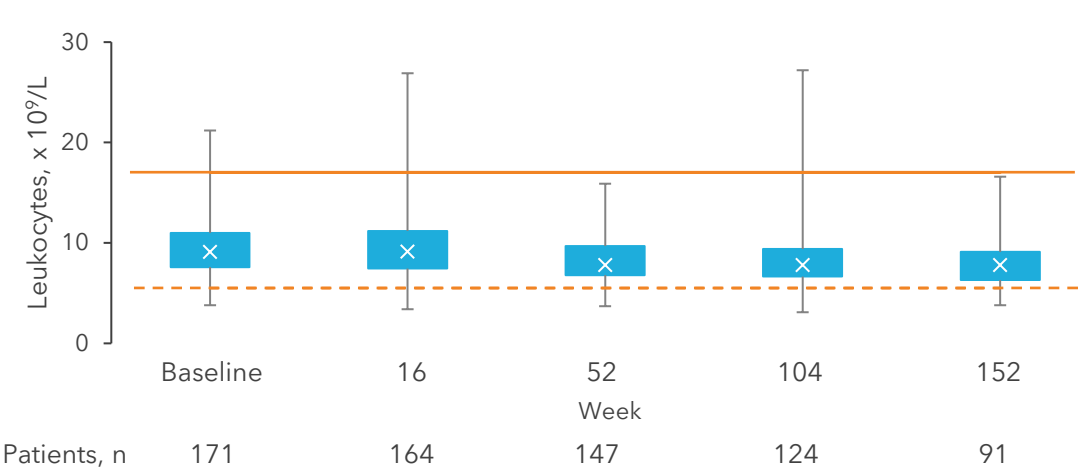
6 months to 5 years (n = 180)

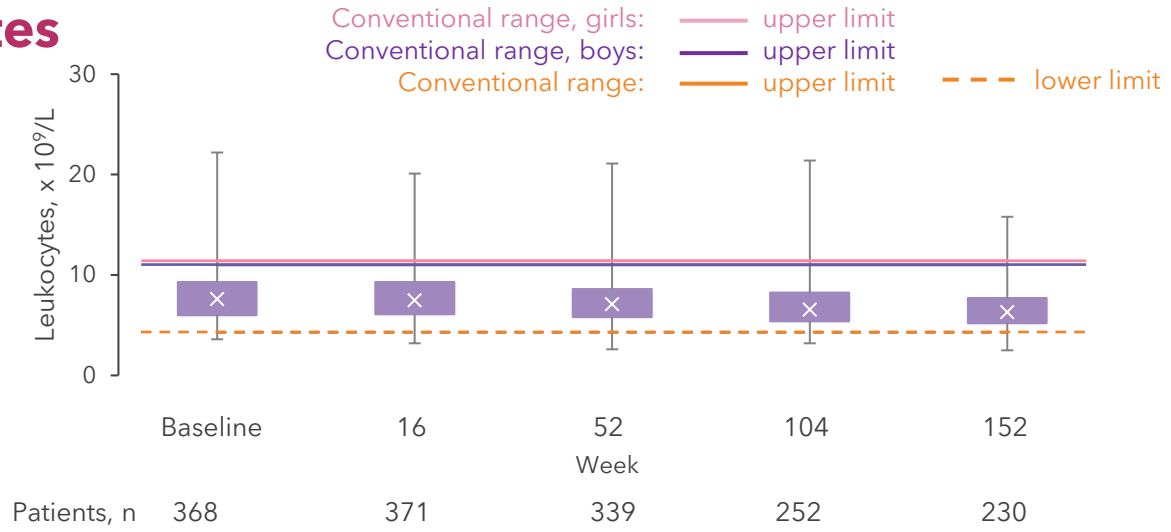


6 to 11 years (n = 383)



Leukocytes





Box and whisker plots report value at visit as minimum, 1st quartile, median, 3rd quartile, and maximum values. Mean denoted as white x. Conventional ranges referenced from Paller AS et al. *Paediatr Drugs.* 25, 67–77 (2023) and Paller AS et al. *Paediatr Drugs.* 23, 515–527 (2021).

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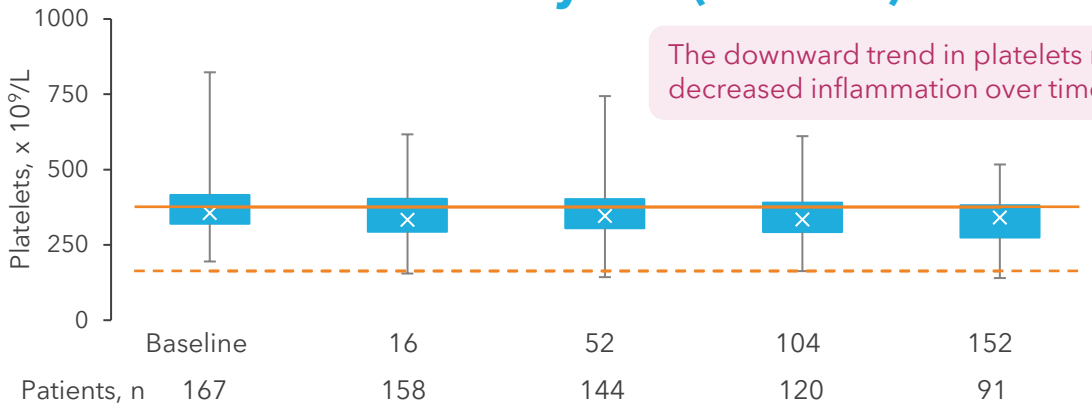
Results

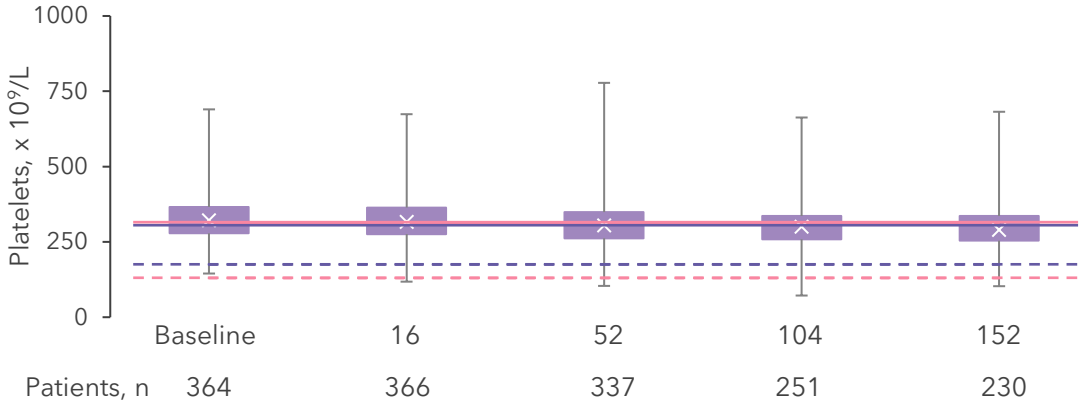
Platelets

6 months to 5 years (n = 180)

The downward trend in platelets may reflect decreased inflammation over time

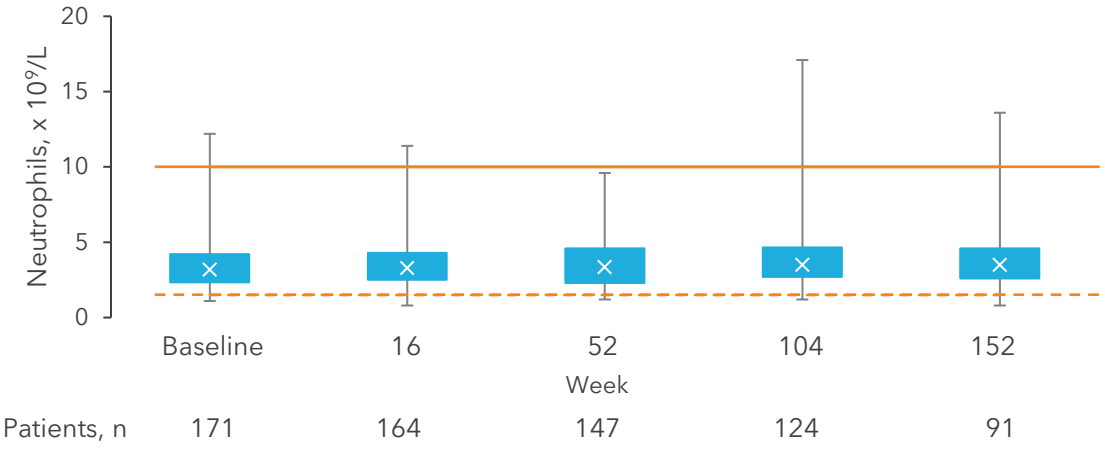


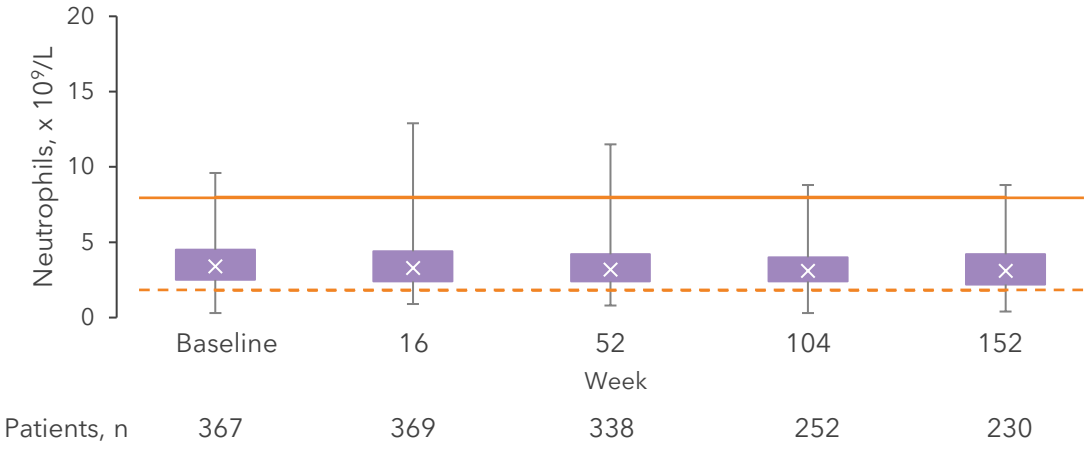
6 to 11 years (n = 383)



Neutrophils

Conventional range, girls: upper limit lower limit
Conventional range, boys: upper limit lower limit
Conventional range: upper limit lower limit





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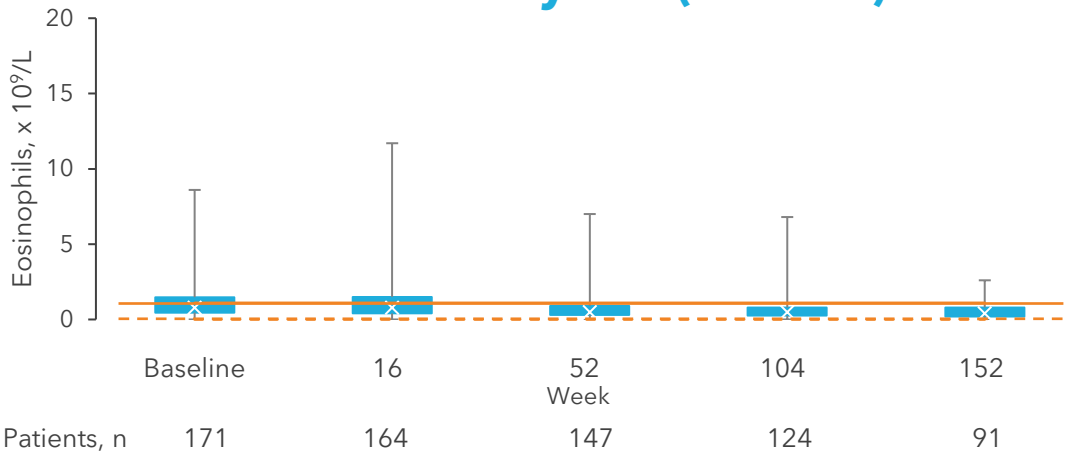
Results

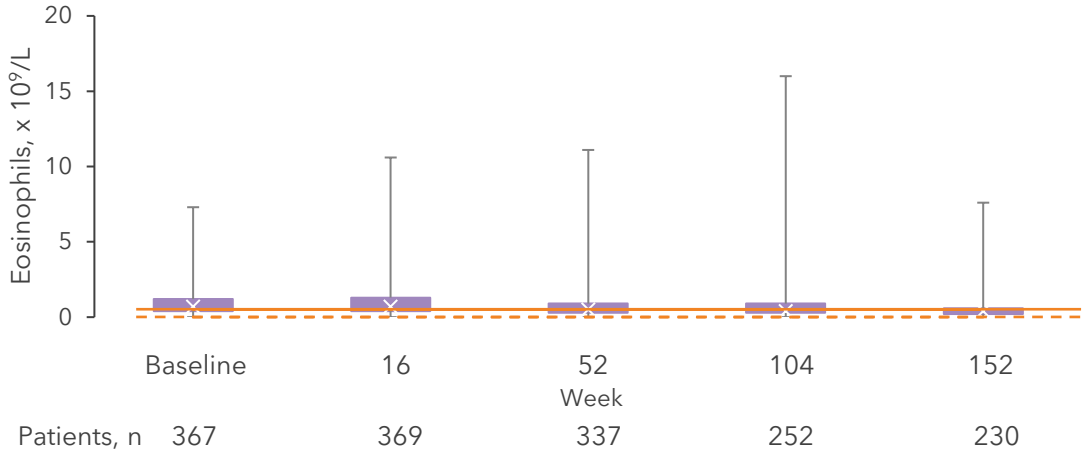
Eosinophils

Conventional range: upper limit lower limit

6 months to 5 years (n = 180)



6 to 11 years (n = 383)



- 10 patients had a Grade 3 eosinophilia event:
  - 1 patient experienced 3 consecutive events
  - No patients reported Grade 3 eosinophilia at Week 152
- 2 patients had 3 consecutive eosinophilia events:
  - 1 patient had Grade 3 at baseline, Weeks 52, and 104
  - 1 patient had Grade 2 at Week 152, and Grade 1 at Weeks 200 and 260

- 11 patients had a single Grade 3 eosinophilia event[a]
- 11 patients had Grade 1/2 eosinophilia events:
  - 7 patients had Grade 1/2 eosinophilia events at > 1 timepoint
  - Most patients had Grade 1 at last follow-up

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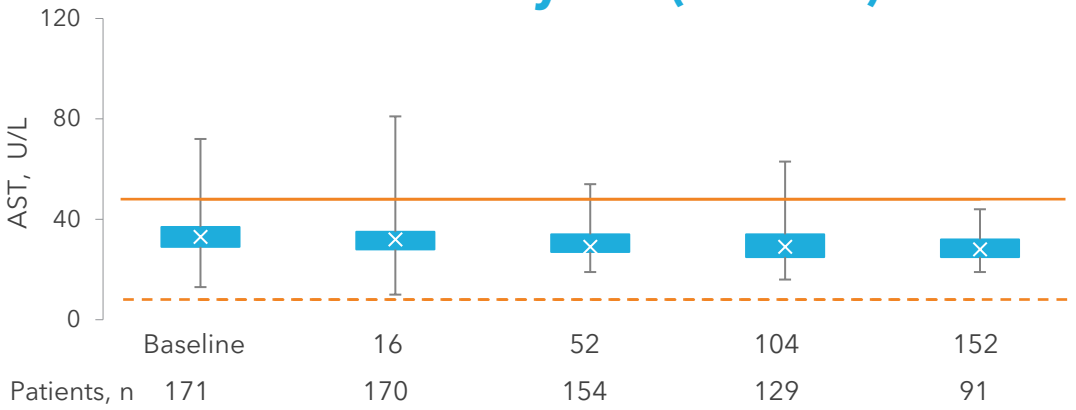
Eosinophilia events were categorized as: **Grade 1** (Mild, 0.5 x 10^9 to 1.5 x 10^9/L); **Grade 2** (Moderate, 1.5 x 10^9 to 5 x 10^9/L); **Grade 3** (Severe, > 5 x 10^9/L).
[a]Two patients also had Grade 1 or Grade 2 eosinophilia events reported at separate timepoints.

Laboratory parameters remained generally stable over 3 years of dupilumab treatment in both age groups

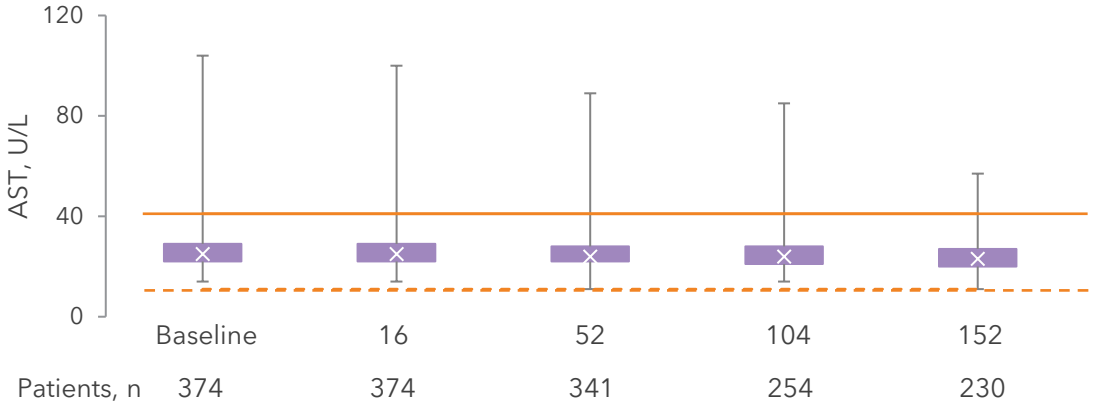
Results

Aspartate aminotransferase

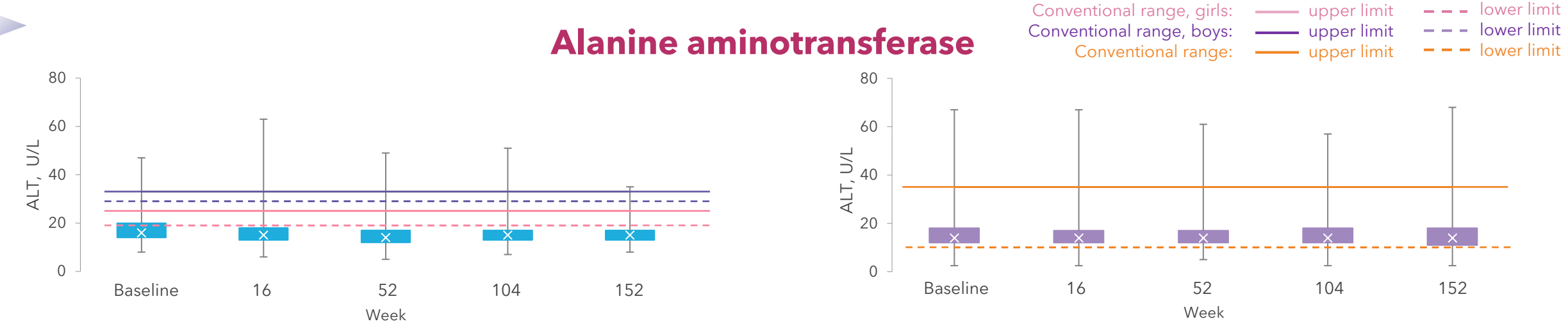
6 months to 5 years (n = 180)



6 to 11 years (n = 383)



Alanine aminotransferase



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ALT, alanine aminotransferase; AST aspartate aminotransferase.

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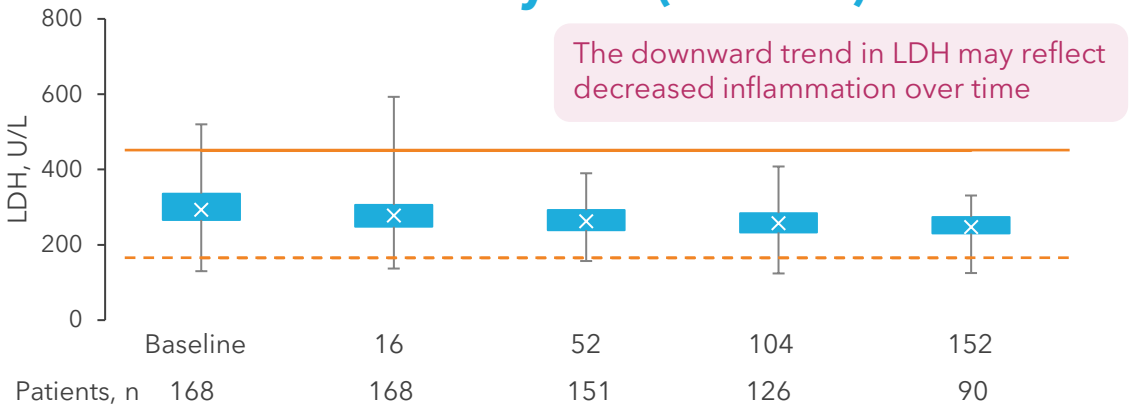
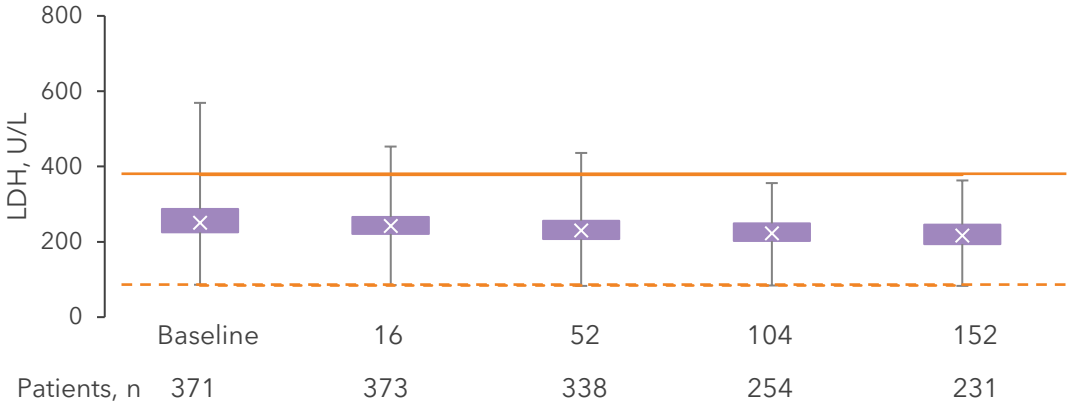
Results

Lactate dehydrogenase

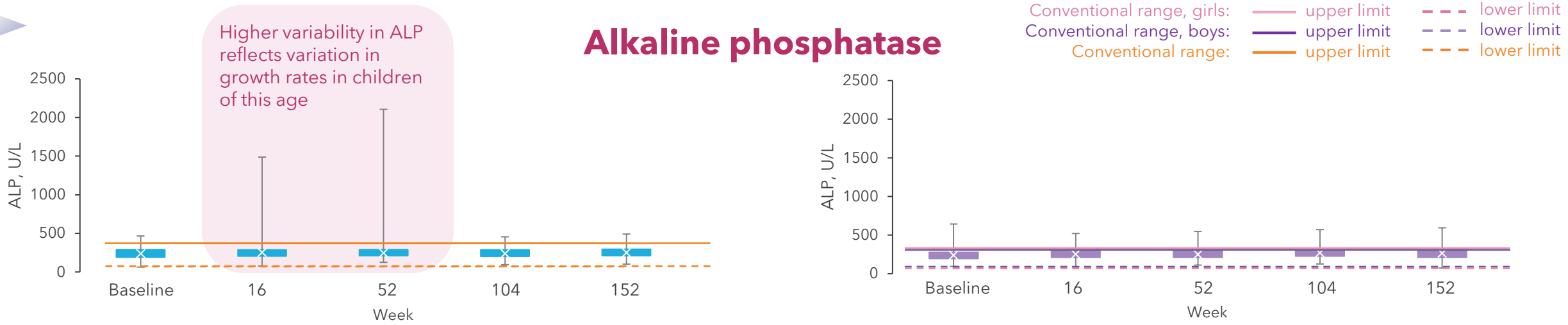
6 months to 5 years (n = 180)



6 to 11 years (n = 383)



Alkaline phosphatase



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[a]At Week 16 one patient experienced >3 ULN. [b]At Week 52 two patients experienced >3 ULN.

ALP, alkaline phosphatase; LDH, lactate dehydrogenase; ULN, upper limit of normal.

Conclusion

Laboratory results of up to 3 years of dupilumab treatment in **children 6 months to 11 years of age** were generally stable

Safety was consistent with the known dupilumab safety profile, supporting **no need for routine laboratory monitoring**