Hematologic Laboratory Parameters in Adults and Children Aged 6 Months to ≥18 Years With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab

Amy S. Paller[1,2], Elaine C. Siegfried[3,4], Faisal A. Khokhar[5], Tayler Gonzalez[6]

[1]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA; [3]Saint Louis University, St. Louis, MO, USA; [4]Cardinal Glennon Children's Hospital, St. Louis, MO, USA; [5]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [6]Sanofi, Cambridge, MA, USA

INTRODUCTION

- Systemic treatments often used for moderate-to-severe atopic dermatitis (AD) have immunosuppressive properties and necessitate laboratory screening and monitoring, adding to treatment burden and concerns of long-term safety

OBJECTIVE

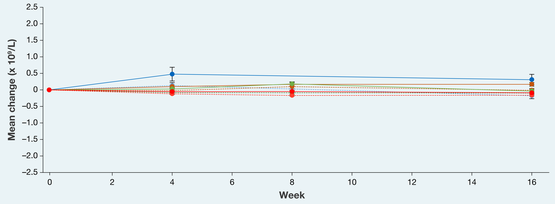
- **To further characterize the safety of dupilumab by evaluating hematology laboratory findings across different age ranges from children aged ≥ 6 months to adults with moderate-to-severe AD in randomized, placebo-controlled, phase 3 trials of dupilumab**

METHODS

- We report hematology parameters from patients with moderate-to-severe AD who participated in any of four randomized, placebo-controlled, phase 3 studies:
  - LIBERTY AD PRESCHOOL (6 months to 5 years; NCT03346434 part B)
    - Dupilumab 200/300 mg every 4 weeks (q4w) + topical corticosteroids (TCS; n=83) or placebo +TCS (n=79)
  - LIBERTY AD PEDS (6–11 years; NCT03345914)
    - Pooled dupilumab +TCS (100/200 mg q2w +TCS [n=122]; 300 mg q4w +TCS [n=120]) or placebo + TCS (n=120)
  - LIBERTY AD ADOL (12–17 years; NCT03054428)
    - Pooled dupilumab (200/300 mg q2w [n=82]; 300 mg q4w [n=83]) or placebo (n=85)
  - LIBERTY AD CHRONOS (≥ 18 years; NCT02260986)
    - Pooled dupilumab (300 mg q2w + TCS [n=110]; 300 mg qw +TCS [n=315]) or placebo +TCS (n=315)

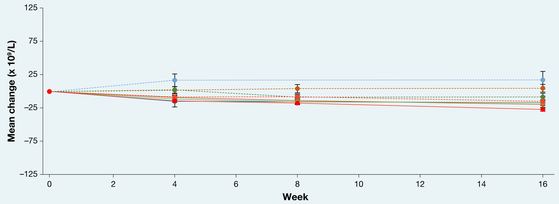
RESULTS

Figure 1. Mean change in eosinophil count over time



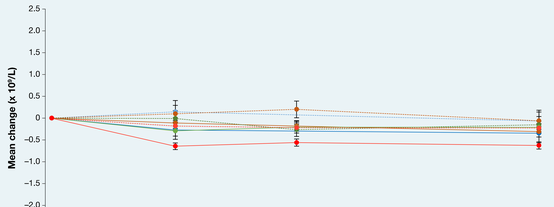
PBO 6m-5y	78	74		72
DUP 6m-5y	82	77		74
PBO 6y-11y	118	111	109	106
DUP 6y-11y	240	218	212	227
PBO 12y-17y	85	78	76	72
DUP 12y-17y	165	160	154	152
PBO 18+	314	302	305	288
DUP 18+	425	401	401	394

Figure 2. Mean change in platelet count over time



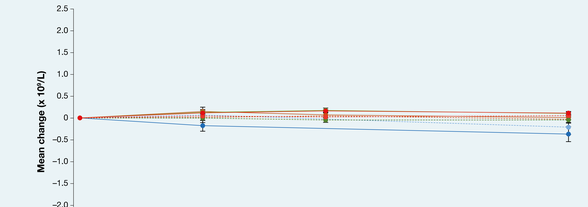
PBO 6m-5y	78	74		71
DUP 6m-5y	81	76		73
PBO 6y-11y	117	107	106	106
DUP 6y-11y	231	204	198	213
PBO 12y-17y	83	74	72	67
DUP 12y-17y	164	155	150	150
PBO 18+	313	300	304	286
DUP 18+	424	398	398	392

Figure 3. Mean change in neutrophil count over time



PBO 6m-5y	78	74		72
DUP 6m-5y	81	76		73
PBO 6y-11y	118	111	109	106
DUP 6y-11y	240	218	211	227
PBO 12y-17y	85	78	76	72
DUP 12y-17y	165	160	154	152
PBO 18+	314	302	305	288
DUP 18+	425	401	401	394

Figure 4. Mean change in lymphocyte count over time



PBO 6m-5y	78	74		72
DUP 6m-5y	82	77		74
PBO 6y-11y	118	111	109	106
DUP 6y-11y	240	218	211	227
PBO 12y-17y	85	78	76	72
DUP 12y-17y	165	160	154	152
PBO 18+	314	302	305	288
DUP 18+	425	401	401	394

- Additionally, in adult patients at Week 52, mean change in eosinophil, neutrophil and lymophocyte counts remained relatively constant while a mild increase in platelet counts was observed

Safety

- 1 patient in the ≥18-years placebo group reported a TEAE of neutropenia that led to treatment discontinuation
- Overall safety was consistent with the known dupilumab safety profile

CONCLUSION

- **No clinically meaningful changes in hematology parameters were observed during dupilumab treatment in patients with moderate-to-severe AD, highlighting that no initial or routine laboratory monitoring for hematology parameters is required during dupilumab treatment of pediatric or adult patients.**

Acknowledgments and funding sources: Data first presented at Eastern Allergy Conference (EAC) 2022. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifiers: NCT03346434 (LIBERTY AD PRESCHOOL), NCT03345914 (LIBERTY AD PEDS), NCT03054428 (LIBERTY AD ADOL), and NCT02260986 (LIBERTY AD CHRONOS). Data analysis was provided by Haixin Zhang, PhD, of Regeneron Pharmaceuticals, Inc. Medical writing/editorial assistance was provided by Nigel De Melo, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

Disclosures: Paller AS: AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, Krystal Biotech, Regeneron Pharmaceuticals Inc., UCB – investigator; AbbVie, Acrotech, Almirall, Amgen, Amryt Pharma, Arcutis Biotherapeutics, Arena Pharmaceuticals, Azitra, BioCryst, BiomX, BMS, BridgeBio, Castle Creek Biosciences, Catawba Research, Eli Lilly, Exicure, Gilead, Incyte, Janssen, Johnson & Johnson, Kamari Pharma, LEO Pharma, Novartis, OM Pharma, Pfizer, Pierre Fabre, RAPT Therapeutics, Regeneron Pharmaceuticals Inc., Sanofi, Seanergy, UCB – consultant with honorarium; AbbVie, Abeona Therapeutics, Bausch Health, Galderma, Novan – data and safety monitoring board. **Siegfried EC:** Dermavant, Eli Lilly, Pfizer, Regeneron Pharmaceuticals, Inc., Verrica Pharmaceuticals – consultant; GSK, LEO Pharma, Novan – data and safety monitoring board; Eli Lilly, Janssen, Regeneron Pharmaceuticals, Inc., Stiefel, Verrica Pharmaceuticals – Principal Investigator in clinical trials. **Khokhar FA:** Regeneron Pharmaceuticals, Inc. – employee and shareholder. **Gonzalez T:** Sanofi – employee, may hold stock and/or stock options in the company.

Presented at the South Beach Symposium (SBS 2023); Miami Beach, Florida, USA; February 9 - 12, 2023.