Efficacy of Dupilumab in Adolescents With Moderate-to-Severe Atopic Dermatitis With and Without Comorbid Asthma: Subgroup Analysis From a Phase 3 Trial (LIBERTY AD ADOL)

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BACKGROUND
- Atopic dermatitis (AD) is a chronic inflammatory skin disease often associated with asthma and/or rhinitis.

- Dupilumab is a humanized monoclonal antibody that selectively inhibits the IL-4 and IL-13 receptors.

OBJECTIVE
- To determine if a history of asthma impacts the efficacy of dupilumab in adolescents with moderate to severe AD.

METHODS
Study design
- This was a randomized, double-blind, placebo-controlled, parallel-group, 2×3 trial of dupilumab in adolescents with moderate-to-severe AD (LIBERTY AD ADOL).

- Patients were randomized to 1:1:1 to receive dupilumab 300 mg every 2 weeks (q2w) (patients with body weight ≥ 60 kg received 300 mg), 300 mg dupilumab (q2w) (patients with body weight < 60 kg received 200 mg of dupilumab; patients with body weight < 40 kg received 100 mg of dupilumab) or placebo (Pbo); regardless of asthma.

- The study was conducted at 296 sites globally.

- Patients received a 600 mg loading dose on Day 1.

- The study duration was 52 weeks, with a 24-week extension.

- No other anti-AD treatments were allowed during the study.

- Baseline demographics and disease characteristics were similar among treatment groups.

RESULTS

- Of the 251 patients randomized, 103 had a history of rhinitis and 84 did not have asthma.

- Baseline demographics and disease characteristics were similar among treatment groups with no history of asthma (Table 1).

- Safety in adolescents was consistent with that seen in adults, and data were collected from 25% of adolescents with moderate-to-severe AD in the US ADOL trial who had a history of asthma.

- Similar to previous findings in the adult population, 5,6 dupilumab improved signs and symptoms of AD in adolescent patients with and without a history of asthma, suggesting that, in adolescent patients 12-16 years of age, the efficacy of dupilumab is not affected by comorbid atopic diseases such as asthma.

CONCLUSIONS
• Similar to previous findings in the adult population, dupilumab improved signs and symptoms of AD in adolescent patients with and without a history of asthma, suggesting that, in adolescent patients with moderate-to-severe AD, the efficacy of dupilumab is not affected by comorbid atopic diseases such as asthma.

REFERENCES

Acknowledgments
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Disclosure
Regeneron Pharmaceuticals, Inc. – Site PI research grants, consulting fees for clinical trials and investigator-related travel; AbbVie – consulting fees for clinical trials and investigator-related travel. Wallee, Regeneron Pharmaceuticals, Inc. – consulting fees for clinical trials and investigator-related travel. Poon, AbbVie, Inc., for providing study drug and/or placebo.

Subgroup of patients with a history of asthma and without a history of asthma (Table 1).

| TABLE 1. Baseline disease characteristics by history of asthma. |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                  | Placebo (n = 51) | Dupilumab 300 mg q2w (n = 47) | Dupilumab 300 mg q4w (n = 48) |
| Age (years)      | 12-16           | 12-16           | 12-16           |
| Disease duration (days) | 72.9 (70.5) | 72.9 (70.5) | 72.9 (70.5) |
| Disease severity | 9.8 (1.6) | 9.8 (1.6) | 9.8 (1.6) |
| Histologic severity | 3.5 (1.6) | 3.5 (1.6) | 3.5 (1.6) |
| Skin thickness | 0.7 (0.4) | 0.7 (0.4) | 0.7 (0.4) |
| Pruritus NRS | 7.6 (1.5) | 7.5 (1.5) | 7.4 (1.5) |

• Similar to previous findings in the adult population, dupilumab improved signs and symptoms of AD in adolescent patients with and without a history of asthma, suggesting that, in adolescent patients with moderate-to-severe AD, the efficacy of dupilumab is not affected by comorbid atopic diseases such as asthma.

CONCLUSIONS
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