In the ECZTRA 6 (NCT03528615) phase 3 trial, tralokinumab 300 mg provided progressive and sustained efficacy in adolescents with moderate-to-severe AD and was well-tolerated with a reassuring long-term safety profile over 52 weeks.

### Methods

#### Study design

- Patients were randomized to tralokinumab 300 mg Q2W or placebo [(n=94) for 16 weeks (Figure 2)].

- At Week 16, patients initiated on tralokinumab and achieving primary endpoints (IGA 0.1 and/or EASI 70) without rescue were re-randomized to tralokinumab 300 mg Q2W or Q4W monotherapy for 36 additional weeks; other patients were switched to open-label tralokinumab 300 mg Q2W plus optional topical corticosteroids (TCS) or placebo.

- Key inclusion criteria:
  - Age 12–17 years
  - History of AD for 1 year
  - AD involvement of ≥ 30% body surface area at screening

- Key exclusion criteria:

#### Statistical methods

- A pre-specified treatment policy approach for the analyses was adopted using observed data, regardless of rescue medication and treatment discontinuation.

- Missing data were imputed using multiple imputations; 100 complete datasets were created via imputations.

- Treatment effects for the binary endpoints were estimated using the Cochran-Mantel-Haenszel method stratified by region and baseline IGA.

- Continuous endpoint data were analyzed using analysis of covariance accounting for the treatment, region, baseline IGA, and baseline outcome value.

- Treatment means for the continuous endpoints were estimated using least squares mean.

- To combine inference from multiple imputations, the estimated treatment means, treatment differences and standard errors were pooled using Rubin’s rule.

- Post hoc analyses were conducted by pooling Weeks 16–52 data for all patients initially randomized to tralokinumab 300 mg Q2W, regardless of the response achieved on Week 16, the dosage regimen received beyond Week 16, or whether discontinuing treatment before Week 16 (imputed data only).

### Results

#### Tralokinumab 300 mg efficacy at Week 16 (vs placebo) and Week 52

- 29.9% of patients treated with tralokinumab 300 mg (29.9%) versus placebo (56.4%) had a mean EASI reduction of ≥ 75% (IBS AD) at Week 16, with further improvement up to Week 52.

- Progression of integrated treatment control (ITC) was observed from baseline up to Week 52, with higher proportions of tralokinumab-treated patients achieving ITC compared with placebo.

#### Tralokinumab 300 mg disease control at Week 16 (vs placebo) and progressive disease control at Week 52

- Patients achieving ITC at Week 16 reduced their IGA score by a mean of 1.7–2.0 units at Week 52, with further improvement up to Week 16. ITC was observed from baseline up to Week 52, with higher proportions of tralokinumab-treated patients achieving ITC compared with placebo.

#### Safety summary for Weeks 0–16 and Weeks 16–52

- The safety profile was consistent with prolonged treatment after Week 16, with most AEs being mild, with UTIs the most common (Table 3).

### Conclusions

- At Week 16, tralokinumab 300 mg Q2W improved EASI and PRS in adolescents with moderate-to-severe AD, with progressive and sustained improvement seen up to Week 52.

- Tralokinumab 300 mg Q2W is an efficacious and well-tolerated treatment option for uncontrolled AD in adolescents, with reassuring long-term safety profile over 52 weeks.

### Background

- In the ECZTRA 6 (NCT03528615) phase 3 trial, tralokinumab 300 mg provided progressive and sustained efficacy in adolescents with moderate-to-severe AD and was well-tolerated with a reassuring long-term safety profile over 52 weeks.

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