Efficacy and Safety of Switching From Dupilumab to Upadacitinib or Continuous Upadacitinib in Moderate-to-Severe Atopic Dermatitis: Results From an Open-Label Extension Trial

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BACKGROUND

Upadacitinib is a potent Janus kinase (JAK) inhibitor with greater inhibitory potency for JAK1, JAK2, and JAK3 than dupilumab. Upadacitinib 45 mg was approved by the European Commission for the treatment of adults with moderateto-severe moderate-to-severe atopic dermatitis (AD) and is under review with the FDA. The Heads Up study was a 24-week head-to-head Phase 3, multicenter, randomized, double-blinded, double-dummy, active-controlled study assessing the long-term safety and efficacy of upadacitinib in adults with moderate-to-severe AD

METHODS

Open-label extension of the head-to-head, Phase 3, multicenter, randomized, double-blinded, double-dummy, active-controlled study comparing the efficacy and safety of upadacitinib 30 mg to dupilumab 300 mg SC injection administered every other week (EOW) starting at the Week 2 visit and until the end of the 24-week switching period. Safety was assessed through 30 days following the last dose of upadacitinib.

RESULTS

RESULTS (CONTINUED)

Figure 1. Heads Up Study Design and Open-Label Extension

Figure 2. Achievement of EASI 75, 90, and NRS 0–4 Through Week 48 Among Those Subjects Who Entered OLE (ITT Population, OC)

Figure 3. Patients Simultaneously Achieving EASI 90 or EASI 100 AND NRS 0–1 Through Week 40 Among Those Subjects Who Entered OLE (ITT Population, OC)

Figure 4. Improvement in Clinical Response After Switching From Dupilumab to Upadacitinib (ITT Population, OC)

Figure 5. Patients Simultaneously Achieving EASI 90 or EASI 100 AND NRS 0–1 Through Week 40 Among Those Subjects Who Entered OLE (ITT Population, OC)

DISCUSSION

- Among patients who did not achieve WP-NRS improvement ≥4 at Week 24 with dupilumab, 57% achieved WP-NRS improvement ≥14 at Week 16 of upadacitinib treatment.
- Among patients receiving continuous upadacitinib, proportions of patients achieving EASI 75, EASI 90, EASI 100, and WP-NRS improvement ≥14 at the end of Heads Up were maintained through Week 16 of the OLE.

CONCLUSIONS

- Patients who switched from dupilumab to Open-Label upadacitinib showed improvements in EASI response and WP-NRS after 40 weeks of continued treatment. These are first data to evaluate the safety and efficacy of upadacitinib 30 mg post Week 4 post-switch, including multi-dimensional improvements with stringent endpoints.
- Patients who continued use of upadacitinib demonstrated sustained skin and itch response through 40 weeks.
- Switching from dupilumab to upadacitinib resulted in increased rates of efficacy and achievement of higher efficacy thresholds.
- The safety profile of upadacitinib 30 mg with continued treatment through 40 weeks and in subjects switching from dupilumab to upadacitinib, was consistent with the safety profile of upadacitinib observed in the Phase 3 pivotal AD studies. Measures included: Treatment emergent adverse events (TEAEs) within the safety database. No new safety risks were observed.

REFERENCES


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DISCLOSURES

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