Efficacy and safety of tildrakizumab 100 mg for plaque psoriasis in patients randomized to treatment continuation vs treatment withdrawal with retreatment upon relapse in reSURFACE 1

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INTRODUCTION

Tildrakizumab is a humanized monoclonal antibody that inhibits IL-23p19, a cytokine that plays an important role in the pathogenesis of psoriasis.1-3 Tildrakizumab has been approved for the treatment of moderate to severe chronic plaque psoriasis (PASI ≥75) in patients who have received previous systemic therapy or phototherapy with failed or intolerable side effects.4 In a randomized, double-blind, placebo-controlled trial, tildrakizumab significantly improved PASI 75 response rates at week 32 compared with placebo.5 In a previous extension study, tildrakizumab demonstrated efficacy and was generally well-tolerated in patients with moderate to severe plaque psoriasis (PASI ≥75) at 100 mg or 200 mg, with a mean duration of follow-up of 25 months.6-9

METHODS

Study design

U.S. reSURFACE 1 was a phase 3, randomized, controlled trial conducted in patients with moderate to severe chronic plaque psoriasis (PASI >10, 20–75) who were eligible for continuation treatment with tildrakizumab 100 mg or placebo.10 Patients in both treatment groups were followed through week 28. Patients who were PASI 75 responders or partial responders at week 28 were rerandomized to receive tildrakizumab 100 mg or placebo at week 28 for a total of 64 weeks of follow-up.10

At study initiation, 309 patients were randomized to tildrakizumab 100 mg (n = 287) or placebo (n = 22) who had moderate to severe chronic plaque psoriasis (PASI 75 or PASI 90 responders at week 28). At week 28, 229 patients in the tildrakizumab arm and 20 patients in the placebo arm achieved PASI 75 responders (Table 2).10

Efficacy

In patients who relapsed upon tildrakizumab withdrawal and were retreated, residual disease resolved in the majority of cases within 12 weeks of retreatment with tildrakizumab 100 mg.10

Safety

In patients randomized to tildrakizumab 100 mg, no serious adverse events were reported.10

RESULTS

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REFERENCES

2. Acknowledgments

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DISCLOSURES

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CONCLUSIONS

Continuation of tildrakizumab 100 mg was associated with low residual disease and a low rate of AEs in patients who relapsed upon tildrakizumab withdrawal and were retreated. The majority of residual disease resolved in the majority of cases within 12 weeks of retreatment with tildrakizumab 100 mg. This analysis suggests that tildrakizumab has a persistent effect on the psoriatic lesion, even in the absence of continued treatment.18-25

1. Week 1: median (IQR) = 238.8 (167, 294) days; Week 2: median (IQR) = 308 (99.7) days

2. Reasons for discontinuation were withdrawal by subject (1.5%), AE (0.7%), lost to follow-up (0.7%), noncompliance with treatment (2.6%), physician decision (0.7%), and protocol violation (0.7%).

3. Of the 113 responders rerandomized to placebo after week 28 who did not relapse, 6.9% (n = 8) relapsed after week 28 and were retreated, or received continuous tildrakizumab 100 mg upon rerandomization to placebo and were retreated, or received continuous tildrakizumab 100 mg upon rerandomization to placebo and were retreated, or received continuous...