Clinical Responses in Patients with Moderate-to-Severe Plaque Psoriasis Following Withdrawal and Re-treatment with Risankizumab or Switching from Ustekinumab to Risankizumab

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INTRODUCTION

Patients with moderate-to-severe plaque psoriasis were randomized to receive subcutaneous injections of risankizumab (18 mg single dose at week 0, 90 or 180 mg at weeks 0, 4, and 16) or ustekinumab (45 or 90 mg, based on body weight at weeks 0, 4, and 16). Patients were followed up through week 48 during the double-blind period.

MATERIALS & METHODS

STUDY DESIGN AND PATIENTS

In the phase 2a randomized, double-blind, placebo-controlled, parallel-group study, 166 patients with moderate-to-severe plaque psoriasis received 90 mg risankizumab for the study period reported here. Abbreviations: OLE = open-label extension; PASI = Psoriasis Area and Severity Index.

RESULTS

• Of the 166 patients randomized in the phase 2a study, 110 (66.3%) patients enrolled in the OLE and received 90 mg risankizumab (Figure 1).

EFFICACY

At OLE entry, PASI 90 response rates for patients previously treated with 18 mg, 90 mg, or 180 mg risankizumab or ustekinumab were 0% (0/22), 53.6% (15/28), 51.5% (17/33), and 14.8% (4/27), respectively, reflecting residual benefit from study drug in the parent study (Figure 2).

At week 24 of the OLE, PASI 90 response rates increased to 68.2% (15/22), 60.7% (17/28), 66.7% (22/33), and 74.1% (20/27) in patients initially treated with 18 mg, 90 mg, or 180 mg risankizumab or ustekinumab, respectively.

Figure 2. PASI 90 Responses Through Week 24 of OLE (NRI)

EFFICACY - CONT.

At OLE entry, PASI 90 response rates for patients previously treated with 18 mg, 90 mg, or 180 mg risankizumab or ustekinumab were 0% (0/22), 39.3% (1/28), 33.3% (1/33), and 7.4% (2/27), respectively, and improved to 31.8% (7/22), 46.4% (13/28), 45.5% (15/33), and 48.1% (13/27), respectively, at week 24 of the OLE (Figure 3).

Figure 3. PASI 100 Responses Through Week 24 of OLE (NRI)

CONCLUSIONS

• The proportions of patients previously treated with 18 mg, 90 mg, or 180 mg risankizumab or ustekinumab achieving static Physician’s Global Assessment of 0 or 1 (sPGA 0/1) at OLE entry were 9.1% (2/22), 57.3% (16/28), 63.6% (21/33), and 25.9% (7/27), respectively, and improved to 72.7% (16/22), 67.9% (19/28), 69.7% (23/33), and 77.8% (21/27), respectively, at week 24 of the OLE (Figure 4).

Figure 4. sPGA Scores of 0/1 Through Week 24 of OLE (NRI)

DISCLOSURES

KA Papp has received honoraria or fees for serving on advisory boards, as a speaker, or as a consultant, grants as an investigator from AbbVie, Amgen, Astra, Biologics, Biogen, Boehringer Ingelheim, Galderma, Genentech, GSK, Hoffmann-La Roche, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sanofi-Aventis, Shionogi, Teva, UCB, and Vifor. KA Papp has received honoraria or fees for serving on advisory boards, as a speaker, or as a consultant, grants as an investigator from AbbVie, Amgen, Astra, Biologics, Biogen, Boehringer Ingelheim, Galderma, Genentech, GSK, Hoffmann-La Roche, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sanofi-Aventis, Shionogi, Teva, UCB, and Vifor. KA Papp has received honoraria or fees for serving on advisory boards, as a speaker, or as a consultant, grants as an investigator from AbbVie, Amgen, Astra, Biologics, Biogen, Boehringer Ingelheim, Galderma, Genentech, GSK, Hoffmann-La Roche, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sanofi-Aventis, Shionogi, Teva, UCB, and Vifor. KA Papp has received honoraria or fees for serving on advisory boards, as a speaker, or as a consultant, grants as an investigator from AbbVie, Amgen, Astra, Biologics, Biogen, Boehringer Ingelheim, Galderma, Genentech, GSK, Hoffmann-La Roche, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi, Sanofi-Aventis, Shionogi, Teva, UCB, and Vifor.

REFERENCES

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SAFETY

An overview of treatment-emergent AEs through 24 weeks of OLE for all patients who entered OLE is presented in Table 1.

Table 1. Summary of Adverse Events Through Week 24 of OLE

CONCLUSIONS

• Switching treatment to risankizumab in patients initially treated with ustekinumab resulted in higher clinical responses, as measured by increases in PASI and sPGA responses at 24 weeks.

• Re-treatment with dose increases from 18 mg risankizumab starting at week 12; however, all patients received 90 mg risankizumab for the study period reported here.

Figure 1

Figure 2

Figure 3

Figure 4