נובמבר 2025

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

SKYRIZI 150mg (Risankizumab 150 mg/1ml)

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע כי העלון לרופא של התכשיר (עט ומזרק מוכנים לשימוש) התעדכן.

העלון התעדכן עם מידע קליני על ספחת רובדית באזורים רגישים (קרקפת ואזור גניטלי) .

בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי. מידע שהתווסף מסומן באדום.

התכשיר מותווה לטיפול במחלות הבאות:

Plaque psoriasis

Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Psoriatic arthritis

Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

להלן השינויים בעלון לרופא:

5.1 Pharmacodynamic properties

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Plaque psoriasis involving the scalp or genital area

The efficacy and safety of risankizumab was assessed in a multicenter, randomised, double-blind, placebo-controlled study (UNLIMMITED) that enrolled subjects 18 years of age and older with moderate to severe scalp psoriasis (UNLIMMITED-S), defined as Psoriasis Scalp Severity Index (PSSI) ≥12, scalp Investigator Global Assessment (scalp IGA) ≥3, and ≥30% of the scalp affected, or moderate to severe genital psoriasis (UNLIMMITED-G), defined as static Physician's Global Assessment of Genitalia (sPGA-G) ≥3 at baseline. All subjects had BSA ≥1% and sPGA ≥3 at baseline.

In UNLIMMITED, subjects were randomised to receive either risankizumab 150 mg or placebo subcutaneously at weeks 0 and 4. Starting at week 16, all subjects received risankizumab 150 mg every 12 weeks until the last dose at week 40.

Scalp area (UNLIMMITED-S)

UNLIMMITED-S enrolled 105 subjects. Baseline BSA involvement was ≥10% for 61.9% of the subjects and <10% for 38.1% of the subjects. Mean baseline BSA involvement was 16.8%. At baseline, 76.2% of subjects had sPGA = 3 and 23.8% had sPGA = 4.

At baseline, 54.3% of subjects were naïve to any systemic therapy (including non-biologic and biologic), 0% of subjects had received prior phototherapy, 15.2% had received prior non-biologic systemic therapy, and 37.1% had received prior biologic therapy.

The results for the primary and key secondary endpoints are presented in Table 6.

Table 6. Efficacy results in adults with scalp psoriasis in UNLIMMITED-S at week 16

Endpoint	Risankizumab (N=51) n (%)	Placebo (N=54) n (%)	Treatment difference (95% CI)
scalp IGA of clear or almost clear (0 or 1)[a]	31 (60.8)	7 (13.0)	47.0 [31.2, 62,8]
PSSI 75[b]	38 (74.5)	12 (22.2)	52.9 [37.5, 68.3]
PSSI 90[c]	27 (52.9)	7 (13.0)	39.8 [24.4, 55.2]
PSSI 100[d]	23 (45.1)	7 (13.0)	31.2 [15.4, 46.9]
Mean change from baseline in PSS	N=44 -6.0	N=49 -1.0	-5.0 [-6.6, -3.3]

All comparisons achieved p<0.001, adjusted treatment difference (95% CI)

[a] Primary endpoint

[b] Achievement of ≥75% improvement from baseline in PSSI

[c] Achievement of ≥90% improvement from baseline in PSSI

[d] Achievement of 100% improvement from baseline in PSSI

A greater proportion of subjects treated with risankizumab achieved a scalp IGA score of 0 at week 16 compared with placebo (41.2% vs 11.1%, respectively).

Scalp Itch Numeric rating scale (NRS) response, defined as achievement of ≥4-point improvement (reduction) from baseline on the Scalp Itch NRS among subjects with baseline scores ≥4, was achieved in a greater proportion of subjects treated with risankizumab at week 16 compared to placebo (50.0% vs 11.1%, respectively).

A greater proportion of subjects treated with risankizumab achieved a DLQI score of 0 or 1 (no impact on health-related quality of life) at week 16 compared with placebo (47.1% vs 11.1%, respectively).

Genital area (UNLIMMITED-G)

UNLIMMITED-G enrolled 109 subjects. Baseline BSA involvement was ≥10% for 63.3% of the subjects and <10% for 36.7% of the subjects. Mean baseline BSA involvement was 17.2%. At baseline, 80.7% of subjects had sPGA = 3 and 19.3% had sPGA = 4.

At baseline, 61.5% of subjects were naïve to any systemic therapy (including non-biologic and biologic), 2.8% of subjects had received prior phototherapy, 16.5% had received prior non-biologic systemic therapy, and 25.7% had received prior biologic therapy.

The results for the primary and all secondary endpoints are presented in Table 7.

Table 7. Efficacy results in adults with genital psoriasis in UNLIMMITED-G at week 16

Endpoint	Risankizumab (N=55) n (%)	Placebo (N=54) n (%)	Treatment difference (95% CI)
sPGA-G of clear or minimal (0 or 1)[a]	38 (69.1)	7 (13.0)	57.0 [42.3, 71.7]

sPGA-G of clear (0)	28 (50.9)	3 (5.6)	46.7 [32.6, 60.8]
DLQI of 0 or 1[b]	33 (60.0)	2 (3.7)	56.5 [43.0, 70.0]
GPI-NRS reduction of ≥4-point from baseline[c]	N=41 20 (48.8)	N=45 3 (6.7)	43.0 [26.6, 59.3]
GenPs-SFQ item 2 score of 0 (never) or 1 (rarely)[d,e]	N=31 22 (71.0)	N=32 7 (21.9)	46.1 [26.7, 65.6]
All comparisons achieved p<0.001, adjusted treatment difference (95% CI) [a] Primary endpoint [b] Total DLQI score of 0 or 1 indicates skin condition has no impact on patient's health-related quality of life [c] Improvement of genital itch severity as measured by a reduction of at least 4 points in the 11-point Genital Psoriasis Itch (GPI) Numeric Rating Scale (NRS) from the Genital Psoriasis Symptom Scale (GPSS) among subjects with baseline score ≥4 [d] Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) Item 2 measures patient-perceived impact on sexual health due to genital area psoriasis on sexual activity frequency (intercourse or other activities) in the past week (uses a scale from 0 to 4 with higher scores indicating greater limitations) [e] Among subjects with baseline score ≥2			

Subjects treated with risankizumab achieved greater reduction in psoriasis symptoms severity in the genital area (itch, pain, discomfort, stinging, burning, redness, scaling, and cracking) from baseline as measured by GPSS at week 16 compared to placebo. The change from baseline in GPSS total score at week 16 was -26.5 for risankizumab and -1.0 for placebo.

A greater proportion of subjects treated with risankizumab compared to placebo achieved at least 2-point reduction on Patient's Global Assessment of Genital Psoriasis (PatGA-Genital), among subjects with baseline score ≥2 (71.7% vs 22.9%, respectively).

The safety profile of risankizumab in studies UNLIMMITED-S and UNLIMMITED-G was consistent with the safety profile observed in previous studies of patients with plaque psoriasis.

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,

אסתר בינשטוק

רוקחת ממונה