Skyrizi®
(risankizumab)

The potential for **nothing left on their skin**:* to patients that's everything[1-4]

NOTHING IS EVERYTHING

*Nothing on the skin: Defined as achievement of 75% PASI 90 and ≥84% sPGA 0/1 at Week 16 and achievement of ≥56% PASI 100 and sPGA 0 at Week 52 in UltIMMa-1 and UltIMMa-2. UltIMMa-1: SKYRIZI (n=304), ustekinumab (n=100).[2]

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

Please refer to the Summary of Product Characteristics for complete prescribing information. [Affiliate to work with local reviewers to insert appropriate web address to visit for full SMPC]

SKYRIZI is an IL-23/p19 inhibitor with:[5-10]

DURABILITY

Nothing less than the opportunity for durable, complete skin clearance[1,2]

- **Twice** the percentage of SKYRIZI patients achieved complete skin clearance vs ustekinumab (PASI 100)
  - UltIMMa-2: 60% (n=294) vs 30% (n=99), respectively, at Week 52*
- Proportion of **patients achieving complete clearance** (PASI 100) maintained through 2.5 years of continuous SKYRIZI treatment in an open-label extension (OLE) study[11,12]
  - Integrated UltIMMa-1 and UltIMMa-2: 64% (n=295/464), observed cases†

*P<0.0001 vs ustekinumab.
†**Observed cases:** no imputation of missing data; patients missing data at a visit were excluded from the observed analysis for that visit.
See the study designs on page 3.

SIMPLICITY

Nothing more than 4 doses per year after initiation doses[1‡]

- **Reliable every-3-month maintenance dosing** requiring no adjustment, regardless of baseline characteristics, including BMI and weight[1,13-15§]
  - SKYRIZI is dosed 150 mg (two 75-mg subcutaneous injections) at Week 0, Week 4, and every 12 weeks thereafter[1]

‡Maintenance dosing every 12 weeks following 2 starter doses at Week 0 and Week 4.
§Numeric trends toward less efficacy were observed in clinical trials in patients weighing more than 130 kilograms. However, this observation is based on a limited number of subjects.

SAFETY

Favorable safety profile[1]

- Reported TEAEs were consistent across all 4 clinical trials, with no new safety signals observed in the Phase 3 program[1,2]
- A safety profile similar to ustekinumab through Week 52 during RCTs[1,2]
- The most frequently reported adverse reactions in Phase 3 clinical trials were:
  - Very common (≥1/10): upper respiratory infection (URI)
  - Common (≥1/100 to <1/10): tinea infections[a], headache[b], pruritus[c], fatigue[d], injection site reactions[e]
  - Uncommon (≥1/1000 to <100): folliculitis
- **Consistent AEs of special interest in a pooled analysis from the first 16 weeks of treatment up to 4+ years[16¶]**
- No reports of active tuberculosis or reactivation of latent TB were reported, including 31 IMMhance study patients with latent TB who did not receive prophylaxis[1]

¶Integrated from five SKYRIZI Phase 2 and Phase 3 trials in patients with moderate to severe plaque psoriasis: Trial 1311.2, UltIMMa-1, UltIMMa-2, IMMhance, and IMMvent.

Important contextual information[1]
Tuberculosis: Prior to initiating treatment with SKYRIZI, patients should be evaluated for tuberculosis (TB) infection. Patients receiving SKYRIZI should be monitored for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating SKYRIZI in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Lab monitoring: SKYRIZI may increase the risk of infection. In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, SKYRIZI should be used with caution. Treatment with SKYRIZI should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Patients treated with SKYRIZI should be instructed to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops such an infection or is not responding to standard therapy for the infection, the patient should be closely monitored and SKYRIZI should not be administered until the infection resolves.

[a]Includes respiratory tract infection (viral, bacterial, or unspecified), sinusitis (including acute), rhinitis, nasopharyngitis, pharyngitis (including viral), tonsillitis.

[b]Includes tinea pedis, tinea cruris, body tinea, tinea versicolor, tinea manuum, onychomycosis.

[c]Includes headache, tension headache, sinus headache.

[d]Includes fatigue, asthenia.

[e]Includes injection site bruising, erythema, hematoma, hemorrhage, irritation, pain, pruritus, reaction, swelling.

This is page 2 of a 4-page document. Please see page 3 for study designs and page 4 for Important Safety Information.

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REAL SKYRIZI RESULTS[1,17]

Complete clearance at Week 52[1,17]

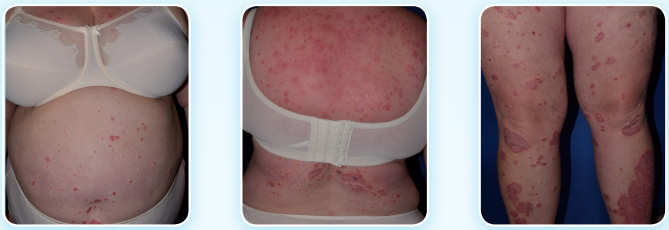
[Insert local disclaimers for use of patient photography here]

Baseline PASI[1]

NO DOSE

35

PASI score

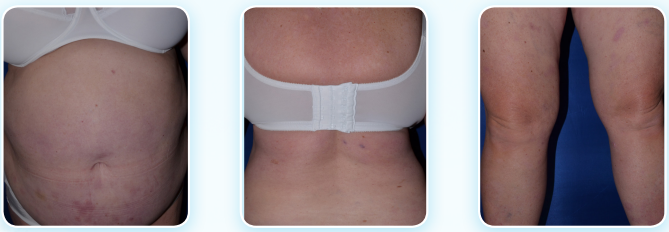


Week 16[1]

AFTER 2 DOSES

97%

Improvement from baseline PASI

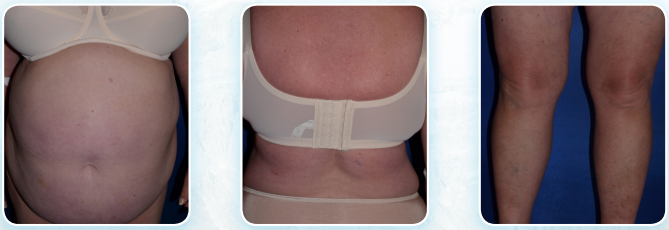


Week 52[1]

AFTER 5 DOSES

100%

Improvement from baseline PASI



Measurements were taken at each time point prior to administration of the next dose.
Patient depicted was a participant in the UltIMMa-2 pivotal trial undergoing continuous treatment with SKYRIZI.[1,2]
DoF ABVRRTI67530

STUDY DESIGNS

UltIMMa-1 and UltIMMa-2 were replicate Phase 3 studies[1,2]

PASI 90 and PASI 100 clearance of psoriatic lesions at Week 52 vs ustekinumab were ranked secondary endpoints.

Data analysis: Missing data were imputed as nonresponders (NRI) for categorical endpoints and by last observation carried forward for continuous endpoints.

Endpoints: Co-primary: Proportion of patients who achieved PASI 90 response and an sPGA score of clear or almost clear (sPGA 0 or 1) at Week 16 vs placebo. Ranked secondary endpoints: All 15 secondary ranked endpoints vs placebo and/or ustekinumab at Week 16 and/or Week 52 were met in both UltIMMa-1 and UltIMMa-2 ($P<0.0001$).

Dosing: SKYRIZI 150 mg (two 75-mg subcutaneous injections) at Week 0, Week 4, and every 12 weeks thereafter. Ustekinumab 45 mg or 90 mg (weight-based per label). Ustekinumab is dosed every 12 weeks after 2 starter doses at Week 0 and Week 4.

Phase 3 multinational randomized, double-blind, placebo-controlled, and active comparator-controlled trial. Patients with moderate to severe plaque psoriasis were randomly assigned 3:1:1 to risankizumab, ustekinumab, or placebo. Following the 16-week double-blind period, patients assigned to placebo switched to risankizumab; other patients continued double-blinded on their originally randomized treatment to Week 52.

UltIMMa-1 and UltIMMa-2 OLE[12]

An ongoing, single-arm, multicenter, open-label extension (OLE) study evaluating the long-term efficacy and safety of SKYRIZI (150 mg). Patients who completed UltIMMa-1 or UltIMMa-2, did not develop any malignancies, did not have >8 weeks' gap between visits, and were candidates for long-term risankizumab therapy were eligible to participate. The OLE data from UltIMMa-1 and UltIMMa-2 also are used in the LIMMitless study.

The UltIMMa-1 and UltIMMa-2 OLE analysis only includes patients who were randomized into the SKYRIZI arm at baseline (n=304 for UltIMMa-1; n=294 for UltIMMa-2).

A total of N=525 continued into the OLE from UltIMMa-1 and UltIMMa-2.

OLE limitations: In an open-label extension, there is a potential for enrichment of the long-term data in the remaining populations. Patients who are unable to tolerate or do not respond to the drug often drop out.

Observed cases (OC): No imputation of missing data; patients missing data at a visit were excluded from the observed analysis for that visit.

Dosing: SKYRIZI 150 mg (two 75-mg subcutaneous injections) at Week 0, Week 4, and every 12 weeks thereafter.

References: **1**. SKYRIZI [Summary of Product Characteristics]. AbbVie Ltd; April 2019. **2**. Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double blind, randomised, placebo controlled and ustekinumab controlled phase 3 trials. *Lancet*. 2018;392(10148):650-661. doi:10.1016/S0140-6736(18):31713-6 **3**. Blome C, Gosau R, Radtke MA, et al. Patient-relevant treatment goals in psoriasis. *Arch Dermatol Res*. 2016;308(2):69-78 doi:10.1007/s00403- 015-1613-8 **4**. Ryan C, Puig Z, Zema C, et al. Incremental benefits on patient-reported outcomes for achieving PASI 90 or PASI 100 over PASI 75 in patients with moderate to severe psoriasis. Poster presented at: 2018 European Academy of Dermatology and Venerology (EADV) Congress; September 12–16, 2018; Paris, France. Poster 2002. **5**. Puig L. PASI90 response: the new standard in therapeutic efficacy for psoriasis. *J Eur Acad Dermatol Venereol*. 2015;29(4):645-648. doi:10.1111/jdv.12817 **6**. Strober B, Papp KA, Lebwohl M, et al. Clinical meaningfulness of complete skin clearance in psoriasis. *J Am Acad Dermatol*. 2016;75(1): 77-82.e7. doi:10.1016/j.jaad.2016.03.026 **7**. Gooderham MJ, Papp KA, Lynde CW. Shifting the focus – the primary role of IL-23 in psoriasis and other inflammatory disorders. *J Eur Acad Derm Venereol*. 2018;32(7):1111-1119. doi:10.1111/jdv.14868 **8**. Gaffen SL, Jain R, Garg AV, Cua DJ. The IL-23-IL-17 immune axis: from mechanisms to therapeutic testing. *Nature Rev Immunol*. 2014;14(9):585-600. doi:10.1038/nri3707 **9**. Girolomoni G, Strohal R, Puig L, et al. The role of IL-23 and the IL-23/TH17 immune axis in the pathogenesis and treatment of psoriasis. *J Eur Acad Dermatol Venereol*. 2017;31(10):1616-1626. doi:10.1111/jdv.14433 **10**. Lynde CW, Poulin Y, Vender R, Bourcier M, Khalil S. Interleukin 17A: toward a new understanding of psoriasis pathogenesis. *J Am Acad Dermatol*. 2014;71(1):141-150. doi:10.1016/j.jaad.2013.12.036 **11**. Data on File, AbbVie Inc. ABVRRTI69326. **12**. Strober B, Eyerich K, Hong C-H, et al. Long-term efficacy and safety of switching from ustekinumab to risankizumab: results from the open-label extension LIMMitless. Poster presented at: 2019 European Academy of Dermatology and Venerology (EADV) Congress; October 9–13, 2019; Madrid, Spain. Poster 1714. **13**. Leonardi C, Gordon K, Longcore M, Gu Y, Puig L. Weight-based analysis of psoriasis area and severity index improvement at 52 weeks of risankizumab or ustekinumab treatment: An integrated analysis of patients with moderate-to-severe plaque psoriasis. Poster presented at: 24th World Congress of Dermatology (WCD); June 10–15, 2019; Milan, Italy. Poster 5248. **14**. Foley P, Strober B, Valdecantos WC, Photowala H, Zhan T, Menter A. Durable efficacy of risankizumab compared with ustekinumab across subgroups of patients with moderate-to-severe plaque psoriasis: integrated analysis of two phase 3 trials. Poster presented at: 2019 American Academy of Dermatology (AAD) Annual Meeting; March 1–5, 2019; Washington, DC. Poster 9780. **15**. Strober B, Valdecantos WC, Zhan T, Lambert H, Menter A. Efficacy of risankizumab in moderate-to-severe plaque psoriasis by baseline characteristics and prior therapies. Poster presented at: Skin Inflammation & Psoriasis International Network (SPIN) 6th Congress; April 25–27, 2019; Paris, France. Poster P081. **16**. Bachelez H, Gordon K, Blauvelt A, et al. The safety of risankizumab in patients with moderate-to-severe psoriasis: analysis of pooled clinical trial data. Poster presented at: 2019 European Academy of Dermatology and Venereology (EADV) Congress; October 9–13, 2019; Madrid, Spain. Poster 1764. **17**. Gordon KB, Strober B, Lebwohl M, et al. Supplement to: Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet*. 2018;392(10148):650-661. doi:10.1016/S0140-6736(18):31713-6

INDICATION[1]

SKYRIZI (risankizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

IMPORTANT SAFETY INFORMATION[1]

SKYRIZI is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. SKYRIZI may increase the risk of infection. In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, SKYRIZI should be used with caution. Treatment with SKYRIZI should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Prior to initiating treatment with SKYRIZI, patients should be evaluated for tuberculosis (TB) infection. Patients receiving SKYRIZI should be monitored for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating SKYRIZI in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Prior to initiating therapy with SKYRIZI, completion of all appropriate immunizations should be considered according to current immunization guidelines. If a patient has received live vaccination (viral or bacterial), it is recommended to wait at least 4 weeks prior to starting treatment with SKYRIZI. Patients treated with SKYRIZI should not receive live vaccines during treatment and for at least 21 weeks after treatment.

The most frequently reported adverse reactions were upper respiratory infections, which occurred in 13% of patients. Commonly (≥1/100 to <1/10) reported adverse reactions included tinea infections, headache, pruritus, fatigue, and injection site reactions.

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