HIGHLIGHTS FROM ULTIMMA-1 AND ULTIMMA-2[1]

PIVOTAL STUDIES AS PUBLISHED IN *THE LANCET* ASSESSING THE

EFFICACY & SAFETY OF RISANKIZUMAB

IN ADULTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS
VS USTEKINUMAB & PLACEBO

Active Comparator: The ustekinumab used as a biologic active control in ultIMMa-1 and ultIMMa-2 was sourced from the European Union. Comparability between non–US-approved ustekinumab and US-approved ustekinumab has not been established.

INDICATION[2]

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

SAFETY CONSIDERATIONS[2]

- SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Avoid use of live vaccines in SKYRIZI patients.

Please see additional Important Safety Information on last page.
Please see full Prescribing Information.

Skyrizi®
risankizumab-rzaa
75mg/0.83mL Injection

FOR ADULTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY

ULTIMMA-1 & 2 STUDY DESIGNS[1]

BASELINE CHARACTERISTICS		ULTIMMA-1 SKYRIZI (n=304)	ULTIMMA-1 UST (n=100)	ULTIMMA-1 PBO (n=102)	ULTIMMA-2 SKYRIZI (n=294)	ULTIMMA-2 UST (n=99)	ULTIMMA-2 PBO (n=98)
Demographics	Mean age, years	48	47	49	46	49	46
	Mean weight, kg	88	89	89	92	92	92
Disease Severity	Mean BSA involvement	26	25	28	26	21	24
	Mean PASI	21	20	21	21	18	19
Biologic Experience	Prior biologic use, %	34	30	39	40	43	43
	Prior TNFi, %	22	19	22	23	24	27
	Prior non-TNFi, %	18	17	24	26	31	26

PASI 90 and PASI 100 are defined as ≥90% and 100% improvement over baseline (respectively) in Psoriasis Area and Severity Index; sPGA 0/1 is defined as Static Physician's Global Assessment score of clear (0) or almost clear (1).

BSA=Body Surface Area; PBO=Placebo; TNFi=Tumor Necrosis Factor Inhibitor; UST=Ustekinumab.

ACTIVE COMPARATOR

The ustekinumab used as a biologic active control in ultIMMa-1 and ultIMMa-2 was sourced from the European Union. Comparability between non–US-approved ustekinumab and US-approved ustekinumab has not been established.

- Replicate phase 3, randomized, double-blind, placebo- and active-controlled studies
- Evaluated the efficacy & safety of SKYRIZI compared with placebo (over 16 weeks) or ustekinumab (over 52 weeks)
- SKYRIZI (150 mg) and ustekinumab (45 mg or 90 mg, based on screening weight per local label) dosed at Weeks 0, 4, 16, 28, 40
- **Co-primary endpoints:** PASI 90 and sPGA 0/1 at Week 16 vs placebo
- **Select secondary endpoints:** PASI 90 and PASI 100 at Week 52 vs ustekinumab

All primary and ranked secondary endpoints of SKYRIZI vs placebo and non–US-approved ustekinumab achieved statistical significance (*P*<0.001).

CO-PRIMARY ENDPOINTS[1,2]

P<0.0001
NRI

PASI 90 at Week 16[1]

	ULTIMMA-1	ULTIMMA-2
SKYRIZI	75% (229/304)	75% (220/294)
PLACEBO	5% (5/102)	2% (2/98)

sPGA 0/1 at Week 16[1]

	ULTIMMA-1	ULTIMMA-2
SKYRIZI	88% (267/304)	84% (246/294)
PLACEBO	8% (8/102)	5% (5/98)

NRI=Non-Responder Imputation.

SAFETY CONSIDERATIONS[2]

- SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Avoid use of live vaccines in SKYRIZI patients.

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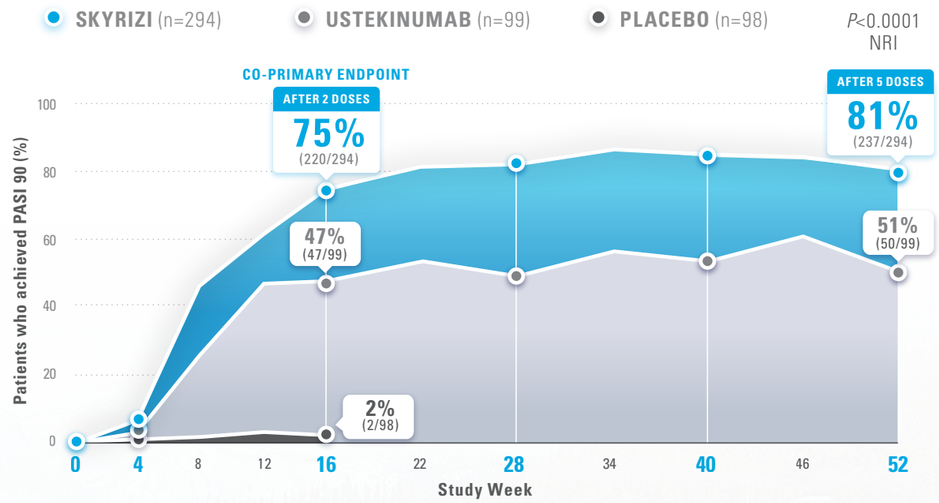
Please see full Prescribing Information.

EFFICACY IN ULTIMMA-1 & 2[1]

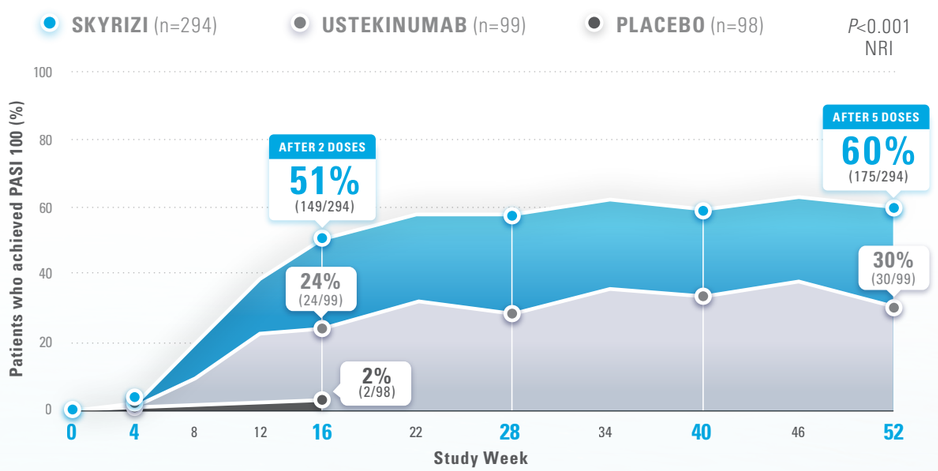
PASI 90 ACHIEVED BY 81% OF PATIENTS AT 1 YEAR IN ULTIMMA-2[1]



ULTIMMA-1 PASI 90 RESULTS[1]:

WEEK 16: SKYRIZI 75%, ustekinumab 42%, placebo 5% (*P*<0.0001); WEEK 52: SKYRIZI 82%, ustekinumab 44% (*P*<0.0001)

PASI 100 ACHIEVED BY 60% OF PATIENTS AT 1 YEAR IN ULTIMMA-2[1]



ULTIMMA-1 PASI 100 RESULTS[1]:

WEEK 16: SKYRIZI 36%, ustekinumab 12%, placebo 0% (*P*<0.001)
WEEK 52: SKYRIZI 56%, ustekinumab 21% (*P*<0.001)

NRI=Non-Responder Imputation.

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WELL-STUDIED SAFETY PROFILE

ADVERSE EVENTS AT WEEK 16[2-4]
(occurring at ≥1%)

	ANY SERIOUS ADVERSE EVENT	UPPER RESPIRATORY INFECTIONS[d]	HEADACHE[e]	FATIGUE[f]	INJECTION SITE REACTIONS[g]	TINEA INFECTIONS[h]
SKYRIZI (risankizumab)[a] (n=1306)	2.4%	13.0%	3.5%	2.5%	1.5%	1.1%
USTEKINUMAB[b] (n=239)	5.0%	11.7%	3.8%	2.9%	3.8%	0.4%
PLACEBO[c] (n=300)	4.0%	9.7%	2.0%	1.0%	1.0%	0.3%

SAFETY THROUGH 52 WEEKS:

Frequency of adverse reactions was similar to the safety profile observed during the first 16 weeks.[2]

[a]Includes data from ultIMMa-1, ultIMMa-2, IMMhance, and IMMvent studies; [b]Includes data from ultIMMa-1, ultIMMa-2, and one phase 2 study; [c]Includes data from ultIMMa-1, ultIMMa-2, and IMMhance studies; [d]Includes: respiratory tract infection (viral, bacterial or unspecified), sinusitis (including acute), rhinitis, nasopharyngitis, pharyngitis (including viral), tonsillitis; [e]Includes: headache, tension headache, sinus headache, cervicogenic headache; [f]Includes: fatigue, asthenia; [g]Includes: injection site bruising, erythema, extravasation, hematoma, hemorrhage, infection, inflammation, irritation, pain, pruritus, reaction, swelling, warmth; [h]Includes: tinea pedis, tinea cruris, body tinea, tinea versicolor, tinea manuum, tinea infection, onychomycosis.

Active Comparator: The ustekinumab used as a biologic active control in ultIMMa-1 and ultIMMa-2 was sourced from the European Union. Comparability between non–US-approved ustekinumab and US-approved ustekinumab has not been established.

IMPORTANT SAFETY INFORMATION AND INDICATION[2]

INDICATION

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

INFECTION

- SKYRIZI® (risankizumab-rzaa) may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.
- In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

PRE-TREATMENT EVALUATION FOR TUBERCULOSIS (TB)

- Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

IMMUNIZATIONS

- Prior to initiating SKYRIZI, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with SKYRIZI.

ADVERSE REACTIONS

- Most common (≥1%) adverse reactions associated with SKYRIZI include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

Please see full Prescribing Information.

References: 1. 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. **2.** SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc. **3.** Leonardi C, Bachelez H, Wu JJ, Sinvhal R, et al. Long-term safety of risankizumab in patients with moderate to severe psoriasis: analysis of pooled clinical trial data. Poster presented at: American Academy of Dermatology Annual Meeting; March 1-5, 2019; Washington, DC. **4.** Data on file, ABVRRTI68139.

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North Chicago, IL 60064 US-SKZD-200191 May 2020