

AN IL-23 INHIBITOR INDICATED FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS
IN ADULTS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY¹

HAVE YOU SEEN THE RESULTS?

SKYRIZI vs COSENTYX[®] (secukinumab)

IMMerge, AN OPEN-LABEL, ASSESSOR-BLINDED, 52-WEEK STUDY²

TAKE A LOOK INSIDE

INDICATION¹

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

SAFETY CONSIDERATIONS¹

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.


Skylar[®]
risankizumab-rzaa
75mg/0.83mL Injection

AN IL-23 INHIBITOR INDICATED FOR ADULTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS¹

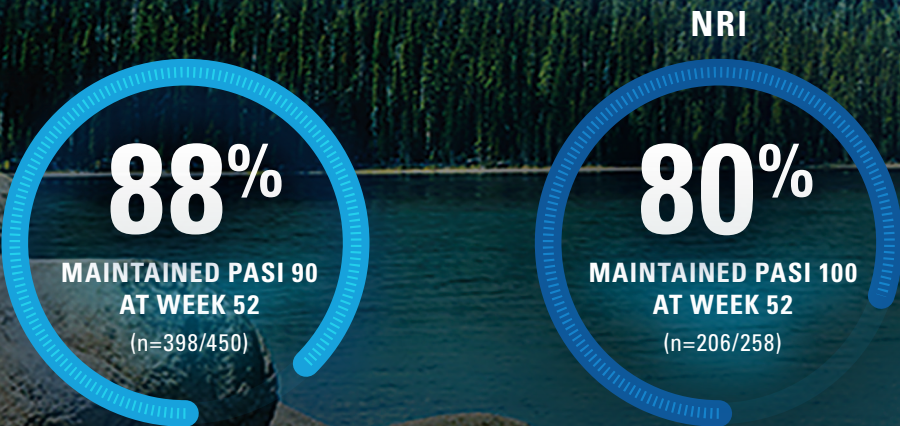
SKYRIZI EFFICACY AT WEEK 16 IN TWO PIVOTAL PHASE 3 STUDIES (NRI)³

CO-PRIMARY ENDPOINTS (P<0.0001)				SECONDARY ENDPOINT (P<0.001)			
PASI 90 at Week 16		sPGA 0/1 at Week 16		PASI 100 at Week 16			
ULTIMMA-1	ULTIMMA-2	ULTIMMA-1	ULTIMMA-2	ULTIMMA-1	ULTIMMA-2		
75% (229/304)	75% (220/294)	88% (267/304)	84% (246/294)	36% (109/304)	51% (149/294)		
5% (5/102)	2% (2/98)	8% (8/102)	5% (5/98)	0% (0/102)	2% (2/98)		

NRI=Non-Responder Imputation.

MAINTENANCE OF RESPONSE¹

In the randomized trials, among patients who achieved PASI 90 or PASI 100 at Week 16

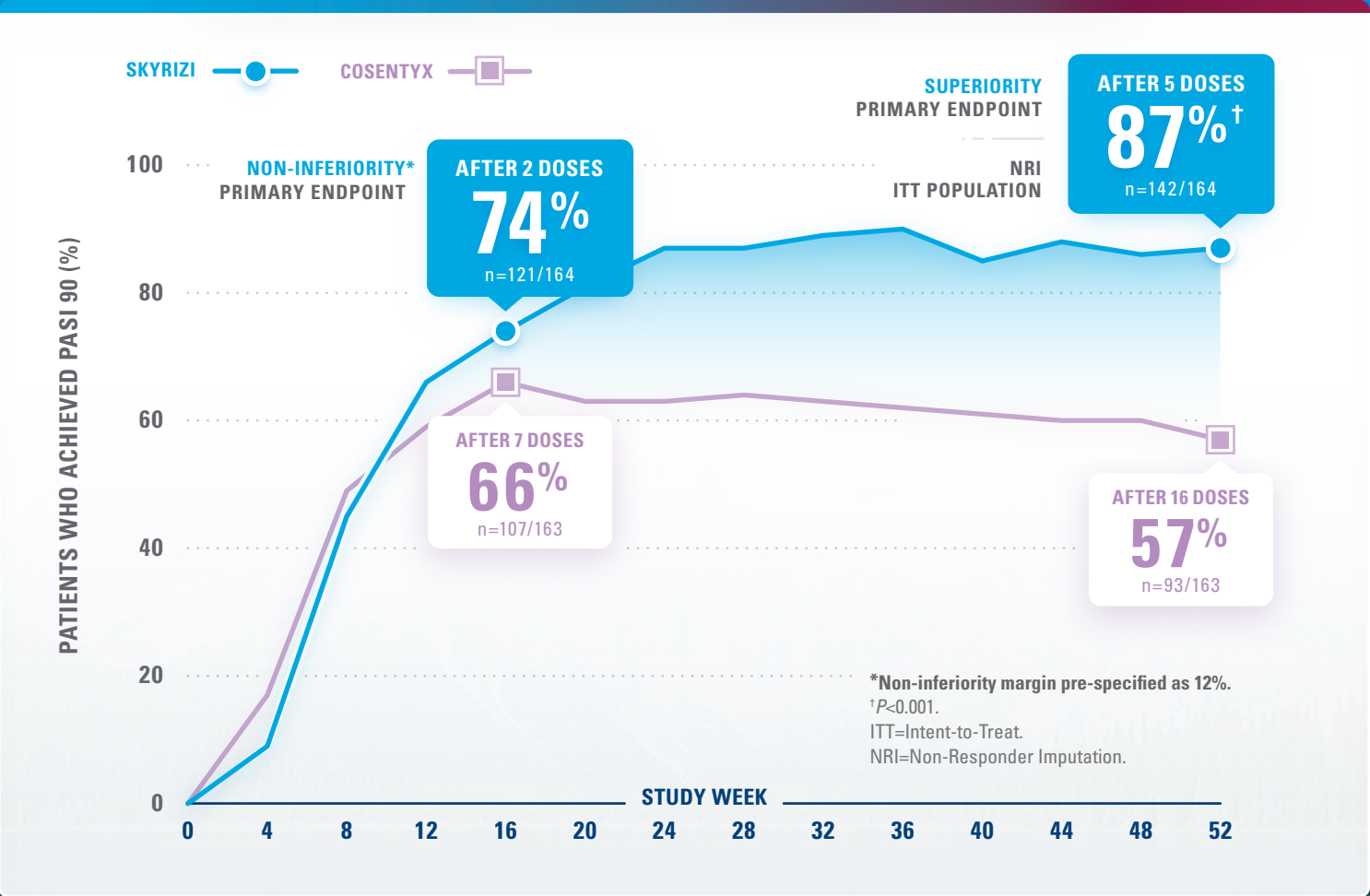


STUDY DESIGN

UltIMMa-1 (N=506) and ultIMMa-2 (N=491) were replicate phase 3, randomized, double-blind, placebo- and active-controlled studies to evaluate the efficacy and safety of SKYRIZI (150 mg) vs placebo over 16 weeks and biologic active control over 52 weeks in adult patients with moderate to severe plaque psoriasis. SKYRIZI (150 mg) was given as 2 subcutaneous injections at Weeks 0, 4, and 16, and every 12 weeks thereafter. Co-primary endpoints were PASI 90 and sPGA 0/1 at Week 16 vs placebo in each study (assessed by non-responder imputation).³

IN IMMerge, AN OPEN-LABEL, ASSESSOR-BLINDED, HEAD-TO-HEAD STUDY^{2,4}

SKYRIZI DEMONSTRATED SUPERIOR RATES OF PASI 90 AT WEEK 52²
NON-INFERIORITY WAS ESTABLISHED AT WEEK 16



STUDY DESIGN²

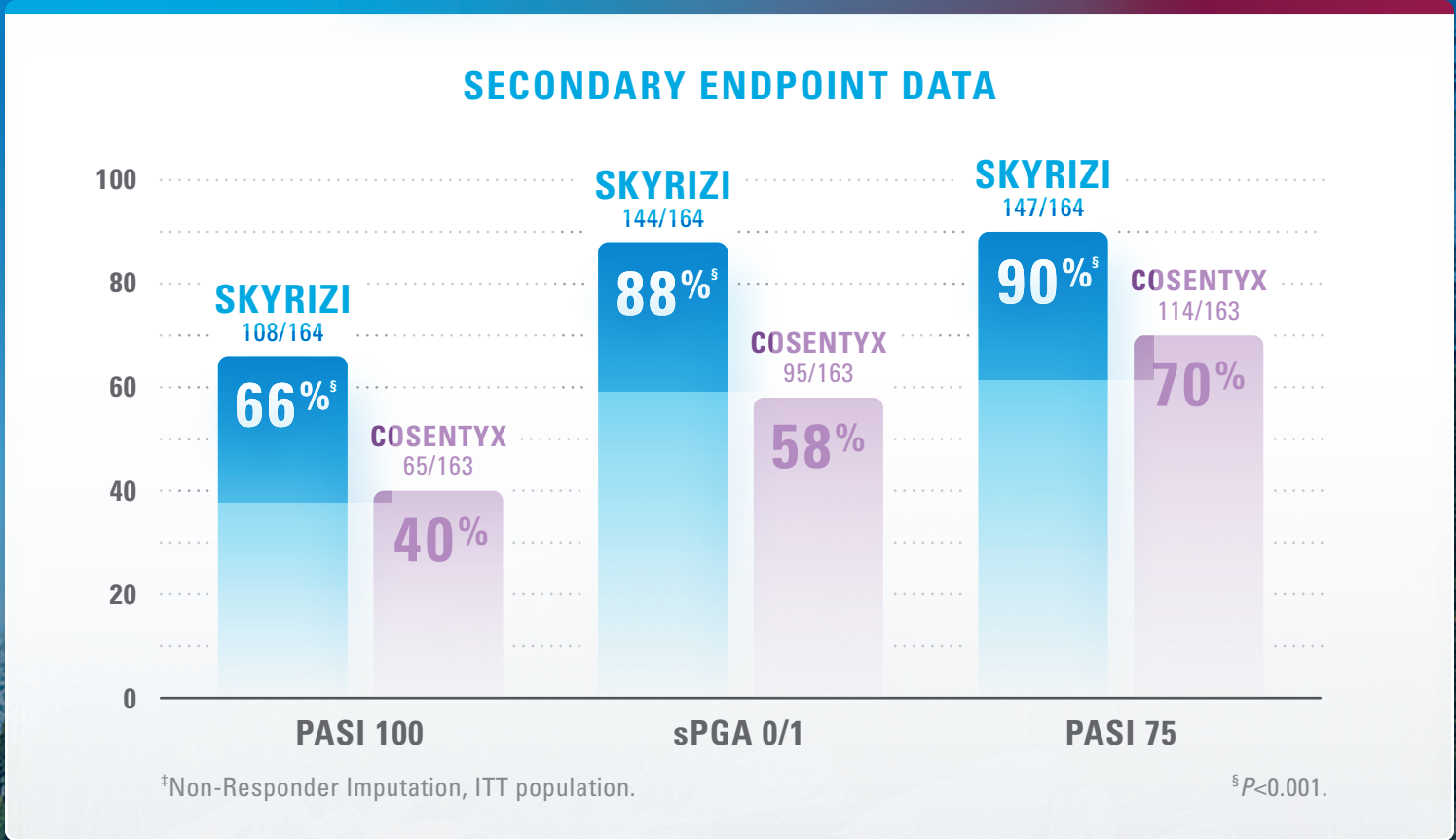
IMMerge was a phase 3, global, multicenter, randomized, open-label, efficacy assessor-blinded, active-comparator study designed to evaluate the safety and efficacy of SKYRIZI compared with Cosentyx in adult patients with moderate to severe plaque psoriasis. Patients were randomized 1:1 to receive:

SKYRIZI (150 mg) (n=164)		OR	COSENTYX® (secukinumab) (300 mg) (n=163)	
Two 75-mg subcutaneous injections	Given at Weeks 0 and 4 , and every 12 weeks until the last dose at Week 40		Two 150-mg subcutaneous injections	Given at Weeks 0, 1, 2, 3, and 4 , and every 4 weeks until the last dose at Week 48

Primary endpoints: PASI 90 (non-inferiority) at Week 16; PASI 90 (superiority) at Week 52
Ranked secondary endpoints: PASI 100, sPGA 0/1, and PASI 75 at Week 52

Cosentyx® is a registered trademark of Novartis AG. See US Prescribing Information for further information.

SKYRIZI DEMONSTRATED SUPERIOR RATES OF PASI 100,
SPGA 0/1, AND PASI 75 AT WEEK 52^{2,4,‡}



SOURCING

In this study, 46 patients outside of the US received non-US-licensed secukinumab. Data regarding comparability between US and non-US secukinumab are not publicly available.⁴

SAFETY CONSIDERATIONS¹

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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Skyrizi
risankizumab-rzaa
75mg/0.83mL Injection

Safety Data from IMMerge²

Adverse Events (AEs) of Interest (%)

	ANY TEAE*	SERIOUS AEs	SEVERE (GRADE ≥3) TEAE	TEAE POSSIBLY RELATED TO STUDY DRUG	SAE POSSIBLY RELATED TO STUDY DRUG	TEAEs LEADING TO DRUG DISCONTINUATION	DEATHS	ADJUDICATED MACE	SERIOUS INFECTION	TUBERCULOSIS	MALIGNANT TUMORS	MALIGNANT TUMORS (EXCLUDING NMSC)	SERIOUS HYPER-SENSITIVITY
SKYRIZI 150 mg (n=164)	71.3	5.5	6.7	29.9	0.6	1.2	0	1.2	1.8	0	0.6	0	0
COSENTYX 300 mg (n=163)	71.2	3.7	4.3	28.2	0.6	4.9	0	0	0	0	1.8	0	0.6

MACE=Major Adverse Cardiac Event; NMSC=Non-melanoma Skin Cancer; SAE=Serious Adverse Event; TEAE=Treatment-Emergent Adverse Event. *Defined as AEs occurring with an onset within 20 weeks after the last dose of study drug administration.

There were no deaths in either treatment arm.

Treatment-emergent AEs occurring in ≥5% in either treatment group (%)

	NASOPHARYNGITIS	UPPER RESPIRATORY TRACT INFECTION	HEADACHE	ARTHRALGIA	DIARRHEA	BRONCHITIS
SKYRIZI 150 mg (n=164)	21.3	12.8	5.5	5.5	5.5	1.8
COSENTYX (secukinumab) 300 mg (n=163)	16.6	8.6	9.2	6.1	5.5	6.7

Refer to full prescribing information for Cosentyx, which reflects differences in rates of adverse events from those observed in the IMMerge trial.

Indication¹

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

Important Safety Information¹

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.** SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc. **2.** Warren RB, Blauvelt A, Poulin Y, et al. Risankizumab vs secukinumab in patients with moderate-to-severe plaque psoriasis: a phase 3 trial. Presented at: 2020 Annual Meeting of the American Academy of Dermatology; June 12-14, 2020; virtual. **3.** 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. **4.** Data on file, ABVVRTI70649.

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