

When PsO patients have a treatment interruption

# Regain skin clearance with COSENTYX<sup>1,2\*</sup>

*"I'm confident clearer skin can  
come back if I ever have to take  
a break in my treatment."*

**LauraLee**

Actual COSENTYX patient since 2015



## The Complete Cosentyx Approach

Give your patients a chance to —————



**Look  
Better<sup>3†</sup>**



**Move  
Better<sup>3†</sup>**



**Feel  
Better<sup>3†</sup>**

**For adults with moderate to severe plaque psoriasis and active psoriatic arthritis**

\*In patients who relapsed after being randomized to placebo in the ERASURE and FIXTURE extension study (multiple imputation analysis) and were retreated with COSENTYX 300 mg. Relapse defined as loss of >50% of maximum PASI improvement compared to baseline of the core study.<sup>1,2</sup>

†In the ERASURE pivotal study at Week 12 in the COSENTYX 300-mg arm, 82% of patients (n=245) achieved a PASI 75 response and 65% of patients achieved IGA 0 or 1 vs 4% and 2% in the placebo group (n=248).<sup>3</sup> In the FIXTURE pivotal study at Week 12 in the COSENTYX 300-mg arm, 76% of patients (n=327) achieved a PASI 75 response and 62% of patients achieved IGA 0 or 1 vs 5% and 3% in the placebo group (n=326), respectively.<sup>3</sup> In the FUTURE 2 pivotal study, for patients with active psoriatic arthritis treated with COSENTYX 300 mg (n=100), 150 mg (n=100), or placebo (n=98), ACR20 response at Week 24 was 51%, 54%, and 15%, respectively.<sup>3</sup> In the ERASURE (N=738) and FIXTURE (N=1306) studies, among the subjects who chose to participate (39%) in assessments of patient-reported outcomes, improvements in signs and symptoms related to itching, pain, and scaling at Week 12 compared with placebo were observed using the Psoriasis Symptom Diary.<sup>3</sup>

**Please see ERASURE and FIXTURE extension, ERASURE, FIXTURE, and FUTURE 2 study designs.**

ACR=American College of Rheumatology; IGA=Investigator's Global Assessment modified 2011; PASI=Psoriasis Area and Severity Index; PsO=plaque psoriasis.

### INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis. COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS** COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

**Please see Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#). Please see [references](#).**

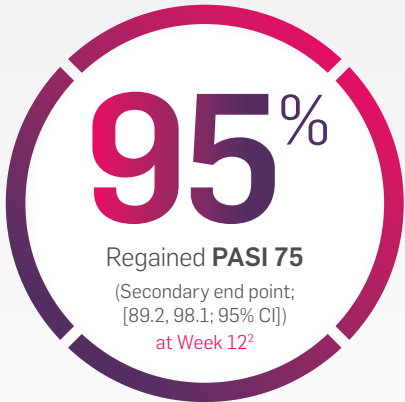


**Cosentyx<sup>®</sup>**  
(secukinumab)

# COSENTYX: Regain skin clearance after a pause in treatment<sup>1,2\*†‡</sup>

**Results from the ERASURE and FIXTURE pivotal studies<sup>3§</sup>:** In the 300-mg arm (n=245) of the ERASURE study at Week 12 in moderate to severe PsO patients: 82% of patients achieved PASI 75, and of those, 70% achieved PASI 90<sup>||</sup>; the majority of patients achieved clear or almost clear skin<sup>3§</sup>; over 80% of patients on COSENTYX 300 mg in the ERASURE and FIXTURE studies who achieved PASI 75 at Week 12 sustained their response at Week 52.<sup>3¶</sup>

**In the ERASURE and FIXTURE extension study, among PASI 75 responders** retreated with COSENTYX 300 mg after relapse on placebo (n=136)<sup>1,2</sup>:



Median time to relapse was 28 weeks for PASI 75 responders on placebo who relapsed and were retreated with COSENTYX 300 mg (exploratory analysis).<sup>2</sup>  
Primary end point in the ERASURE and FIXTURE extension study was loss of PASI 75 response from Week 52 to Week 68 in patients who were PASI 75 responders at Week 52 of the core study. At Week 68, the cumulative rate of loss of PASI 75 response was 25.4% on COSENTYX 300 mg vs 64.7% on placebo-300 mg; *P*<0.0001 (FAS).<sup>4</sup>

In post-hoc subgroup analyses of prior PASI 90 and PASI 100 responders retreated with COSENTYX 300 mg after relapse on placebo

- 79% of prior PASI 90 responders regained PASI 90 at Week 16 (n=117)<sup>1</sup>
- 67% of prior PASI 100 responders regained PASI 100 at Week 16 (n=67)<sup>1</sup>

**No new safety signals:** Adverse events were consistent with pivotal trials, with no unexpected safety findings<sup>1,2</sup>

\*In placebo patients who relapsed during the extension study and were retreated with COSENTYX 300 mg (multiple imputation analysis).<sup>2</sup> 181 patients were randomized to the placebo group at the start of the extension study to be retreated with COSENTYX 300 mg upon relapse; of those, 136 met relapse criterion. Relapse defined as loss of >50% of maximum PASI improvement compared to baseline of the core study. No retreatment was needed for the 16% of placebo patients who maintained their responses (n=29).<sup>1</sup>

†At Week 12, after relapse and retreatment, PASI 75 was achieved by 82% of patients in the COSENTYX 150-mg arm (n=123). Median time to relapse was 20 weeks for patients on placebo who were retreated with COSENTYX 150 mg (exploratory analysis).<sup>2</sup>

‡Patients who experienced relapse at any visit received secukinumab (300 mg or 150 mg) at Weeks 0 (week of relapse), 1, 2, 3, and 4, then every 4 weeks, thereby restarting secukinumab.<sup>1</sup>

§In ERASURE, % of patients achieving an end point on 150 mg (n=245) vs placebo (n=248) at Week 12: PASI 75 (71 vs 4), IGA 0 or 1 (51 vs 2), and PASI 90 (39 vs 1). In FIXTURE, results on 300 mg (n=327) vs placebo (n=326) at Week 12: PASI 75 (76 vs 5), IGA 0 or 1 (62 vs 3), and PASI 90 (54 vs 2). In FIXTURE, results on 150 mg (n=327) vs placebo at Week 12: PASI 75 (67 vs 5), IGA 0 or 1 (51 vs 3), and PASI 90 (42 vs 2). At Week 12 in ERASURE, 65% of patients on COSENTYX 300 mg achieved IGA mod 2011 0 or 1 vs 2% of patients on placebo. All comparisons, *P*<0.001.<sup>3</sup>

||In ERASURE, 59% of patients achieved PASI 90 on 300 mg vs 1% for placebo at Week 12.<sup>3</sup>

¶In the COSENTYX 300-mg treatment arm, 81% and 84% of patients in ERASURE and FIXTURE, respectively, who achieved PASI 75 at Week 12 sustained their response at Week 52. In the COSENTYX 150-mg treatment arm, 72% and 82% of patients in ERASURE and FIXTURE, respectively, who achieved PASI 75 at Week 12 sustained their response at Week 52.<sup>3</sup>

Please see ERASURE, FIXTURE, ERASURE and FIXTURE extension [study designs](#).

CI=confidence interval; FAS=full analysis set.

## IMPORTANT SAFETY INFORMATION (cont)

### WARNINGS AND PRECAUTIONS

**Infections** COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in subjects treated with COSENTYX compared to placebo-treated subjects. In placebo-controlled clinical trials in patients with moderate to severe plaque psoriasis, higher rates of common infections such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%), and mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo.

# Demonstrated PsO safety profile

## PsO safety profile at Week 12<sup>3</sup>

- Infections were reported in 28.7% of patients on COSENTYX (n=1382) vs 18.9% on placebo (n=694)<sup>#</sup>
- Serious infections occurred in 0.14% of patients treated with COSENTYX (n=1382) vs 0.3% of those receiving placebo (n=694)

## Adverse reactions reported by >1% of patients with plaque psoriasis through Week 12 in pivotal trials<sup>3</sup>

	COSENTYX 300 mg (n=691)	COSENTYX 150 mg (n=692)	Placebo (n=694)
Nasopharyngitis	11.4%	12.3%	8.6%
Diarrhea	4.1%	2.6%	1.4%
Upper respiratory tract infection	2.5%	3.2%	0.7%
Rhinitis	1.4%	1.4%	0.7%
Oral herpes	1.3%	0.1%	0.3%
Pharyngitis	1.2%	1.0%	0.0%
Urticaria	0.6%	1.2%	0.1%
Rhinorrhea	1.2%	0.3%	0.1%

## Inflammatory bowel disease in patients with PsO<sup>3</sup>

Inflammatory bowel disease reported in patients treated with COSENTYX	Plaque PsO up to 52 weeks (n=3430)
Crohn's disease exacerbation	3
Crohn's disease new onset	0
Ulcerative colitis exacerbation	2
Ulcerative colitis new onset	2

**No routine lab monitoring required:** Prior to initiating treatment with COSENTYX, evaluate for tuberculosis<sup>3</sup>

**Low immunogenicity:** Neutralizing antibodies developed in <0.5% of patients at Year 1 and were not associated with loss of efficacy<sup>3\*\*</sup>

#Phase III data showed an increasing trend for some types of infection with increasing serum concentration of COSENTYX, including *Candida* infections, herpes viral infections, staphylococcal skin infections, and infections requiring treatment.<sup>3</sup>

\*\*The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.<sup>3</sup>

## IMPORTANT SAFETY INFORMATION (cont)

**Infections (cont)** A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis and ankylosing spondylitis. The incidence of some types of infections appeared to be dose-dependent in clinical studies. Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

**Please see Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#).**



In the SCULPTURE Extension Study,

# 5 YEARS of experience: A consistent safety profile in PsO<sup>5,6\*</sup>

Treatment-emergent AEs <sup>a</sup> : 300 mg (FI) <sup>5,6</sup>	Up to Year 1 (300 mg extension subgroup only)	Year 1 to Year 5 (300 mg [FI] arm from extension only)			
	n=168	n=168	n=157	n=142	n=134
All AEs, n (IR)	131 (204.6)	126 (166.3)	109 (139.2)	91 (118.5)	77 (87.2)
Nonfatal SAEs, n (IR)	14 (8.8)	11 (6.9)	13 (9.1)	13 (10.1)	11 (8.0)
Death, n (IR)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7) <sup>b</sup>
Frequent AEs, n (IR)					
Nasopharyngitis	30 (20.1)	27 (18.1)	25 (18.8)	17 (13.5)	15 (11.1)
Hypertension	11 (6.8)	8 (5.1)	3 (2.0)	7 (5.3)	5 (3.6)
Back pain	7 (4.3)	9 (5.7)	9 (6.2)	3 (2.2)	3 (2.1)
URTI	12 (7.5)	11 (7.1)	5 (3.5)	5 (3.8)	5 (3.6)
Headache	10 (6.2)	7 (4.4)	4 (2.7)	3 (2.2)	1 (0.7)
AEs of special interest, n (IR)					
Opportunistic infections (other than TB and candidiasis)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tuberculosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida infections - Vulvovaginal candidiasis - Oral candidiasis	3 (1.8) 0 (0.0)	3 (1.9) 1 (0.6)	1 (0.7) 0 (0.0)	0 (0.0) 1 (0.7)	0 (0.0) 0 (0.0)
Neutropenia <sup>a†</sup>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MACE	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.7) <sup>b</sup>
Crohn's disease	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ulcerative colitis	0 (0.0)	2 (1.2) <sup>c</sup>	1 (0.7)	0 (0.0)	0 (0.0)
Malignant or unspecified tumors (excl. NMSC)	0 (0.0)	2 (1.2) <sup>d</sup>	0 (0.0)	0 (0.0)	1 (0.7) <sup>e</sup>

<sup>a</sup>Patient exposure is calculated as a sum of individual subject durations in days divided by 365 for each interval<sup>5</sup>; <sup>b</sup>Death was due to MACE, which was not considered by the investigators to be related to study drug; patient had ≥2 preexisting MACE risk factors<sup>5</sup>; <sup>c</sup>Of the 2 cases of ulcerative colitis in year 2, 1 case was an exacerbation of previously existing ulcerative colitis; <sup>d</sup>1 case of cholangiocarcinoma, 1 case of invasive ductal breast carcinoma; <sup>e</sup>1 case of breast cancer.<sup>5</sup>  
A subject with multiple occurrences of the same AE in a one-year interval was counted only once, while a subject with multiple occurrences of the same AE in different year intervals was counted for each year.<sup>5</sup>  
AE=adverse event; FI=fixed interval; IR=incidence rate per 100 subject-years; MACE=major adverse cardiac event; NMSC=nonmelanoma skin cancer; SAE=serious adverse event; TB=tuberculosis; URTI=upper respiratory tract infection.

## Consistent, long-term safety in PsO and PsA<sup>6-8</sup>

- In PsO at **Week 12** and at **Year 5**<sup>3,6</sup>
- In PsA at **Week 16** and at **Year 5**<sup>3,8</sup>

The safety profile observed in patients with PsA treated with COSENTYX is consistent with the safety profile observed in PsO<sup>3</sup>

<sup>\*</sup>Safety data up to year 1 based on a post-hoc analysis of the SCULPTURE Core study in only those patients treated with 300 mg who achieved PASI 75 at week 12, rerandomized to 300-mg FI arm, and reconsented at week 52 to enter the Extension study. Year-1 to year-5 safety data are presented in this same patient subpopulation, thus not all patients who started with 300 mg in the Core study are included.  
<sup>†</sup>Includes neutropenia adverse events reported by investigators in the SCULPTURE study; does not include lab reports of neutropenia.  
PsA=psoriatic arthritis.

# COSENTYX: Experience that matters for you and your patients

- **#1 prescribed biologic therapy** in rheumatology in the US for patients with PsA starting or switching biologic agents<sup>9†</sup>
- **5 years** of consistent safety data in PsO and PsA<sup>6-8</sup>
- **12+ years** of clinical evidence<sup>10§</sup>
- **16+ trials** in dermatology and rheumatology<sup>11</sup>
- **>140,000 patients** prescribed in the US<sup>12||</sup>
- **>1,000,000 prescriptions** written in the US by >18,000 unique prescribers<sup>13,14||</sup>

<sup>†</sup>NBRx share as prescribed by rheumatologists, allocated using Symphony Health patient longitudinal data to limit product use to ICD10 codes for PsA and/or PsO. NBRx is the IQVIA NPA™ New to Brand measure showing the volume of prescriptions associated with first-time patient use of a product.<sup>9</sup>  
<sup>§</sup>Studied in patients since 2007. FDA approved for moderate to severe PsO in 2015 and for active PsA and AS in 2016.  
<sup>||</sup>Across PsO, PsA, and AS indications.

AS=ankylosing spondylitis.

## IMPORTANT SAFETY INFORMATION (cont)

**Pre-treatment Evaluation for Tuberculosis** Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

**Inflammatory Bowel Disease** Caution should be used when prescribing COSENTYX to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in patients treated with COSENTYX during clinical trials in plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

**Hypersensitivity Reactions** Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated. The removable cap of the COSENTYX Sensoready® pen and the COSENTYX prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

**Vaccinations** Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines. Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

**MOST COMMON ADVERSE REACTIONS** Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

**Please see Important Safety Information throughout and full Prescribing Information, including Medication Guide.**



For adults with moderate to severe plaque psoriasis and active psoriatic arthritis

# COSENTYX: Regain skin clearance and discover experience that matters

- **95% of PASI 75 responders** regained PASI 75 at Week 12 after retreatment with COSENTYX 300 mg<sup>2</sup>
- **Experience that matters:** #1 prescribed biologic therapy in rheumatology in the US for PsA patients starting or switching biologic agents; >1,000,000 prescriptions written in the US<sup>9,13</sup>

## The Complete Cosentyx Approach

Give your patients a chance to —————



Look  
Better<sup>3</sup>



Move  
Better<sup>3</sup>



Feel  
Better<sup>3</sup>

**PRESCRIBE**



**Cosentyx<sup>®</sup>**  
(secukinumab)

### INDICATIONS

COSENTYX<sup>®</sup> (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis. COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS** COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

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Please see [references](#).

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COS-1388486





## Study designs

**The ERASURE study**<sup>1,2</sup> was a multicenter, randomized, double-blind, placebo-controlled trial of 738 patients.<sup>2</sup> Patients were randomized to one of 3 arms: COSENTYX 300 mg\* (n=245), COSENTYX 150 mg\* (n=245), or placebo† (n=248).<sup>1,2</sup> All patients were adults with moderate to severe PsO who had a BSA  $\geq 10\%$ , PASI score  $\geq 12$ , and IGA mod 2011 score  $\geq 3$  and were candidates for systemic therapy or phototherapy.<sup>2</sup> Patients were followed for up to 52 weeks.<sup>1</sup> Co-primary end points were the proportion of subjects who achieved a reduction in PASI score of  $\geq 75\%$  (PASI 75) from baseline to Week 12 and the proportion of patients who achieved a score of 0 or 1 (clear or almost clear) on the IGA mod 2011 at Week 12.<sup>2</sup> Other evaluated outcomes included the proportion of subjects who achieved a reduction in PASI score of  $\geq 90\%$  (PASI 90) from baseline at Week 12, maintenance of efficacy (PASI 75 and IGA mod 2011 clear or almost clear) to Week 52 in patients who were responders at Week 12, and improvements in itching, pain, and scaling at Week 12 based on the Psoriasis Symptom Diary®.<sup>2</sup>

\*Initial dosing for COSENTYX: once weekly for 5 weeks, Weeks 0, 1, 2, 3, and 4; maintenance: once every 4 weeks, Weeks 8 through 48.<sup>2</sup>

†Placebo nonresponders (who did not achieve PASI 75 at Week 12) were rerandomized 1:1 to COSENTYX 150 mg or COSENTYX 300 mg at Weeks 12, 13, 14, 15, and 16, followed by the same dose every 4 weeks.<sup>1,2</sup>

**The FIXTURE study**<sup>1,3</sup> was a multicenter, randomized, double-blind, placebo-controlled trial of 1306 patients.<sup>3</sup> Patients were randomized to one of 4 arms: COSENTYX 300 mg\* (n=327), COSENTYX 150 mg\* (n=327), placebo† (n=326), or a biologic active control: etanercept‡ (n=326).<sup>1,38</sup> All patients were adults with moderate to severe plaque psoriasis who had a BSA  $\geq 10\%$ , PASI score  $\geq 12$ , an IGA mod 2011 score  $\geq 3$ , and were candidates for systemic therapy or phototherapy.<sup>3</sup> Patients were followed for up to 52 weeks.<sup>1</sup> Co-primary end points were the proportion of subjects who achieved a reduction in PASI score of  $\geq 75\%$  (PASI 75) from baseline to Week 12 and clear or almost clear on the IGA mod 2011 at Week 12, evaluated using NRI analysis.<sup>3</sup> Other evaluated outcomes included the proportion of subjects who achieved a reduction in PASI score of  $\geq 90\%$  (PASI 90) from baseline at Week 12, maintenance of efficacy (PASI 75 and IGA mod 2011 clear or almost clear) to Week 52 in patients who were responders at Week 12, and improvements in itching, pain, and scaling at Week 12 based on the Psoriasis Symptom Diary®.<sup>3</sup>

\*Initial dosing: once weekly for 5 weeks, Weeks 0, 1, 2, 3, and 4; maintenance: once every 4 weeks, Weeks 8 through 48.<sup>3</sup>

†Placebo nonresponders (who did not achieve PASI 75 at Week 12) were rerandomized 1:1 to COSENTYX 150 mg or COSENTYX 300 mg at Weeks 12, 13, 14, 15, and 16, followed by the same dose every 4 weeks.<sup>1,3</sup>

‡Etanercept 50 mg was administered SC twice per week from randomization until Week 12, followed by 50 mg every week from Week 12 through Week 51. To maintain blinding, patients also received 2 placebo COSENTYX injections at the COSENTYX regimen. COSENTYX patients also received etanercept placebo twice per week from randomization through Week 12, and then once per week until Week 51.<sup>3</sup>

§In this study, n=326 for etanercept represents a randomized set and n=323 was used in the analysis of efficacy end points (PASI 75 and IGA mod 2011 0/1) presented.

BSA=body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; SC=subcutaneously.

**The ERASURE and FIXTURE extension study**<sup>4</sup> was a multicenter, double-blind, randomized, withdrawal trial of COSENTYX in patients completing 52 weeks in either the ERASURE or FIXTURE core studies.<sup>4</sup>

Patients who were treated with COSENTYX 300 mg or 150 mg during the maintenance period in either the ERASURE or FIXTURE core studies and who exhibited PASI 75 at Week 52 were eligible to be rerandomized 2:1 to continue the same COSENTYX dose or receive placebo (withdrawal from active treatment).<sup>4</sup> Placebo patients who experienced relapse (defined as loss of  $>50\%$  of maximum PASI improvement compared with baseline of the core study) at any visit were retreated with 5 weekly doses of COSENTYX 300 mg or 150 mg, followed by 1 dose every 4 weeks.<sup>4</sup>

Retreatment results are for patients retreated with COSENTYX after relapsing on placebo in the ERASURE and FIXTURE extension study.<sup>4</sup>

Primary end point was loss of PASI 75 response from baseline (Week 52) up to Week 68. Other end points included PASI 50/75/90 and IGA mod 2011 0/1 response rates over time in patients who were PASI 75 responders at Week 52, and PASI 50/75/90 response rates over time in patients who were PASI 75 responders at Week 52 and retreated with COSENTYX 300 mg or 150 mg after relapse on placebo.<sup>4</sup>

**The FUTURE 2 study**<sup>1,5-8</sup> was a Phase III, multicenter, randomized, double-blind, placebo-controlled trial that evaluated 397 adult patients with active PsA ( $\geq 3$  swollen and  $\geq 3$  tender joints) despite use of NSAIDs, corticosteroids, or DMARDs. Patients had a diagnosis for  $\geq 5$  years and were randomized in a 1:1:1 ratio to receive COSENTYX 150 mg (n=100), 300 mg (n=100), or placebo (n=98) subcutaneously at Weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks. Patients who received placebo were rerandomized (1:1) to COSENTYX 150 mg or 300 mg every 4 weeks, at Week 16 or Week 24, based on responder status. The primary end point was the percentage of patients with ACR20 response at Week 24.<sup>5</sup>

After Week 24, patients knew they were taking the active treatment but remained blind to the dose until after 1 year. After 1 year, patients were unblinded and continued to receive the same active dose as open-label treatment and were assessed every 8 weeks through 2 years and every 12 weeks from 2 years to 4 years.<sup>5</sup> Starting at Week 128, patients whose signs and symptoms were not fully controlled and might improve further with an increase in dose as judged by the investigator, were up dosed from 150-mg dose to 300-mg dose. At Week 208, 45 patients from the 150-mg dose arm had been up dosed to 300 mg.<sup>6,7</sup> A 75-mg arm was included in this study, but not shown and is not an approved dose.<sup>1</sup> Study population was mixed: two-thirds of patients were anti-TNF $\alpha$ -naïve and one-third were anti-TNF $\alpha$ -experienced (patients could have been exposed to up to 3 different TNF $\alpha$  inhibitors).<sup>5</sup> At baseline, 44% of patients treated with COSENTYX were treated with concomitant MTX.<sup>5</sup>

ACR=American College of Rheumatology; BMI=body mass index; DMARD=disease-modifying antirheumatic drug; MTX=methotrexate; NSAID=nonsteroidal anti-inflammatory drug; PsA=psoriatic arthritis; TNF=tumor necrosis factor.

**References:** **1.** COSENTYX [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; January 2020. **2.** Data on file. AIN457A2302 Clinical Study Report. Novartis Pharmaceuticals Corp; September 2013. **3.** Data on file. AIN457A2303 Clinical Study Report. Novartis Pharmaceuticals Corp; September 2013. **4.** Data on file. CAIN457A2302E1 Clinical Study Report. Novartis Pharmaceuticals Corp; May 2018. **5.** Data on file. CAIN457F2312 Clinical Study Report. Novartis Pharmaceuticals Corp; October 2014. **6.** Data on file. CAIN457F2312 (FUTURE 2): 3-Year Interim Report. Novartis Pharmaceuticals Corp; September 2017. **7.** Data on file. CAIN457F2312 (FUTURE 2): 4-Year Interim Report. Novartis Pharmaceuticals Corp; 2018. **8.** McInnes IB, Mease PJ, Kirkham B, et al; for the FUTURE 2 Study Group. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo controlled, phase 3 trial. *Lancet*. 2015;386(9999):1137-1146.

Please see Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#).

## References for:

# When PsO patients have a treatment interruption, regain skin clearance with COSENTYX

**References:** **1.** Blauvelt A, Reich K, Warren RB, et al. Secukinumab re-initiation achieves regain of high response levels in patients who interrupt treatment for moderate to severe plaque psoriasis. *Br J Dermatol.* 2017;177(3):879-881. doi: 10.1111/bjd.15656. **2.** Data on file. Data Analysis Report Study CAIN457A2302E1. Novartis Pharmaceuticals Corp; December 2, 2015. **3.** COSENTYX [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; January 2020. **4.** Data on file. CAIN457A2302E1 Clinical Study Report. Novartis Pharmaceuticals Corp; May 2014. **5.** Data on file. CAIN457A2304E1 Clinical Study Report. Novartis Pharmaceuticals Corp; February 2018. **6.** Bissonnette R, Luger T, Thaçi D, et al. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to-severe psoriasis through 5 years of treatment (SCULPTURE Extension Study). *J Eur Acad Dermatol Venereol.* 2018;32(9):1507-1514. **7.** Data on file. Study CAIN457A2304E1. Clinical Study Report. Novartis Pharmaceuticals Corp; March 2018. **8.** Data on file. CAIN457F2312 (FUTURE 2): 5-Year Report. Novartis Pharmaceuticals Corp; May 2019. **9.** IQVIA NPA Weekly Tracker as of December 2019. Data on File for step-by-step PsA share calculation by Novartis Pharmaceuticals Corp. **10.** Data on file. AIN457A2102 Clinical Study Report. Novartis Pharmaceuticals Corp; March 2009. **11.** ClinicalTrials.gov. Clinical trials of secukinumab in psoriasis and psoriatic arthritis. <https://clinicaltrials.gov/ct2/results?cond=psoriasis+psoriatic+arthritis&term=secukinumab+Novartis+Investigative+Site+&cnty=&state=&city=&dist=&Search=Search>. Accessed March 31, 2020. **12.** Data on file. New to Brand Monthly Audit from June 2015 to May 2019. Novartis Pharmaceuticals Corp; June 2019. **13.** Data on file. IQVIA NPA Data April 2019. Novartis Pharmaceuticals Corp; April 2019. **14.** Data on file. Symphony Health. Novartis Pharmaceuticals Corp; April 2019.

PsO=plaque psoriasis.

## INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis. COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS** COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

**Please see Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#).**



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