

## Cosentyx<sup>®</sup> clinical trial program in psoriasis<sup>1-9</sup>

- There are four pivotal trials for Cosentyx<sup>®</sup> (secukinumab) in psoriasis
- Four extension studies are exploring the long-term sustainability of Cosentyx
- Two head-to-head trials demonstrate the superiority of Cosentyx over Enbrel<sup>®\*</sup> and Stelara<sup>®\*\*</sup>
- Three trials demonstrate the efficacy of Cosentyx in difficult-to-treat scalp psoriasis, nail psoriasis, and palmoplantar psoriasis (of the hands and feet)
- More than 10,000 patients have been treated with Cosentyx across multiple indications in the clinical trial program

### Pivotal trials in psoriasis

The Cosentyx clinical trial program in psoriasis was made up of 10 Phase II and Phase III studies.

#### Pivotal studies: strength, speed and sustainability

The approval of Cosentyx in psoriasis is based on four pivotal Phase III trials: ERASURE<sup>2</sup>, FIXTURE<sup>2</sup>, FEATURE<sup>3</sup> and JUNCTURE<sup>4</sup>, which involved 2,403 patients with moderate-to-severe plaque psoriasis<sup>1</sup>. Across all trials, the co-primary endpoints were the proportion of patients who achieved a reduction in Psoriasis Area Severity Index (PASI) score of at least 75% (PASI 75 response) from baseline to Week 12 and treatment success (clear or almost clear skin) on the Investigator's Global Assessment modified 2011 (IGA 0/1)<sup>1</sup>.

**ERASURE:** A randomized, double-blind, placebo-controlled study, in 738 patients with moderate-to-severe chronic plaque-type psoriasis, to assess safety and efficacy at 12 weeks of either Cosentyx 300 mg or 150 mg with long-term follow up to 52 weeks<sup>1,2</sup>.

**FIXTURE:** A randomized, double-blind, double-dummy study, in 1,306 patients with moderate-to-severe chronic plaque type psoriasis, to assess the safety and efficacy at 12 weeks of either Cosentyx 300 mg or 150 mg, Enbrel (etanercept) 50 mg, or placebo with long-term follow up to 52 weeks<sup>1,2</sup>.

**FEATURE:** A randomized, double-blind, placebo-controlled study, in 117 patients, to assess the safety, tolerability and usability of a self-administered pre-filled syringe of Cosentyx 300 mg or 150 mg or placebo over 12 weeks<sup>1,3</sup>.

**JUNCTURE:** A randomized, double-blind, placebo-controlled study, in 182 patients, to assess the safety, tolerability and usability of the SensoReady pen in patients who self-administered of either Cosentyx 300 mg or 150 mg or placebo over 12 weeks<sup>1,4</sup>.

### Results

- All primary endpoints were achieved with Cosentyx 300 mg and 150 mg

\*Enbrel is a registered trademark of Amgen Inc. \*\*Stelara is a registered trademark of Janssen Biotech Inc.

## PASI 75 response achieved at Week 12<sup>1</sup>

	150 mg	300 mg	Placebo
ERASURE	72%	82%	5%
FIXTURE	67%	77%	5%
FEATURE	70%	76%	0%
JUNCTURE	72%	87%	3%

## IGA mod 2011 0/1 scores (clear or almost clear skin)<sup>1</sup>

	150 mg	300 mg	Placebo
ERASURE	51%	55%	2%
FIXTURE	51%	62%	3%
FEATURE	53%	69%	0%
JUNCTURE	53%	73%	0%

- In the ERASURE study, Cosentyx was associated with a fast onset of efficacy with a 50% reduction in mean PASI response by Week Three for the 300 mg dose<sup>1,2</sup>

## Extension studies

### Extension studies exploring sustainability

Researchers are following patients in the ERASURE, FIXTURE, SCULPTURE and STATURE trials which have all been extended to capture long-term safety and efficacy data for Cosentyx over five years<sup>1,2,5</sup>.

## Results from the SCULPTURE study:

- Over the extended treatment period from Year 1 (Week 52) to the end of Year 5 (Week 260), PASI 75/90/100 response rates remained consistent<sup>5</sup>
- PASI 75 and PASI 90 response rates were achieved by 89% and 69% of psoriasis patients, respectively, at Year 1 ('as observed' analysis) and this high rate was maintained to Year 5 (89% and 66%, respectively)<sup>5</sup>
- In addition, 44% of psoriasis patients achieved completely clear skin (PASI 100) at Year 1 and this rate was maintained to Year 5 (41%)<sup>5</sup>
- Cosentyx continued to have a favorable and consistent safety profile, and low immunogenicity<sup>5</sup>

## Head-to-head trials

### CLEAR study: Cosentyx shows superiority to Stelara

A 52-week, randomized, double-blind, head-to-head study, in 669 patients with moderate-to-severe plaque psoriasis, comparing the efficacy, long-term safety and tolerability of Cosentyx 300 mg versus Stelara (ustekinumab, dosing per label)<sup>6,7</sup>.

## Results so far:

- Cosentyx was superior to Stelara in achieving and sustaining PASI 90 response (79% versus 58%) at Week 16<sup>6,7</sup>

- Cosentyx remained consistently superior to Stelara in achieving and sustaining a PASI 90 response (76% versus 61%) and significantly better in achieving PASI 100 (clear skin) response (46% versus 36%) at Week 52<sup>†6,7</sup>
- Response rates with Cosentyx were maintained to Week 104, with a 75% PASI 90 response (compared to 78% at Week 52), and a 47% PASI 100 response (compared to 48% at Week 52)<sup>11</sup>. Cosentyx showed significantly greater and sustained DLQI 0/1 responses versus Stelara (72% versus 59%) at Week 52<sup>†</sup>
- This remained high over two years, with 66% achieving DLQI 0/1 responses at Week 104 compared to 72% at Week 52<sup>11</sup>
- Patients in the Stelara arm of the study discontinued after the Week 52 database lock

<sup>†</sup>Exploratory endpoints

## Difficult-to-treat psoriasis

### SCALP

A 24-week, randomized, double-blind, placebo-controlled study in 102 patients with moderate-to-severe scalp psoriasis to assess the safety and efficacy of Cosentyx 300 mg or 150 mg or placebo<sup>8</sup>.

### TRANSFIGURE

A 128-week, randomized, double-blind, placebo-controlled study in 198 patients with moderate-to-severe psoriasis and significant nail involvement to assess the safety and efficacy of Cosentyx 300 mg or 150 mg or placebo<sup>12</sup>.

### GESTURE

A 132-week, randomized, double-blind, placebo-controlled study in 201 patients with moderate-to-severe palmoplantar psoriasis to assess the safety and efficacy of Cosentyx 300 mg or 150 mg or placebo<sup>9</sup>.

### Results so far:

- In the SCALP study, PSSI 90 responses were achieved by a significantly greater percentage of patients receiving Cosentyx 300 mg (52.9%) than placebo (2.0%) at Week 12 ( $P < 0.001$ )<sup>8</sup>
- In the TRANSFIGURE study, a mean -38% NAPSI improvement from baseline (Nail Psoriasis Severity Index) was observed with Cosentyx 300 mg and -14% with Cosentyx 150 mg<sup>12</sup>. At Week 32, PASI 90 responses were achieved in 72% of patients receiving Cosentyx 300 mg and 61% receiving Cosentyx 150 mg. PASI 100 responses were achieved in 37% of patients receiving Cosentyx 300 mg and 28% receiving Cosentyx 150 mg<sup>12</sup>
- In the GESTURE study, approximately 60% of patients receiving Cosentyx 300 mg achieved clear or almost clear palms and soles with Cosentyx, as measured by ppIGA response (palmoplantar Investigator's Global Assessment) at 1.5 years<sup>13</sup>

## Safety and tolerability


### Safety

- Cosentyx has been shown to have a favorable safety profile and low immunogenicity in clinical trials across multiple indications in which more than 10,000 patients have been treated with Cosentyx. A further 100,000 patients have been treated with Cosentyx in the post-marketing setting<sup>14</sup>
- The risk-benefit assessment for Cosentyx has not changed in the post-market setting
- The most common side effects in psoriasis studies were nasopharyngitis, headache and upper respiratory tract infection<sup>1,2</sup>

The Cosentyx clinical trial program includes long-term extension studies that will continue to collect safety information and data over an extended period of time. In addition, an eight-year psoriasis registry study consisting of more than 3,000 patients exposed to Cosentyx will also provide long-term safety data<sup>13</sup>.

### References

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