SECUKINUMAB PHASE III CLINICAL TRIAL PROGRAM IN **PSORIATIC ARTHRITIS (PSA)**

PsA is a painful, debilitating, long-lasting inflammatory disease causing inflammation of joints and skin.

SECUKINUMAB IN PSA

The first multi-center, randomized, placebo-controlled Phase III studies to evaluate the efficacy of secukinumab in IL-17A inhibition in PsA

The studies enrolled 1,003 patients with active PsA[1-4]

	Duration	Dosage
FUTURE 1	**FUTURE 1** is a 2-year study, although patients who complete the study may be eligible to enter a planned extension trial	Patients received an intravenous loading dose every two weeks for the first four weeks of treatment followed by monthly subcutaneous doses of 75mg or 150 mg compared to placebo
FUTURE 2	**FUTURE 2** is a 5-year study	Study compared subcutaneous weekly loading dose and dose range secukinumab 75 mg, 150 mg and 300 mg to placebo Patients dosed every 4 weeks up to Week 256

RESULTS OVERVIEW

In FUTURE 1 more than 80% of secukinumab-treated patients experienced no progression of joint structural damage, which affects two-thirds of PsA patients[1,2,6,7]

Between 50% to 54% of secukinumab patients achieved at least ACR 20 in both FUTURE 1 (150 mg; p<0.0001) and FUTURE 2 (150 and 300 mg; p<0.0001) at Week 24.[1-4]** This is in comparison to **17.3%** and **15.3%** of placebo patients who achieved ACR 20 in FUTURE 1 and FUTURE 2, respectively[1-4]

Secukinumab demonstrated rapid, significant and sustained improvements in skin psoriasis consistent with Phase III psoriasis study results in both studies[1-5]

Secukinumab patients experienced rapid onset of effect - Week 1 in FUTURE 1 (p<0.0001) and Week 3 in FUTURE 2 (150 mg p<0.0001 and 300 mg p<0.001) which was sustained through 52 weeks of treatment[1-4]

Clinical benefits with secukinumab were observed in patients who had not been previously treated with the current standard of care, anti-tumor-necrosis-factor (anti-TNF) medicine; and also in patients who had an inadequate or no response to anti-TNFs[1,2,8,9]

Secukinumab was well tolerated in all Phase III studies, with a safety profile that was consistent with that observed in the large psoriasis clinical trial program involving nearly 4,000 patients[1-4,10]

**The American College of Rheumatology response criteria (ACR 20) at Week 24 is a standard tool used to assess improvement (at least 20% improvement) in PsA signs and symptoms

Date of preparation: May 2015

NOVARTIS PHARMACEUTICALS

REFERENCES

1. Mease PJ, McInnes IB, Kirkham B, et al. Secukinumab, a human anti–interleukin-17A monoclonal antibody, improves active psoriatic arthritis and inhibits radiographic progression: efficacy and safety data from a phase 3 randomized, multicenter, double-blind, placebo-controlled study. Oral presentation at: ACR/ARHP Annual Meeting, Boston, MA, USA, 2014. Presentation number 948.

2. Novartis data on file. 2014. FUTURE1 clinical study report.

3. McInnes IB. Secukinumab, a Human Anti-Interleukin-17A Monoclonal Antibody, Improves Active Psoriatic Arthritis: 24-Week Efficacy and Safety Data from a Phase 3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study Using Subcutaneous Dosing. Oral presentation at: ACR/ARHP Annual Meeting, Boston, MA, USA, 2014. Presentation number 948.

4. Novartis data on file. 2014. FUTURE 2 clinical study report.

5. Langley RG, Elewski BE, Lebwohl M, et al. Secukinumab in Plaque Psoriasis - Results of Two Phase Three Trials. N Engl J Med. 2014; 371(4):326-338

6. van der Heijde D, Landewé R, Mease P, et al. Secukinumab, A Monoclonal Antibody to Interleukin-17A, Provides Significant and Sustained Inhibition of Joint Structural Damage in Active Psoriatic Arthritis Regardless of Prior TNF Inhibitors or Concomitant Methotrexate: a Phase 3 Randomized, Double-Blind, Placebo-Controlled Study. Oral presentation at: ACR/ARHP Annual Meeting, Boston, MA, USA, 2014. Presentation number 954.

7. Coates LC, Navarro-Coy N, Brown SR, et al. The TICOPA protocol (TIght COntrol of Psoriatic Arthritis): a randomised controlled trial to compare intensive management versus standard care in early psoriatic arthritis. BMC Musculoskelet Disord. 2013;21;14:101.

8. Gossec L, Smolen JS, Gaujoux-Viala C, et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. Ann Rheum Dis. 2012;71:4-12.

9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011; 65:137-74.

10. Novartis data on file. 2013: Clinical study reports for CAIN457A2302 [ERASURE] ; CAIN457A2303 [FIXTURE] ; CAIN457A2304 [SCULPTURE] ; CAIN457A2307 [JUNCTURE] ; CAIN457A2308 [FEATURE].

NOVARTIS
PHARMACEUTICALS