SECUKINUMAB PHASE III CLINICAL TRIAL PROGRAM IN **ANKYLOSING SPONDYLITIS (AS)**

AS is a painful, progressively debilitating inflammatory disease caused by inflammation of the spine.

SECUKINUMAB IN AS

The first multi-center, randomized, placebo-controlled Phase III studies to evaluate the efficacy of secukinumab in IL-17A inhibition in AS compared to placebo, and to assess the safety, tolerability and long-term effectiveness in patients with AS

The studies enrolled a total of 590 patients with active, moderate-to-severe AS and evaluated secukinumab 75 mg and 150 mg versus placebo[1,2]

	Duration	Dosage
MEASURE 1	**MEASURE 1** is a 2-year study, although patients who complete the study may be eligible to enter a planned extension trial	Intravenous loading every two weeks for the first four weeks of treatment followed by monthly subcutaneous doses (75 mg or 150 mg) that aimed to provide high exposure for induction of response in order to confirm the clinical benefit observed in an initial proof-of-concept study[1]
MEASURE 2	**MEASURE 2** is a 5-year study	Subcutaneous loading regimes only[2] – which may be more convenient for patients and have shown strong efficacy in other therapy areas

RESULTS OVERVIEW

Secukinumab met the primary endpoint of ASAS20* in both studies demonstrating rapid and statistically significant improvements versus placebo in the signs and symptoms of AS at Week 16

MEASURE 1

60.8% and **59.7%** for secukinumab 150 mg and 75 mg at Week 16[1,2]

Versus 28.7% for placebo; p<0.0001[1,2]

MEASURE 2

61.1% and **41.1%** for secukinumab 150 mg and 75 mg[1,2]

Versus 28.4% for placebo; p<0.001 for 150 mg, p=0.0967 for 75 mg[1,2]

More than 73% of secukinumab 150 mg patients sustained significant clinical improvements after 1 year[3]

Nearly twice as many secukinumab 150 mg patients (more than 45%) who had an inadequate response or intolerance to the current standard of care, anti-tumor-necrosis-factor (anti-TNF) medicine achieved an ASAS20 response in MEASURE 1 and MEASURE 2 (p<0.05, MEASURE 1; p<0.05, MEASURE 2) compared to placebo patients in both studies (under 25%)[1,2]

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

*The ASAS20 Assessment of Spondyloarthritis International Society criteria response is a standard tool used to assess clinical improvement in AS

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NOVARTIS PHARMACEUTICALS

REFERENCES

1. Baeten D, Braun J, Baraliakos X, et al. Secukinumab, a monoclonal antibody to interleukin-17A, significantly improves signs and symptoms of active ankylosing spondylitis: results of a 52-week phase 3 randomized placebo-controlled trial with intravenous loading and subcutaneous maintenance dosing. Oral presentation at: ACR /ARHP Annual Meeting, Boston, MA, USA, 2014. Presentation number 820.

2. Sieper J, Braun J, Baraliakos X, et al. Secukinumab, a monoclonal antibody to interleukin-17A, significantly improves signs and symptoms of active ankylosing spondylitis: results of a phase 3, randomized, placebo-controlled trial with subcutaneous loading and maintenance dosing. Poster presentation at: ACR/ARHP Annual Meeting, Boston, MA, USA, 2014. Presentation number 536.

3. Sieper et al. Secukinumab Significantly Improves Signs and Symptoms of Active Ankylosing Spondylitis: 52-Week Data from MEASURE 2, A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial with Subcutaneous Loading and Maintenance Dosing. EULAR Annual Meeting, Rome Italy, 2015. Oral presentation (presentation number xxx)