Ustekinumab is Associated with Significant Improvement in Overall Health-Related Quality of Life in Moderate-to-Severe Psoriasis Patients

Richard G. Langley,1 Brad Schenkel,2 Yuhua Wang,3 Alexa B. Kimball4

1Dahoussiec University, Halifax, Nova Scotia, Canada; 2A&J Pharmaceutical Services L.L.C; Worldwide Health Economics & Pricing, Malvern, Pa, USA; 3Centocor Research and Development, Inc., Malvern, Pa, USA; 4Harvard Medical School, Boston, Mass, USA

Abstract

Purpose: This analysis examines the impact of ustekinumab on overall health-related quality of life (HRQoL).

Methods: At a total of 766 patients were enrolled in the PHOENIX I study. Patients were randomized to one of three treatment groups in a 1:1:1 ratio to placebo, ustekinumab 45 mg, or ustekinumab 90 mg for the ustekinumab group; patients received treatment at baseline, week 4, and every 12 weeks thereafter. Patients randomized to placebo at baseline crossed over to receive 45 mg or 90 mg ustekinumab at weeks 12, 16, and every 12 weeks thereafter. Overall HRQoL was assessed using the MOS Short-Form (SF-36), a validated tool used to compare improvement in the physical and mental component summary (PCS, MCS) scores between treatment groups.

Results: Baseline SF-36 scores were similar across treatment groups, with a mean PCS score of 47.9 in all mean MCS scores of 46.1. Compared with the placebo group, patients in each ustekinumab dose group had significantly greater improvements from baseline in the combined ustekinumab group at weeks 12 and 16. Additionally, patients in the placebo group who had crossed-over to ustekinumab (45 mg or 90 mg) at week 12 achieved improvements in PCS (2.0 and 2.5) and MCS (2.1 and 2.5) scores that were similar in magnitude to those observed in patients receiving randomization to ustekinumab.

Conclusions: Ustekinumab significantly improved overall quality of life related to both physical and mental health in patients with moderate to severe psoriasis.

Objective

The purpose of this analysis was to examine the impact of ustekinumab on overall and disease-specific quality of life (QoL) in patients with moderate to severe psoriasis.

Introduction

Psoriasis is a chronic inflammatory skin disease affecting approximately 2-3% of the population's world population. The negative impact of psoriasis on health-related quality of life (HRQoL) is considered comparable with that of other major systemic diseases. Interleukins-12 and -23 are cytokines that may play a role in the pathogenesis of psoriasis. Ustekinumab (INTN 1275) is an IgG1 kappa monoclonal antibody to IL12/23p40. PHOENIX I is a Phase 3 trial evaluating the safety and efficacy of ustekinumab for the treatment of moderate to severe psoriasis. To evaluate the impact of ustekinumab on HRQoL among patients with moderate to severe psoriasis, data from the PHOENIX 1 study were analyzed.

Study Design

PHOENIX I is a multicenter, randomized, double-blind, placebo-controlled study of ustekinumab in patients with moderate to severe plaque psoriasis (≥75% body surface area [BSA] involvement). Eligible patients were at least 18 years old, had a diagnosis of plaque psoriasis for at least 6 months, and a PASI 12 score of >14. Patients were randomized to one of three treatment groups in a 1:1:1 ratio to placebo, ustekinumab 45 mg, or ustekinumab 90 mg for the ustekinumab group; patients received treatment at baseline, week 4, and every 12 weeks thereafter. Patients randomized to placebo at baseline crossed over to receive 45 mg or 90 mg ustekinumab at weeks 12, 16, and every 12 weeks thereafter. Overall HRQoL was assessed using the MOS Short-Form (SF-36), a validated tool used to compare improvement in the physical and mental component summary (PCS, MCS) scores between treatment groups.

Results

A greater proportion of patients in the ustekinumab groups than in the placebo group achieved a DLQI score of 0 or 1 (63.1% and 52.4% in ustekinumab 45 mg and 90 mg, respectively, vs. 46.8% in the placebo group). At Week 12, patients in each ustekinumab dose group had significantly greater improvements from baseline in the combined ustekinumab group at weeks 12 and 16. Additionally, patients in the placebo group who had crossed-over to ustekinumab (45 mg or 90 mg) at week 12 achieved improvements in PCS (2.0 and 2.5) and MCS (2.1 and 2.5) scores that were similar in magnitude to those observed in patients initially randomized to ustekinumab.

Conclusions

Ustekinumab rapidly and significantly improves disease-specific quality of life, an improvement that is maintained over time. Ustekinumab significantly improves multiple aspects of overall quality of life, including both physical and mental functioning.

References


This study was supported by Centocor Research & Development, Inc.