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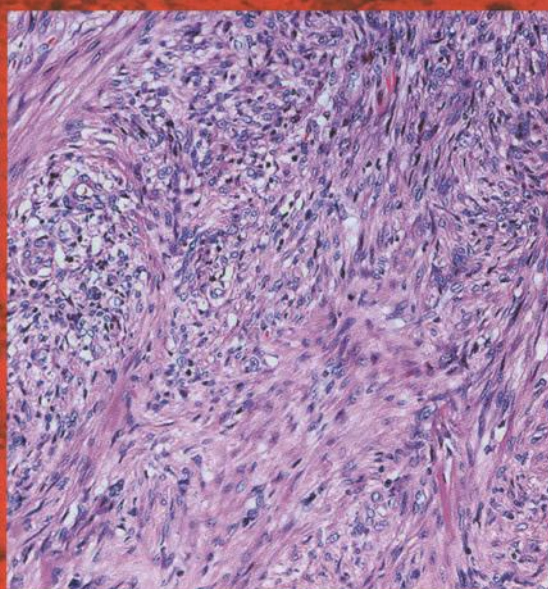
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ORIGINAL ARTICLE

Treatment of plaque-type psoriasis with oral CF101: data from an exploratory randomized phase 2 clinical trial

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Abstract

Aims CF101 demonstrated a marked anti-inflammatory effect in Phase 2 studies conducted in patients with rheumatoid arthritis and dry eye syndrome. The aim of this study was to evaluate the safety and efficacy of CF101 for the treatment of patients with moderate to severe plaque-type psoriasis.

Materials and methods This was a phase 2, multicentre, randomized, double-blind, dose-ranging, placebo-controlled study. Seventy five patients with moderate to severe plaque-type psoriasis were enrolled, randomized and treated with CF101 (1, 2, or 4 mg) or placebo administered orally twice daily for 12 weeks. Safety and change from base line of Psoriasis Area and Severity Index (PASI) score and physician's global assessment (PGA) score over 12 weeks.

Results In the 2 mg CF101-treated group, a progressive improvement in the mean change from baseline in the PASI score vs. placebo throughout the study period was observed, with a statistically significant difference on weeks 8 and 12 ($P = 0.047$; $P = 0.031$, respectively). In this group, 35.3% of the patients achieved PASI ≥ 50 response, and 23.5% of the patients achieved a PGA score of 0 or 1. CF101 was safe and well tolerated.

Conclusions CF101 was well tolerated and demonstrated clear evidence of efficacy in patients with moderate to severe plaque psoriasis.

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Conflicts of interest

None declared.

Introduction

Psoriasis is a chronic inflammatory skin disease with the potential for multisystem pathology and negative impact on the quality of life of the patients. It is characterized by epidermal hyper proliferation and immature differentiation, as a result of complex interactions between T cells, dendritic cells and keratinocytes.^{1,2} Th1 cytokines such as INF- γ , TNF- α , IL-23, Th17 cytokines have shown to play a major role in inducing and maintaining inflammation and epidermal alterations in psoriasis.³

Registration number and name of the trial: NCT00428974, Safety and Efficacy Study of CF101 to Treat Psoriasis.

CF101 is an oral anti-inflammatory agent that binds with high affinity and selectivity to the A₃AR, a Gi protein-associated cell surface receptor. The A₃AR is over expressed in inflammatory cells, whereas healthy cells show low or no receptor expression. High A₃AR expression levels have been found in synovial fluid cells and peripheral blood mononuclear cells (PBMCs) derived from patients with rheumatoid arthritis (RA), indicating that circulating cells reflect the receptor status in remote inflammatory tissue.⁴⁻⁷ Similarly, over-expression of A₃AR has been described in PBMCs of patients with psoriasis and patients with Crohn's Disease, suggesting that this is a general phenomenon in immunoinflammatory diseases.⁷⁻¹⁰