



CF101 for the Treatment of Autoimmune Inflammatory Diseases: Data from Phase 2 Clinical Trials in Patients with Rheumatoid Arthritis, Psoriasis and Dry Eye Syndrome

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Objective: A₃ adenosine receptor (A₃AR) is over-expressed in inflammatory cells and was suggested as a novel target to combat inflammation. Pharmacology studies show that CF101 (IB-MECA), a highly selective A₃AR agonist, acts as an anti-inflammatory agent via a mechanism which entails de-regulation of the NF-κB signaling pathway and inhibition of TNF-α. This study presents a summary of 3 human Phase II clinical trials looking at the safety and efficacy of CF101 in patients with Rheumatoid Arthritis (RA), Psoriasis and Dry Eye syndrome.

Methods: The studies were Phase 2, multicenter, randomized, double-masked, parallel-group. Patients were treated orally with either CF101 (0.1, 1, 2 or 4 mg) or matching placebo given twice daily for 12 weeks. Efficacy was tested as follows: RA - % of patients achieving ACR20; Psoriasis - Area and Severity index (PASI) and Physician's Global Assessment (PGA) scores; Dry Eye Syndrome – corneal fluorescein staining. Safety was evaluated by clinical and laboratory tests.

Results: CF101 was very well tolerated and treatment resulted in a statistically significant improvement of the clinical signs and symptoms of each disease. Furthermore, in the RA study, statistically significant correlation between A₃AR expression at baseline and patients' response to CF101 was observed, suggesting the receptor as a biological predictive marker.

Conclusions: The anti-inflammatory and the excellent safety profile of CF101 supports further clinical development of this drug candidate for the treatment of autoimmune inflammatory disease.