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.