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Safety and Efficacy of CF101 in Rheumatoid Arthritis Patients: A Phase II Study. Rumen M. Stoilov[1], Rodina N. Licheva[2], Mariyana K. Mihay-lova[3], Tatiana Reitblat[4], Emil A. Dimitrov[1], Krasimira M. Shimbova[1], Girish Bhatia[5], Amit Pispati[6], Alexandra Gurman-tein[8],sBalbir[7], B R Bagaria[5], Boytcho A. Oparanov[2], Sari Fishman[8], Zivit Harpaz[8], Motti Farb veiShira Cohen[8], Michael H. Silverman[8] and Pnina Fishman[8]. [1]Multiprofile Hospital for Act cTreatment "Sv. Ivan Rilski" - EAD, Clinic of Rheumatology, Sofia, Bulgaria, [2]Diagnosti ,rConsulting Center, Rheumatology office, Sofia, Bul-garia, [3]3Diagnostic Consulting Cente anip Rheumatology office, Sofia, Bulgaria, [4]Barzilai Medical Center, Ashkelon, Israel, [5]Mal umbai,m Multispeciality Hospi- tal, mumbai, India, [6]Bhatia Hospital Medical Research Society, . India, [7]Rambam Medical Center, Haifa, Israel, [8]CanFite Biopharma Ltd, Petah Tikva, Israel

Background/Purpose: CF101, is a highly selective A_3 adenosine recep-tor (A_3AR) agonist, didemonstrated safety and anti-inflammatory effect in Phase 2 clinical studies of rheumato sed onaarthritis (RA) and Psoriasis. A_3AR has been defined as a biological predictive marker, b t baselineaa significant correlation found in a former Phase II study, between its over-expression . and positive patients' response to CF101 treatment

Methods: This was a Phase 2, multicenter, randomized, double-blind, placebo-controlled, deparallel-group study designed to assess the efficacy and safety of CF101 1mg, administer ACRsorally twice daily to patients with active RA for 12 weeks. Primary efficacy endpoint wa ent-To-t20 response at week 12, with all-cause dropouts considered as non-responders, in the In n-oTreat (ITT) population. Secondary efficacy included: ACR 20/50/70 by visit, ITT, using n . responder imputation

>Seventy nine patients were enrolled for the study based on inclusion criteria of A_3AR acebolfrom 1.5 units and were randomized for two groups receiving CF101 1 mg (n = 42), or P . ((n = 37

Results: CF101 achieved ACR20 of 48.6%, statistically significantly higher than in the Placebo group (25.0%) at week 12 (P=0.0352). CF101 showed superiority in ACR50 and he lowtACR70 values vs. placebo although not statistically significant, most probably due to ninumber of patients. Interestingly, ACR20, ACR 50 and ACR 70 response rate at week 12 r compared toepatients with no prior systemic therapy, i.e., naïve patients were significantly high . the response of the whole patient population treated with CF101

The proportion of patients experiencing any adverse event (AE) was similar for both groups (16.7% for the CF101 group and 16.2% for the Placebo group). Two AEs, RA and rash, were . considered possibly related to CF101. The majority of AEs were considered to be mild

Conclusion: CF101 was very well tolerated and reached the primary endpoint in the current thistudy demonstrating clear evidence of efficacy as a monotherapy for 12 weeks in patients w . active RA

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