EULAR recommendations advocate MTX as first line of therapy for RA patients who do not achieve a treatment target within Period-1. This indicates that starting with MTX followed by ADA in insufficient responders to MTX is an appropriate strategy; a small subset of pts responds more slowly to MTX/ADA combination from start (Table 1). ACR20/50/70 scores for the Rescue-ADA arm from week 26 to week 78 were sizeable (51%, 34%, and 19%, respectively). OL-ADA Carry On arm achieved ACR20/50/70 from week 26 baseline in 27%, 15%, and 8% of pts, respectively, at week 78. Age, patient and physician’s global assessment of disease, and tender/swollen joint counts were all predictors of achieving DAS28 (CRP) <3.2 at week 78.

Conclusion: When advanced to OL-ADA + MTX therapy, pts initially not achieving stable LDA target at week 26 following MTX monotherapy demonstrated improvements in clinical and functional outcomes at week 52 and week 78, structural progression was minimal. Some improvement was also seen among pts who did not yet attain stable LDA at week 26 on ADA + MTX but continued this treatment; however, it remains unknown whether pts who were not in LDA at week 78 might have benefitted from earlier treatment adjustment in an attempt to further improve outcomes.

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Method: OPTIMA was a 78 week, randomized, double-blind, double-treatment period study designed to compare safety and efficacy of ADA + MTX with placebo (PBO) + MTX in early RA pts. Following ADA + MTX or PBO + MTX treatment for 26 weeks (Period-1), non-responders (NR) were defined as pts failing to achieve a stable LDA target of DAS28 (CRP) <3.2 at week 22 and week 26 and given OL-ADA + MTX for an additional 52 weeks (Period-2). OL-ADA Carry On and Rescue-ADA arms, respectively. Period-2 responders were defined as those achieving LDA at week 52 following OL-ADA + MTX therapy. Logistic regression analysis was conducted with baseline and week 26 disease characteristics as variables.

Results: Compared with responders, Period-1 NR began the study with higher overall disease activity. Among these, 78/259 (30%) OL-ADA Carry On and 157/348 (45%) Rescue-ADA pts achieved DAS28 (CRP) <3.2 following 26 weeks of OL-ADA + MTX therapy; 33/259 (13%) and 49/348 (14%) OL-ADA Carry On and Rescue-ADA pts, respectively, had DAS28 (CRP) <3.2 at week 52 and achieved DAS28 (CRP) <3.2 at week 78. Mean values of responders’ clinical, radiographic, and functional outcomes were much lower than those of NR and were similar to those seen for pts who achieved the treatment target within Period-1. This indicates that starting with MTX followed by ADA in insufficient responders to MTX is an appropriate...