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OP0162

ABATACEPT TREATMENT FOR PATIENTS WITH EARLY ACTIVE PRIMARY SJÖGREN'S SYNDROME: OPEN-LABEL EXTENSION PHASE OF A RANDOMIZED CONTROLLED PHASE III TRIAL

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Background: Abatacept (CTLA-4-Ig) targets the CD80/CD86:CD28 co-stimulatory pathway required for full T-cell activation and T-cell dependent activation of B-cells. The Abatacept Sjögren Active Patients phase III (ASAPIII) trial is a mono-center, investigator-initiated, placebo controlled study with an open-label extension phase (NCT02067910), which assessed the efficacy and safety of weekly subcutaneous abatacept (125mg) in patients with early active primary Sjögren's syndrome (pSS). Previous analyses of the double blind phase showed no significant effect of abatacept treatment compared to placebo on the primary endpoint, difference in EULAR Sjögren's syndrome disease activity index (ESSDAI) at week 24.¹

Objectives: To evaluate the efficacy and safety of extended (48 weeks) open label abatacept treatment in pSS patients.

Methods: Included patients had biopsy-proven pSS, fulfilled the AECG and ACR-EULAR criteria, had disease duration ≤7 years (median 2 years), ESSDAI ≥5, and 89% were anti-SSA positive. All 40 patients who received abatacept (ABA) in week 0-24 were subsequently treated with abatacept from week 24-48. Of the 40 patients who received placebo (PLB) in week 0-24, 2 were lost to follow up, and 38 were treated with abatacept from week 24-48. Systemic disease activity (ESSDAI), patient reported symptoms (ESSPRI), serological outcomes (RF and IgG), ocular staining score (OSS) and unstimulated whole salivary flow (UWS) were assessed. We evaluated whether outcomes improved within treatment groups, from week 0 to subsequent visits and from week 24 to subsequent visits:

1. Within ABA→ABA treated patients:
 - a. Week 0-48 to assess overall efficacy.
 - b. Week 24-48 to assess additional efficacy of long term treatment.
2. Within PLB→ABA treated patients:
 - a. Week 0-24 to assess whether a placebo effect occurred.
 - b. Week 24-48 to assess short-term efficacy of open label ABA.

GEE modeling was used to test significance of changes over time. Missing data were not imputed.

Results: ESSDAI and ESSPRI were improved within ABA/ABA patients between week 0-48 with additional efficacy after week 24, and within PLB/ABA patients after switching to ABA. Significant decreases in ESSDAI and ESSPRI were also seen within PLB treated patients between week 0-24 (Figure 1). IgG and RF were improved within ABA/ABA patients between week 0-48 with additional efficacy after week 24, and within PLB/ABA patients after switching to ABA. OSS was improved within ABA/ABA treated patients between week 0-48. UWS only showed significant improvement in week 36 within ABA/ABA treated patients. No changes in IgG, RF, OSS or UWS were seen within PLB treated patients. No deaths occurred. One serious adverse event possibly related to intervention occurred during ABA treatment.

Conclusion: ESSDAI and ESSPRI improved significantly during 48-week treatment with abatacept. Placebo treated patients also showed significant improvement in both indices and further improvement occurred after switching to abatacept. Biological activity was decreased by abatacept treatment. 48-week abatacept treatment improved OSS, and might improve UWS. Abatacept was well tolerated by pSS patients.

References:

- [1] van Nimwegen et al. *Lancet Rheumatol.* Published online 31-01-2020

Figure 1. ESSDAI (A) and ESSPRI (B) during ABA/ABA treatment and PLB/ABA treatment in pSS

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OP0163

2019 UPDATE OF THE JOINT EUROPEAN LEAGUE AGAINST RHEUMATISM AND EUROPEAN RENAL ASSOCIATION–EUROPEAN DIALYSIS AND TRANSPLANT ASSOCIATION (EULAR/ERA-EDTA) RECOMMENDATIONS FOR THE MANAGEMENT OF LUPUS NEPHRITIS

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Background: Up to 40% of systemic lupus erythematosus (SLE) patients develop kidney disease, which represents a major cause of morbidity.

Objectives: To update the 2012 EULAR/ERA-EDTA recommendations for the management of lupus nephritis (LN).

Methods: We followed the EULAR standardised operating procedures for the publication of treatment recommendations. Delphi-based methodology led to 15 questions for systematic literature review (SLR), which was undertaken by three fellows.

Results: The changes include recommendations for treatment targets, use of glucocorticoids and calcineurin inhibitors (CNI), and management of