

**DISEASE REMISSION IS ACHIEVED AT 2YEARS IN OVER HALF OF MTX NAIVE PATIENTS WITH EARLY EROSIIVE RA TREATED WITH ABATACEPT PLUS MTX: AGREE TRIAL**

Westhovens R. Robles M. Nayiager S. Wollenhaupt J. Durez P. Gomez R J. Grassi W. Haraoui B. Shergy W. Park SH. Genant H. Peterfy C. Bathon J. Becker J

Leuven, Belgium. Mentpec, Mexico. Durban, SA. Hamburg, Germany. Brussels, Belgium. Coruna, Spain. Ancona, Italy. Montreal, Canada. Huntsville, USA. Seoul, Korea. SF, USA. SF, USA. Baltimore US. BMS US. Argentina

Intensive treatment of patients early in the RA disease process is becoming a standard of care making disease remission, as a treatment goal, more attainable. Here we report the clinical and safety outcomes in methotrexate naïve patients with early erosive RA treated with a combination of abatacept + methotrexate through 24 months.

**Methods:** The AGREE trial was a 24 month study with a 12 month double-blind period (DB) and 12 month open label period (OL). During DB, patients were randomized to ABA (~10 mg/kg dose based on weight range) + MTX (dosed up to 20 mg) or placebo (PLA) + MTX. All patients completing DB and entering OL received ABA + MTX. Safety was assessed in all pts receiving &#8805;1 dose of ABA in OL. Clinical outcomes evaluated included DAS28 remission (DAS28 <2.6), low disease activity state (LDAS, DAS28 <= 3.2), and ACR responses.

**Results:** All 459 pts completing DB entered OL; 94.3% completed OL. Remission, LDAS, and ACR responses were sustained or increased from 12 to 24 months in original ABA + MTX arm (Table), with over half (55.2%) in remission at 24 months. Proportion achieving these outcomes in the original MTX alone arm increased after initiating ABA in OL, with 44.5% in remission at 24 months. Rates (per 100 pt yrs) of serious AE (6.42 vs 8.35) and serious infections (1.73 vs 2.04) were similar in the OL vs DB respectively. Autoimmune events occurred at a similar rate in OL as in DB (1.30 vs 2.47, respectively). Two deaths occurred. No malignancies or TB were reported.

**Conclusions:** Sustained disease remission is an achievable goal for many patients with early RA when treatment with combination of ABA + MTX is initiated early. Consistent with the long-term safety experience in patients with longer standing disease no new or unexpected safety signals occurred in this population. These data support the use of ABA + MTX in an early RA population.

| <b>Clinical Outcomes, (%)</b> |  |                     |   |                     |
|-------------------------------|--|---------------------|---|---------------------|
|                               | <b>ABA + MTX (DB &amp; OL) (N=232)</b> |                     | <b>MTX Alone (DB)→ ABA + MTX (OL) (N=227)</b> |                     |
|                               | <b>Baseline to Yr 1</b>                | <b>Yr 1 to Yr 2</b> | <b>Baseline to Yr 1</b>                       | <b>Yr 1 to Yr 2</b> |
| <b>DAS(28) Remission</b>      | 46.1                                   | 55.2                | 26.9  | 44.5                |
| <b>LDAS</b>                   | 60.8                                   | 71.1                | 43.2  | 60.4                |
| <b>ACR 50</b>                 | 64.7                                   | 74.1                | 50.2  | 67.0                |
| <b>ACR 70</b>                 | 48.3                                   | 53.9                | 31.7  | 49.8                |
| <b>ACR 90</b>                 | 18.5                                   | 22.0                | 7.5   | 22.9                |