Rheumatoid arthritis - non biologic treatment and small molecules.

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RAPID AND CONCURRENT IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES OF RHEUMATOID ARTHRITIS WITH BARICITINIB IN RA-BEAM

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Background: The efficacy and safety of baricitinib (BARI), an oral selective Janus kinase (JAK)1/JAK2 inhibitor, were evaluated in the randomized, controlled trial, RA-BEAM (NCT01710358), in patients (pts) with active rheumatoid arthritis (RA) and inadequate responses (IR) to methotrexate (MTX), who were also receiving concomitant non-biological DMARDs. The study was designed to determine the effect of BARI vs placebo (PBO) on patient-reported outcomes (PROs) at week 12. The key secondary efficacy endpoint was the least-squares mean (LSM) change from baseline in the American College of Rheumatology (ACR) 20% improvement score (ACR20).

Objectives: To compare the time to onset and magnitude of improvement across different patient-reported outcomes (PROs) of BARI, adalimumab (ADA) and placebo (PBO) during the first 12 weeks of treatment in RA-BEAM.

Methods: 1,305 pts on stable background MTX were randomized 3:3:2 to PBO, BARI 4mg, or ADA 40mg. In this intent-to-treat analysis, least-squares means (KL6), pain (0-100mm visual analog scale [VAS]), and active disease (PSA) were assessed at week 12 vs baseline (BL). Statistical analysis included ANCOVA and mixed-effects models for the change from BL to week 12, with a treatment-by-time interaction term included to model the response.

Results: Significant improvements (P<0.05) with BARI vs PBO were observed as early as week 1 for pain (VAS), psoriasis area and severity index (PASI), patient global assessment (PGA), and patient global assessment of disease activity (PtGA). The median time to ACR20 by week 12 was 2.6 weeks for BARI compared with 4.0 weeks for ADA and 4.5 weeks for PBO. The percentage of pts achieving ACR20 at week 12 was similar across the groups (35.1% for PBO vs 35.7% for BARI vs 34.2% for ADA).

Conclusion: BARI improves patient-reported outcomes across multiple domains, with rapid onset of improvement in RA-BEAM compared to placebo.

Disclosure of Interests: None declared

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