A Multicenter Study Assessing the Efficacy and Safety of Repository Corticosteroid Injection in Patients With Rheumatoid Arthritis: Preliminary Interim Data From the Open-label Treatment Period

1Roy Fleischmann, 2Daniel E. Furst, 3Richard Brasington, 4Erin Connolly-Strong, 5Jingyu Liu, and 6Matthew E. Barton
1University of Texas Southwestern Medical Center, Dallas, TX, USA; 2David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; 3Washington University School of Medicine, St. Louis, MO, USA; 4Malinkrodt ARD Inc., Bedford, NJ, USA; 5formerly employee of Malinkrodt ARD Inc., Bedford, NJ, USA

Background: Rheumatoid Arthritis (RA) is a chronic autoimmune disorder characterized by persistent inflammation of joints and surrounding tissues, leading to joint damage, disability, and increased risk of comorbidities. 

Methods: A randomized, double-blind, parallel group, multicenter, 2-period, 12-week study was conducted to confirm the efficacy and safety of DEXASIR® (dexamethasone 4 mg) in ambulatory patients with persistently active RA. Patients were randomized to receive DEXASIR® subcutaneously (SC) twice weekly (Q2W) for 12 weeks or placebo (PBO) injections. 

Results: A total of 264 patients received study drug: 134 in the Q2W group and 130 in the PBO group. The proportion of patients who achieved low disease activity (LDA) increased from Week 8 to Week 12 in the Q2W group, compared with the PBO group (Figure 1). The proportion of patients who achieved LDA was statistically significantly greater in the Q2W group compared with the PBO group at Week 12 (Figure 2). 

Efficacy Results

- LDA at Week 12: 60% (96/134) vs. 35% (45/130) (p = 0.0011)

Safety Results

- No SAEs or deaths reported

Conclusions: DEXASIR® appears to be an acceptable and effective alternative for treating RA, with comparable safety to PBO. 

References: 