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REPOSITORY CORTICOTROPIN INJECTION (RCI) ATTENUATES DISEASE ACTIVITY IN PATIENTS WITH PERSISTENTLY ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) REQUIRING CORTICOSTEROIDS: RESULTS FROM A 44-WEEK OPEN-LABEL EXTENSION STUDY

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Background: We recently reported results from a pilot 8-week randomized double-blind placebo (PBO)-controlled study of RCI in subjects with persistently active SLE involving skin and/or joints despite moderate dose corticosteroids for ≥ 4 weeks[a]. Although the primary endpoint of this study (resolution of disease active for SLEDAI rash or arthritis with no worsening of other organ systems by BILAG) was not met, RCI therapy (40U daily or 80U every other day SC) led to improvement in several measures of disease activity, including total hybrid SLEDAI (hSLEDAI), total BILAG, CLASI Activity scores, and Tender and swollen joint count, as compared with PBO.

Objectives: To describe the topline results of a 44-week open-label extension (OLE) of this study of RCI in persistently active SLE.

Methods: 33/38 subjects completed the double-blind phase of the study and opted to enroll in the OLE. Of these 33, 22 had received RCI and 11 PBO during the prior 8 weeks. The dose of RCI could be adjusted beginning at week 9, with the goal of achieving a stable dose (16, 40 or 80U SC, 1-3x/week) to control disease activity no later than Week 28. Beginning at Week 20, investigators were encouraged to taper background prednisone. Disease activity was assessed monthly by hSLEDAI, BILAG, CLASI, Tender & swollen joint counts, and physician's global assessment (PGA).

Results: 20 subjects completed the OLE, 13/22 from the RCI/RCI and 7/11 from the PBO/RCI groups. No unexpected adverse events were observed.

OLE baseline *mean (SD)*	RCI/RCI (n=22)	PBO/RCI (n=11)
Total hSLEDAI	5.8 (3.02)	9.1 (3.42)
Total BILAG	6.8 (4.31)	13.5 (8.82)
PGA	28.73 (21.05)	39.09 (27.24)
CLASI activity (of those > 0)	4.8 (4.25) (n=17)	7.0 (7.00) (n=9)
Tender & swollen joint count (of those > 0)	4.6 (1.67) (n=5)	5.0 (2.94) (n=4)
Prednisone (mg/day)	8.98 (1.67)	16.36 (8.09)

Results *proportion (%)*		
SLEDAI rash or arthritis domain 0 & no new BILAG prior to steroid taper	5/10 (50%)	2/7 (28.6%)
SRI (week 52)	10/13 (76.9%)	6/7 (85.7%)
Prednisone to <7.5 mg/day (week 52)	9/13 (69.2%)	3/7 (42.9%)
Prednisone decreased > 50%	7/13 (53.8%)	4/7 (57.1%)
Severe flares (SFI) (week 52)	2/22 (9.1%)	3/11 (27.3%)
Change from OLE baseline at week 52 *mean (SD)*		
Total hSLEDAI	-1.5 (2.79)	-4.7 (3.77)
Total BILAG	-1.2 (5.58)	-7.0 (8.35)
PGA	-9.92 (16.02)	-14.14 (13.70)
CLASI Activity	-3.0 (4.92)	-2.8 (1.6)
Tender & swollen joint count	-2.0 (5.66)	-2.5 (4.95)

Conclusions: These data demonstrate that subjects in the RCI/RCI group had a durable response to therapy over 52 weeks, whereas those in the PBO/RCI group experienced improvements in disease activity during the OLE that were generally comparable to the improvements seen with RCI treatment from the blinded phase of the trial.

References: Furie R, Das M, Li D, Smythe S, Mathura E, Becker P. Repository Corticotropin Injection (H.P. Acthar® Gel) Attenuates Disease Activity in Patients with Persistently Active Systemic Lupus Erythematosus (SLE) Requiring Corticosteroids [abstract]. Arthritis Rheumatol. 2015; 67 (suppl 10).

Disclosure of Interest: P. Becker Shareholder of: Mallinckrodt Pharmaceuticals Inc, Employee of: Mallinckrodt Pharmaceuticals Inc, R. Furie: None declared, M. Mitrane Consultant for: Mallinckrodt Pharmaceuticals Inc, E. Zhao Employee of: Mallinckrodt Pharmaceuticals Inc

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