Figure 1A. Mean Change from Baseline in Total BILAG Scores.

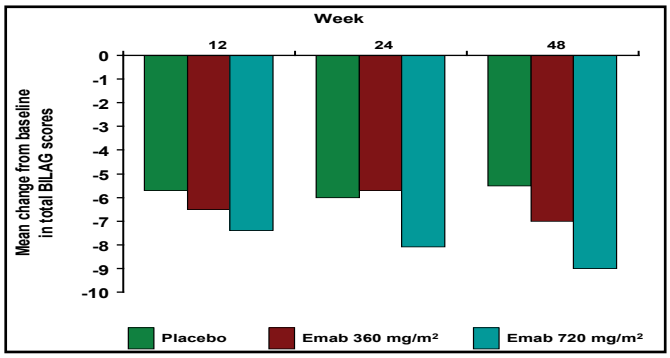

Figure 1B. Percent of Sustained BILAG.

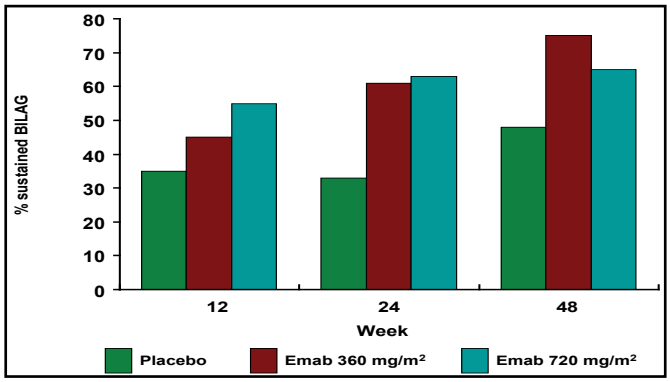

Table 1: Week 12 BILAG Scores and Global Disease Assessments (ITT Population).

	Epratuzumab 360 mg/m2 n=34	Epratuzumab 720 mg/m2 n=10	Placebo n=30
BILAG response[a]	15 (44%)	2 (20%)	9 (30%)
Per protocol pop. (total n=46)	6 (54%)	1 (25%)	3 (21%)
BILAG A/B to C	11 (32%)	0	6 (20%)
Total BILAG score[b] reduction from baseline	6.4	7.2	5.8
Time to sustained[d] A/B Flare Reduction			
Kaplan-Meier Q1 days	36	35	48
Median days (95% CI)	93 (61-301)	84 (35-NC)	NC (138-NC)
Hazard ratio vs Placebo	2.18[c]	1.21	
Improved physician global assessment[e]	76%	80%	60%
Improved patient global assessment[e]	67%	70%	53%

A=primary endpoint response definition; b=A/B/C/D/E = 9/3/1/0/0; c =HR p-value=0.021; d=at 2 consecutive visits; e=≥20% improvement on 5-category scale

The most commonly reported adverse event (AE) overall was upper respiratory infection, which occurred in 35% of patients in the placebo group, 20% of patients in the epratuzumab 360 mg group, and 27% of patients who were treated with epratuzumab 720 mg. The most common AEs (≥10% incidence with epratuzumab) included headache, arthralgia, nausea, pyrexia, abdominal pain, oral candidiasis, peripheral edema, chest pain, cough, and blurred vision. The incidence of SAEs, infusion-related AEs, and infections was similar between placebo and epratuzumab treatment groups.

Treatment with both doses of epratuzumab resulted in clinically meaningful efficacy, as evidenced by improvements in BILAG, physician and patient global assessment, and clinically meaningful corticosteroid sparing in patients with moderate and severe SLE flares. "These initial clinical results for epratuzumab are very encouraging," said Dr. Petri. "Developing new compounds for SLE patients is critical because currently available treatments, such as immunosuppressants and corticosteroids, often have serious and debilitating side effects. We look forward to seeing results from other clinical trials involving epratuzumab."

Joint Lavage in Knee Osteoarthritis

Intra-articular injection (IAI) with corticosteroids is a procedure that is commonly used in the management of osteoarthritis (OA). Parmigiani et al., Universidade Federal de São Paulo, São Paulo, Brazil, reported results from a randomized, double-blind, controlled study that compared medium-term effectiveness and tolerance between IAI with triamcinolone hexacetonide plus joint lavage (JL/TH Group) versus IAI with triamcinolone hexacetonide alone (TH Group) in patients with OA of the knee.

Patients with primary knee OA, with pain in at least one of the knees and grades II and III on the Kellgren-Lawrence index (KL II and III), were randomly assigned to treatment with joint lavage with 0.9% saline solution (1000 ml) followed by a 60-mg injection of triamcinolone hexacetonide (3 ml) (the JL/TH group) or to simulated joint lavage followed by a 60-mg injection of TH (3 ml) (the TH group). Patients were evaluated at baseline and at Weeks 1, 4, 8, and 12 by an observer, blinded to the treatment regimen. The following tools were used: visual analog scale (VAS) for pain at rest and during movement; goniometry; Womac index; Lequesne questionnaire;

timed 50-foot walk; subjective perception of improvement; Likert scale (0-5) for improvement assessment; the need for nonhormonal anti-inflammatory medication and analgesics; and the number and type of local side effects. Statistical significance was set at p=0.05.

A total of 60 patients (mean age 63.7 ± 8.53 years; mean disease duration 5.69 ± 5.01 years). Thirty-three patients were KL II; 27 were KLIII. The study population was predominantly women (88.3%); 48.3% was white. The sample was homogeneous at baseline for all demographic variables as well as the use of symptom and chondroprotective medications, KL index, functional indexes, and previous IAIs.

Although both groups were found to have improved statistically in the intragroup analysis, there was no statistical difference in the intergroup analysis regarding any of the variables that were studied throughout the 12-week period (Tables 1 and 2).

Table 1. Mean Clinical and Functional Measures at Baseline and Weeks 1, 4, 8, and 12.

	JL/TH (n=30)	IAI/TH (n=30)	p
VAS for pain at rest (0-10cm)			
T0	(+) 6.27 (±1.89)	(+) 6.40 (±1.69)	0.23
T1	1.90 (±2.16)	2.20 (±1.95)	
T4	1.17 (±1.68)	2.0 (±1.98)	
T8	2.30 (±2.23)	3.40 (±3.10)	
T12	(-) 2.53 (±2.70)	(-) 2.47 (±3.10)	
VAS for pain during movement (0-10cm)			
T0	(+) 7.70 (±0.84)	(+) 7.70 (±0.70)	0.207
T1	2.67 (±2.40)	3.0 (±2.20)	
T4	1.63 (±1.97)	2.83 (±2.48)	
T8	3.17 (±2.63)	4.0 (±2.89)	
T12	(-) 3.27 (±3.05)	(-) 3.47 (±3.35)	
Flexion (degrees)			
T0	(+) 92.23 (±15.19)	(+) 94.03 (±13.51)	0.523
T1	99.90 (±12.19)	102.73 (±10.88)	
T4	105.40 (±9.36)	108.17 (±9.51)	
T8	106.67 (±10.45)	107.67 (±11.12)	
T12	(-) 109.83 (±9.42)	(-) 108.83 (±12.37)	

One septic post-trauma arthritis event occurred in Week 8 in the JL/TH group. There were 5 cases of local hypochromia and 1 case of seepage from the JL orifice that was resolved spontaneously in the JL/TH group. One case of metrorrhagia and 1 case of hypochromia local were reported in the TH group.

The results of this study led the investigators to conclude that the combination of joint lavage and triamcinolone hexacetonide IAI is not more effective in the medium term than IAI triamcinolone hexacetonide alone for the treatment of moderate degrees of primary knee OA.

Table 2. Womac Index Score at Baseline and Weeks 1, 4, 8, and 12.

	JL/TH (n=30)	IAI/TH (n=30)	p
Womac pain - Mean (±SD)			
T0	(+) 9.07 (±3.87)	(+) 10.03 (±3.22)	0.275
T1	2.60 (±2.39)	2.20 (±1.92)	
T4	1.90 (±2.34)	1.83 (±1.91)	
T8	1.80 (±2.27)	3.37 (±3.53)	
T12	(-) 2.13 (±3.10)	(-) 2.80 (±3.93)	
Womac function - Mean (±SD)			
T0	(+) 4.30 (±2.15)	(+) 4.10 (±1.99)	0.745
T1	0.93 (±1.11)	1.10 (±1.24)	
T4	1.07 (±1.34)	0.97 (±1.25)	
T8	1.13 (±1.31)	1.47 (±1.53)	
T12	(-) 1.10 (±1.47)	(-) 1.30 (±1.74)	
Womac stiffness - Mean (±SD)			
T0	(+) 30.27 (±13.89)	(+) 32.03 (±2.07)	0.62
T1	11.93 (±8.22)	10.97 (±7.90)	
T4	8.97 (±9.16)	8.17 (±8.74)	
T8	8.57 (±9.73)	11.77 (±11.78)	
T12	(-) 8.33 (±11.99)	(-) 10.20 (±13.20)	

The RADIATE Study

Although anti-TNF therapies are established treatments for rheumatoid arthritis (RA), significant proportions of patients do not achieve an adequate response, or become refractory to them. Paul Emery, MD, PhD, University of Leeds, Leeds, UK, presented data from the RADIATE study (NCT00106522), a randomized, double-blind study that investigated the efficacy and safety of treatment with tocilizumab (TCZ) plus methotrexate (MTX) in patients with moderate to severe RA and a prior history of failed anti-TNF therapy.

Patients who enrolled in the RADIATE study received placebo (n=158), TCZ 4 mg/kg (n=161), or TCZ 8 mg/kg (n=170) every 4 weeks plus MTX for 24 weeks. The primary study