Methods Patients with active (SLEDAI-2K/C2) autoantibody-positive SLE receiving standard therapy were randomised to weekly subcutaneous injections of atacicept (75 or 150 mg) or placebo for 24 weeks.

Results In the ITT population (n=306), there was a trend towards improved SRI-4 response rates with both atacicept doses vs placebo at Week 24 (primary analysis, Screening as baseline). In a sensitivity analysis using Day 1 as baseline, both atacicept doses significantly increased SRI-4 responses (Table 1). In patients with high disease activity (HDA, n=158), serologically active (SA) disease (n=84), or both (HDA SA, n=69), enhanced improvements in SRI-4 and SRI-6 response rates were seen with atacicept (Tables 1 and 2; Figure 1). Atacicept significantly reduced severe flares in the ITT (75 mg: BILAG A p=0.019; 150 mg: SLEDAI flare index [SFI] p=0.002) and HDA populations (75 mg: BILAG A HR=0.1, SFI HR=0.3; 150 mg: BILAG A HR=0.3, SFI HR=0.2; all p<0.05). At Week 24, serum IgG was reduced from baseline by ~25% and ~30% with atacicept 75 and 150 mg, respectively (Figure 2); serum complement C3 and C4 increased while IgM, IgA, and anti-dsDNA antibodies decreased with atacicept. Risk of SAEs and serious/severe infections did not increase with atacicept (Table 3).

Conclusions Atacicept demonstrated evidence of efficacy in SLE, particularly in HDA and SA patients, with reduction in disease activity and severe flares, and showed a favourable safety profile.

Methods Patients with active SLE receiving standard therapy were randomised to weekly subcutaneous injections of atacicept (75 or 150 mg) or placebo for 24 weeks.

Results In the ITT population (n=306), there was a trend towards improved SRI-4 response rates with both atacicept doses vs placebo at Week 24 (primary analysis, Screening as baseline). In a sensitivity analysis using Day 1 as baseline, both atacicept doses significantly increased SRI-4 responses (Table 1). In patients with high disease activity (HDA, n=158), serologically active (SA) disease (n=84), or both (HDA SA, n=69), enhanced improvements in SRI-4 and SRI-6 response rates were seen with atacicept (Tables 1 and 2; Figure 1). Atacicept significantly reduced severe flares in the ITT (75 mg: BILAG A p=0.019; 150 mg: SLEDAI flare index [SFI] p=0.002) and HDA populations (75 mg: BILAG A HR=0.1, SFI HR=0.3; 150 mg: BILAG A HR=0.3, SFI HR=0.2; all p<0.05). At Week 24, serum IgG was reduced from baseline by ~25% and ~30% with atacicept 75 and 150 mg, respectively (Figure 2); serum complement C3 and C4 increased while IgM, IgA, and anti-dsDNA antibodies decreased with atacicept. Risk of SAEs and serious/severe infections did not increase with atacicept (Table 3).

Conclusions Atacicept demonstrated evidence of efficacy in SLE, particularly in HDA and SA patients, with reduction in disease activity and severe flares, and showed a favourable safety profile.