Belimumab, an anti-BLyS monoclonal antibody, is the first biologic available for SLE treatment. We studied its effectiveness and safety in clinical practice.

Methods Multicentric cohort study of SLE patients, fulfilling the 2012 SLICC classification criteria, treated with belimumab in rheumatology departments and registered in the Portuguese registry Reuma.pt.

Results Thirty-eight patients were included: 37 (97.4%) female, aged 46.2±13.9 years, mean disease duration of 11.9±8.6 years. The reasons for prescribing belimumab were: multiforgan involvement in 20 (52.6%), haematologic disorders in 9 (23.7%), cutaneous manifestations in 5 (13.0%), arthritis in 3 (7.9%), necrotizing vasculitis in 1 (2.6%). Belimumab was administered intravenously for a mean of 22.3±20.3 months.

SRI response was achieved in 14/27 (51.9%), 12/20 (60%) and 11/12 (91.7%) at 6, 12 and 24 months of belimumab treatment, respectively. Mean SLEDAI significantly decreased from 8.2±3.9 at baseline to 3.8±2.2, 4.1±3.2 and 3.1±1.6 at 6, 12 and 24 months, respectively.

Anti-dsDNA antibodies significantly decreased at 6, 12 and 24 months and C3 increased at 12 months of belimumab (table 1). We found a significant reduction in mean daily prednisolone dosage (p<0.001) from baseline (10.8±5.1 mg) to the last evaluation under belimumab (5.5±3.0 mg).

Eleven (28.9%) patients discontinued belimumab: loss of effectiveness in 4, lost to follow-up in 4, adverse events in 3 (urinary tract infections, acute myocardial infarction, breast cancer). Three presented infections related to belimumab.

Conclusions We confirmed belimumab effectiveness and safety in real-life active SLE patients.