Objective
To evaluate all-cause mortality and AEs in adult patients with active, anti-dsDNA positive SLE meeting treatment (n=59) or placebo (n=59) over 52 weeks.

Methods
Study design and patients
- BASE (BEL115467; NCT01705977) is a multicentre, placebo-controlled, double-blind, parallel-group study to assess the effectiveness of belimumab, in addition to standard-of-care (SoC).
- The study included patients with active, anti-dsDNA-positive, SLE with SELENA-SLEDAI (≤9) ≥5/11, ≤6 months since first SLE diagnosis, ≤90-days active anti-dsDNA, ≤3 concomitant SLE medications, no therapy within 90 days of randomization.
- Patients were randomized to receive belimumab (10 mg/kg IV) or placebo, plus SoC,

Results

Conclusions
- No suicides were observed.
- No suicide-related deaths were reported.
- Suicidal ideation and suicidal behaviour were infrequent events (0.20% belimumab and 0.10% placebo).
- SAEs were similar between groups.
- No differences in SELENA-SLEDAI or other outcomes were observed.
- No unexpected safety concerns were identified.
- No cancer-related deaths were observed.

References