Triple positivity was defined as positive antibodies against cardiolipin and β2GPI and a positive test for lupus anticoagulant.
**Results:** 32 pts had high or medium level of aPL (anticardiolipin antibodies IgG,IgM, anti-β2glycoprotein antibodies IgG,IgM), 6 had low or normal level of aPL. 12 pts were triple positive. APPT and thrombin time before inclusion to trial were 44,2 [36,5;53,5] and 16,1 [14,9;17,0], on 24 week after dabigatran etexilate start 51,0 [40,5;65,7] and 163,5 [108,7;240,0] and on 48 week 58,7 [45,6;63,2] and 194,1 [152,6;255,2] respectively.1 patient was excluded due to non-compliance. During follow-up period from 1,5 to 12 (10,6±3,2) months 7 pts (22,6%, 20,7 per 100 patient-years) experienced reccurent thrombosis including superficial vein thrombosis (n=2; 6,5%, 5,9 per 100 patient-years), thrombosis of paranephric veins (n=1; 3,2%, 2,9 per 100 patient-years), acute cerebrovascular disorders (n=4; 12,9%, 11,8 per 100 patient-years). All pts with reccurent thrombosis had high or medium level of aPL; 2/7 were triple positive, both had acute cerebrovascular disorders. 5 pts (16,1%, 14,8 per 100 patient-years) experienced bleeding: 2 hemorrhoidal bleedings, 1 uterine bleeding, 2 nasal bleedings. There was no case of severe bleeding.
**Conclusions:** Dabigatran etexilate could be used in patients with APS in the case of warfarin non-effectiveness. These findings need to be confirmed in larger studies.
**Disclosure of Interest:** None declared
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## SAT0231 SAFETY OF SUBCUTANEOUS BELIMUMAB IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A 6-MONTH OPEN-LABEL EXTENSION STUDY

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**Background:** Intravenous belimumab (BEL) 10 mg/kg is approved in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE), on standard SLE therapy (SoC). A Phase III, double-blind (DB), study of subcutaneous (SC) BEL 200 mg weekly plus SoC showed efficacy and safety in patients with SLE.
**Objectives:** The ongoing safety and efficacy of BEL 200 mg SC weekly were assessed in a 6-month open-label extension (OLE) study.
**Methods:** Patients with SLE who completed BLISS-SC (BEL112341; NCT01484496), a Phase III, randomised (2:1), DB, placebo (PBO)-controlled, 52-week trial of BEL 200 mg SC, were eligible to enter a 6-month OLE; the outcomes are reported here. Patients were maintained on weekly BEL (BEL group) or switched from PBO to BEL (PBO to BEL group). Baseline differed according to study treatment (Day 0 of the DB phase for BEL; Week 52 of the DB phase for PBO to BEL). The primary focus was safety, evaluated by adverse event (AE) reporting, laboratory tests and immunogenicity. OLE AEs were those occurring on or after the first OL dose. Efficacy evaluations were conducted, at reduced frequency, as per the DB phase[1].
**Results:** Overall, 677 patients completed the DB phase, 662 entered the OLE; 625 completed. Mean baseline Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index scores were 10.4 (BEL group) and 5.8 (PBO to BEL group, implying better SoC in the DB phase); Systemic Lupus International Collaborating Clinics/ACR Damage Index scores were similar (0.7 and 0.6, respectively). Most OLE AEs were mild/moderate in severity. Despite differences in BEL exposure (BEL: 1 year [DB]; 6-month OLE, and PBO to BEL: 6-month OLE), OLE AE rates were similar (table). Infections and infestations were the most frequent AEs (190/662, 28.7%; drug-related, 55/662, 8.3%; serious AEs [SAEs]; 17/662, 2.6%). AEs of depression/suicide/self-injury (12/662, 1.8%), infections of special interest (17/662, 2.6%), post-injection systemic reactions (21/662, 3.2%) and local injection site reactions (4/662, 0.6%), were low. Two deaths occurred (metabolic acidosis; pneumonia and acute respiratory failure); unrelated to study drug. The percentage of patients worsening (≥2 grade) from baseline was low for all clinical laboratory parameters. Three patients had anti-BEL immune responses during the OLE or follow-up; this resolved on subsequent testing. Efficacy was maintained across the OLE.

| Patients, n (%) | PBO to BEL 200 mg SC (n=206) | BEL 200 mg SC (n=456) | Total (N=662) |
|---|---|---|---|
| AE | 106 (51.5) | 220 (48.2) | 326 (49.2) |
| Treatment-related AE | 26 (12.6) | 58 (12.7) | 84 (12.7) |
| SAE | 14 (6.8) | 25 (5.5) | 39 (5.9) |
| Severe AE | 9 (4.4) | 17 (3.7) | 26 (3.9) |
| AE leading to study drug discontinuation | 5 (2.4) | 12 (2.6) | 17 (2.6) |
| Death | 1 (0.5) | 1 (0.2) | 2 (0.3) |

**Conclusions:** No new differences in safety and efficacy of BEL 200 mg SC plus SoC were seen in this 6-month OLE study compared with the DB phase.
**References:**
[1] Stohl W et al. Arthritis Rheumatol 2017;doi:10.1002/art.40049.
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## SAT0232 B-CELL SUBPOPULATION DYNAMICS IN SLE PATIENTS FOLLOWING RITUXIMAB THERAPY

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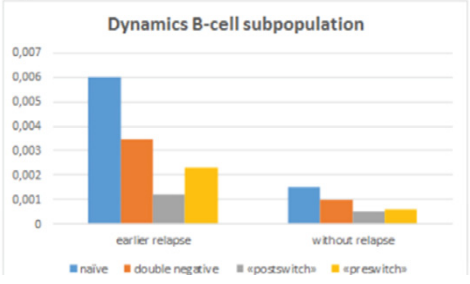
**Objectives:** To study B-cell subpopulation dynamics in SLE patients following Rituximab (RTX) therapy.
**Methods:** The study included 31 SLE pts (3m/28f) with high (SLEDAI2K≥10–28 pts.) and moderate (SLEDAI2K<10–3 pts.) disease activity; out of them 12 pts with SLE nephritis, 5 pts with neurolupus and 8 with vasculitis. RTX was administered to pts who failed to respond to glucocorticoids (GCs) and cytostatics (CTs). B-cells subpopulations were assessed before RTX administration (Mo0), and at Mo3 and Mo6 of RTX therapy. RTX was administered at 500 to 2000 mg doses depending on disease activity. The absolute counts of CD19+ B-cells, the total population of memory B-cells (CD19+CD27+), "preswitch" (CD19+IgD+CD27+) and "postswitch" (CD19+IgD-CD27+) memory B-cells, "naive" (CD19+IgD+CD27-), plasma cells (CD19+CD38+) and double negative B-cells (CD19+CD27-IgD) were measured. All B cell subsets were analyzed with multicolor flow cytometry using a panel of monoclonal antibodies to B-lymphocytes' surface membrane markers.
**Results:** Following initiation of RTX SLE clinical and lab activity indices have decreased in all 31 pts by Mo3 and Mo6 of follow up (SLEDAI-2K Mo0–Me 15 [12;18], Mo3-Me 6 [4;10], Mo6–Me 4 [2;8]), as well as absolute count CD19+ B-cell population (Mo0–Me 0,119x$10^9$/l [0,05;0,26], Mo3–Me 0x$10^9$/l [0;0,003], Mo6-Me 0,004x$10^9$/l [0;0,02]). B-cell repopulation by Mo6 in 15 out of 31 pts without signs of relapse and 4 pts with earlier relapse SLE was dependent on "naïve" B-cells (Me 0,0015x$10^9$/l [0,0002;0,01] vs Me 0,006x$10^9$/l [0,0033;0,008]), double negative (Me 0,001x$10^9$/l [0,0002;0,002] vs Me 0,0035x$10^9$/l [0,0018;0,005]) "postswitch" (Me 0,0005x$10^9$/l [0,00008;0,003] vs Me 0,0012x$10^9$/l [0,0003;0,0035]) and "preswitch" memory B-cells (Me 0,0006x$10^9$/l [0,00007;0,001] vs Me 0,0023x$10^9$/l [0,0005;0,005]).

Figure: dynamics of lymphocyte subpopulations in patients with early relapse and without relapse SLE/




**Conclusions:** Decrease in clinical and lab SLE activity was documented in all 31 pts by Mo3 after one course of RTX therapy. In 4 pts with earlier relapse SLE at Mo6 B-cell was found repopulation and significant increase "naïve" B-cells, double negative, "postswitch" and "preswitch" memory B-cells compared with the group without relapse.
**Disclosure of Interest:** None declared
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## SAT0233 HIGH ANTI-DSDNA CONTENT IN SLE IMMUNE COMPLEXES IS ASSOCIATED WITH CLINICAL REMISSION FOLLOWING BELIMUMAB TREATMENT

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**Background:** Systemic lupus erythematosus (SLE) is considered driven by