MTX-IR pts with RA. However, clinical outcomes of all 3 regimens, including tofacitinib 5 mg BID monotherapy, were comparable. There were no new or unexpected safety issues.

References:
[1] Machado et al. Rev Bras Reumatol 2013;53:419–430.

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New treatments in SLE, Sjögren's and APS

OP0231 THE EFFECT OF "TRIPLE THERAPY" WITH ANTICOAGULATION PLUS CORTICOSTEROIDS PLUS PLASMA EXCHANGE AND/OR INTRAVENOUS IMMUNOGLOBULINS ON THE MORTALITY OF CATASTROPHIC ANTIPHOSPHOLIPID SYNDROME (CAPS) PATIENTS

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Background: Triple therapy (anticoagulation plus corticosteroids plus plasma exchange and/or intravenous immunoglobulins) is empirically prescribed for the management of catastrophic antiphospholipid syndrome (CAPS). However, previous analyses have been inconsistent regarding the beneficial effect of triple therapy on patients' survival.

Objectives: The objective of this study was to assess the effect that triple therapy has on the mortality risk of CAPS patients.

Methods: In a cohort including 525 episodes of CAPS (CAPS Registry), we evaluated the relationship between triple therapy and mortality. Patients were grouped in three based on their treatments: a) triple therapy (anticoagulation plus corticosteroids plus plasma exchange and/or intravenous immunoglobulins); b) drugs included in the triple therapy but in different combinations; c) none of the treatments included in the triple therapy. The primary endpoint was all-cause mortality. Multivariate logistic regression models were used to compare mortality risk between groups taking into account a set of possible confounding variables.

Results: The "CAPS registry" cohort included 525 episodes of CAPS accounting for 502 patients. After excluding 38 episodes (7.2%), a total of 487 episodes of CAPS accounting for 471 patients (mean age 38 years; 67.9% female; primary APS patients 68.8%) were analyzed. Overall, 177 (36.3%) patients died. Triple therapy was prescribed in 197 episodes (40.5%), other combinations in 278 (57.1%), and none of those treatments in 12 episodes (2.5%). According to these three groups, mortality rate increased up to 27.9%, 40.6%, and 75%, respectively. Triple therapy was positively associated with a higher chance of survival when compared to non-treatment (adjusted odds ratio [OR]: 7.7 95%; confidence interval [95CI] 2.0–29.7) or to treatment with other combinations of drugs included in the triple therapy (adjusted OR 6.8; 95CI 1.7–26.9). Triple therapy accounted for a 64% decrease of the risk of death in patients with CAPS that received this combination of drugs.

Conclusions: Triple therapy is independently associated to a higher survival rate among CAPS.

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Disclosure of Interest: None declared

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OP0232 SUSTAINED SAFETY AND EFFICACY OVER 10 YEARS WITH BELIMUMAB (BEL) PLUS STANDARD SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) THERAPY (SOC) IN PATIENTS WITH SLE

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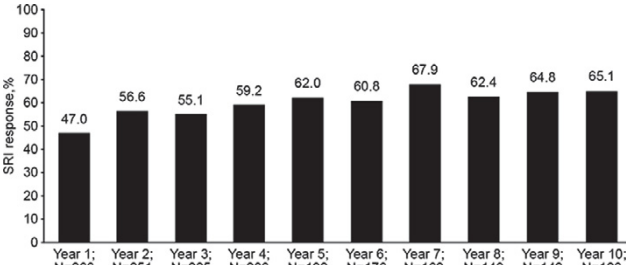
Background: Preliminary safety and efficacy data from the Phase II BEL open-label extension study (LBSL02; NCT00071487) have been reported.

Objectives: Here we present the final 10-year data.

Methods: This was a multicentre, open-label, continuation trial (BEL112626; NCT00583362) of BEL + SoC in patients with a satisfactory response in the parent study. Patients received intravenous BEL 10 mg/kg every 4 weeks. Baseline was prior to the first ever dose of BEL.

Results: Of 298 patients in the continuation trial, 131 (44%) remained at Year 10. Total BEL exposure was 2154 patient-years. Adverse events (AEs) remained stable or decreased (Table). Two deaths (pseudomonal lung infection; cytomegaloviral pneumonia) were possibly related to BEL. SLE Responder Index (SRI) response increased (Figure). A British Isles Lupus Assessment Group (BILAG) flare (1 new A/2 new B scores) occurred in 72.6% of patients and 41.9% had a severe flare (SLE Flare Index). Prednisone dose decreased from baseline to Year 10 (Table). Of patients receiving >7.5 mg/day baseline prednisone, 32.6%



Abstract OP0232 – Table 1

	0–1y (N=296)	1–2y (N=294)	2–3y (N=276)	3–4y (N=250)	4–5y (N=223)	5–6y (N=209)	6–7y (N=192)	7–8y (N=178)	8–9y (N=169)	9–10y (N=152)	10–11y (N=131)
Incidence of ≥1 AE, n (%)											
Overall	291 (98.3)	283 (96.3)	260 (94.2)	239 (95.6)	203 (91.0)	190 (90.9)	182 (94.8)	162 (91.0)	157 (92.9)	137 (90.1)	105 (80.2)
Resulting in discontinuation	2 (0.7)	3 (1.0)	3 (1.1)	7 (2.8)	5 (2.2)	6 (2.9)	6 (3.1)	1 (0.6)	3 (1.8)	5 (3.3)	2 (1.5)
Serious AE	41 (13.9)	43 (14.6)	50 (18.1)	30 (12.0)	40 (17.9)	33 (15.8)	35 (18.2)	34 (19.1)	28 (16.6)	25 (16.4)	14 (10.7)
Serious infections/infestations	11 (3.7)	13 (4.4)	9 (3.3)	9 (3.6)	6 (2.7)	6 (2.9)	12 (6.3)	10 (5.6)	8 (4.7)	5 (3.3)	5 (3.8)
Death	1 (0.3)	0	1 (0.4)	1 (0.4)	0	1 (0.5)	2 (1.0)	0	0	1 (0.7)	0
		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10
Prednisone											
median % change from baseline;		-0.4;	-25.0;	-36.9;	-50.0;	-48.3;	-60.0;	-62.5;	-70.0;	-66.7;	-65.8;
25th, 75th percentile (n)		-50.0, 0 (186)	-74.2, 0 (172)	-80.0, 0 (153)	100.0, 0 (140)	-100.0, 0 (128)	0 (115)	-100.0, -10.7 (105)	-100.0, -1.6 (94)	-100.0, -0 (91)	-100.0, 0 (84)