Conclusion: Consistent benefit in favor of anifrolumab 300 mg vs placebo was observed in W52 BICLA responses across C_{ave} subgroups. C_{ave} was a significant covariate of efficacy in IFNGS test–high patients who completed treatment. There was no evidence of exposure-driven HZ, non-opportunistic serious infections, infusion-related reactions, or malignancy during the TULIP trials.

REFERENCES:

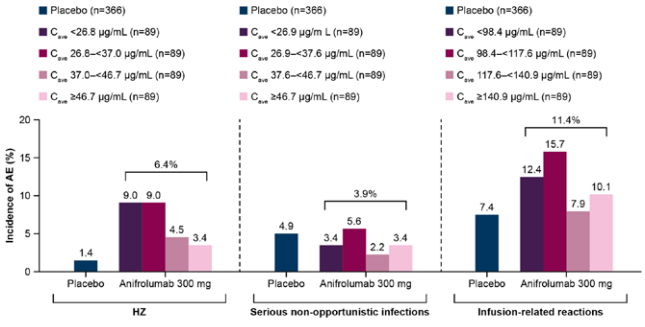
[1] Furie R. *Lancet Rheumatol.* 2019;1:e208–19.
[2] Morand E. *N Engl J Med.* 2020;382:211–21.

Table 1. Exposure–BICLA Analysis for Pooled TULIP Data

BICLA response, W52	PK subgroup[a]	Anifrolumab 300 mg, n/N[b] (%)	Anifrolumab vs placebo difference, % [95% CI]
All patients (n=722)	Q1	40/100 (40)	9.6 [–1.0, 20.3]
	Q2	44/98 (44)	13.4 [2.6, 24.2]
	Q3	43/81 (53)	22.5 [10.7, 34.3]
	Q4	44/77 (58)	27.4 [15.4, 39.4]
	Placebo	112/366 (31)	–
Patients completing treatment (n=574)	Q1	40/75 (54)	12.7 [0.1, 25.2]
	Q2	44/74 (57)	15.5 [2.7, 28.3]
	Q3	43/74 (58)	17.2 [4.7, 29.8]
	Q4	44/75 (60)	18.7 [6.2, 31.2]
	Placebo	112/276 (41)	–
IFNGS test–high patients completing treatment (n=470)	T1	44/81 (54)	15.4 [3, 27.8]
	T2	46/81 (54)	15.4 [2.8, 27.9]
	T3	52/81 (66)	26.7 [14.7, 38.7]
	Placebo	88/227 (39)	–

BICLA, British Isles Lupus Assessment Group–based Composite Lupus Assessment;CI, confidence interval; IFNGS, interferon gene signature; PK, pharmacokinetic; Q, quartile; T, tertile.[a]PK was stratified by quartiles/tertiles based on sample size.[b]n, number of BICLA responders; N, number of patients in the subgroup.

Figure. Incidence of HZ, serious non-opportunistic infections, and infusion-related reactions by anifrolumab 300 mg PK quartiles in patients with SLE



AE, adverse event; HZ, herpes zoster; PK, pharmacokinetic; SLE, systemic lupus erythematosus.

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POS0685 MYCOPHENOLATE MOFETIL IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS: FIVE-YEARS DRUG SURVIVAL IN RENAL AND NON-RENAL INVOLVEMENT

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Background: The updated EULAR recommendations for the management of systemic lupus erythematosus (SLE) underline the use of Mycophenolate Mofetil (MMF) in the treatment of different disease related manifestations (1). Several randomized controlled trials have demonstrated the efficacy of MMF in lupus nephritis (LN) patients but only case series and open-labelled trials have analyzed the use of this drug in other than LN features. Moreover, no data are available about the MMF retention rate in a real-life setting.

Objectives: The present study aims at evaluating the 5-years drug retention rate (DRR) of MMF in a large monocentric SLE cohort. Secondly, we investigated the influence of MMF in disease activity changes and chronic damage progression.
Methods: We performed a longitudinal study including all the SLE patients (ACR 1997 criteria) starting MMF treatment in our Lupus Clinic. Data about indications, mean dosage, duration of treatment and reasons for drug withdrawal were registered. The DRR was estimated using the Kaplan–Meier method. Disease activity and chronic damage were assessed by SLE Disease Activity Index 2000 (SLEDAI-2K) and SLICC Damage Index (SDI), respectively.
Results: The present analysis included 162 SLE patients (M/F 22/140, median age at the disease diagnosis 25.5 years, IQR 13). At the beginning of MMF treatment, we registered a median age of 34 months (IQR 21) and a median disease duration of 72 months (IQR 123). The most frequent indications for prescribing MMF were LN (101 patients, 62.3%) and musculoskeletal manifestations (39, 24.1%), followed by neuropsychiatric involvement (10, 6.2%), and others disease related manifestations (12, 7.4%; in particular skin involvement, hematological features, myositis, vasculitis). MMF was administered at a mean daily dosage of 2.1±0.6 grams; no differences in dosage were found between the different indications (p=ns).
At the longitudinal analysis, we registered a median treatment duration of 30 months (IQR 55). Figure 1 reported data about DRR: in particular, at 60 months follow-up we observed a DRR of 61.1% for LN patients, which was similar to that registered for patients without renal involvement (NLN) (60.5%; p=ns). Interestingly, the DRR at 60 months was higher in the subgroup of patients treated for joint involvement (75.4%), even without reaching a statistically significant difference. During the observation period, 92 patients (59.2%) discontinued MMF (median treatment duration at discontinuation 25 months, IQR 35). Interestingly, the main cause of withdrawal was the achievement of persistent remission, observed in 20 patients (21.7%), followed by loss of efficacy (19 patients, 20.5%), drug intolerance and pregnancy planning (17 patients for both reasons, 18,4%). Furthermore, our analysis confirmed MMF efficacy, as demonstrated by the significant reduction in SLEDAI-2k values after 4, 12 and 24 months of treatment (p< 0.0001 for all the time-points in comparison with baseline). In addition, MMF resulted able to control chronic damage progression, as demonstrated by the lack of significant increase in SDI values (baseline: 0.6, IQR 1; last observation: 0.93, IQR 1; p=ns).
Conclusion: The evaluation of a large SLE cohort demonstrated a good retention rate for MMF. In particular, our results demonstrated that MMF is also a safe and effective drug for SLE manifestation other than LN, in particular for joint involvement. Moreover, it is able to control disease activity and to prevent the progression of chronic damage.

REFERENCES:

[1] Fanouriakis A et al. Ann Rheum Dis. 2019 Jun;78(6):736-745.

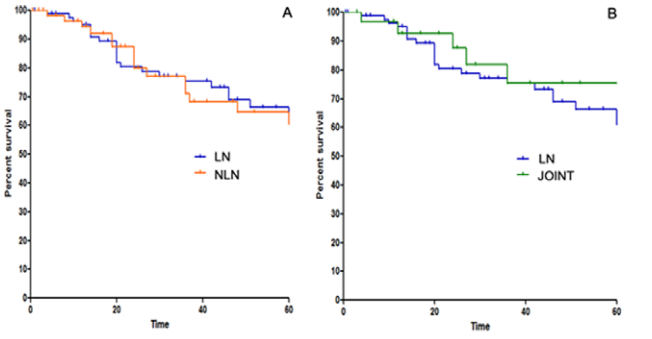

Figure 1. Kaplan–Meier survival curve of MMF treatment. The time of MMF treatment is expressed as months. DRR of MMF therapy at 60 months was similar in LN patients and NLN patients (Figure 1A). Interestingly, the DRR was higher in in the subgroup of patients with joint involvement (75.4%), even without reaching a significant difference (Figure 1B).

Disclosure of Interests: None declared

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POS0686 BARICITINIB DECREASES ANTI-DSDNA AND IGG ANTIBODIES IN ADULTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS FROM A PHASE 2 DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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