Table 1. Efficacy at Week 26

	All Patients [1]		Subgroups			
			N/O		R/R	
	Mavrilimu- mab (N=42)	Placebo (N=28)	Mavrilimu- mab (N=24)	Placebo (N=11)	Mavrilimu- mab (N=18)	Placebo (N=17)
Patients with Flare, n (%)	8 (19.0)	13 (46.4)	3 (12.5)	4 (36.4)	5 (27.8)	9 (52.9)
Time to Flare (weeks) [2]						
Median, 95% CI	NE	25.1	NE	NE	NE	22.6
	(NE, NE)	(16.0, NE)	(NE, NE)	(11.7, NE)	(16.4, NE)	(16.0, NE)
HR (Mavrilimumab vs Placebo), 95% CI [3]	0.38 (0.15, 0.92)		0.29 (0.06, 1.31)		0.43 (0.14, 1.30)	
P-value [4] [5]	0.0263		0.0873		0.1231	
Sustained Remission (%), 95% CI [6]	83.2 (67.9, 91.6)	49.9 (29.6, 67.3)	91.3 (69.3, 97.7)	62.3 (27.7, 84.0)	72.2 (45.6, 87.4)	41.7 (17.4, 64.5)
Difference in Proportions (95% CI) [7]	33.3 (10.7, 55.8)		28.9 (-2.7, 60.5)		30.6 (-2.1, 63.2)	
P-value [5] [7]	0.0038		0.0727		0.0668	

NE = Not estimable.[1] Total mITT population. Stratified by randomization strata.[2] Kaplan-Meier.[3] Cox proportional-hazards model; treatment as covariate.[4] Log-rank test.[5] N/O and R/R subgroups not powered for significance; nominal p values reported.[6] Kaplan-Meier Survival Estimates with standard error.[7] Two-sided p-value for the difference in sustained remission between 2 arms using normal approximation. Placebo arm is reference.

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OP0060

COMPARATIVE STUDY ON ANTI-TNF VS TOCILIZUMAB FOR TREATMENT OF REFRACTORY UVEITIC CYSTOID MACULAR EDEMA DUE TO BEHCET'S DISEASE. MULTICENTER STUDY OF 49 PATIENTS

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Background: Posterior segment involvement is the most serious affection of uveitis in Behçet's disease (BD), with cystoid macular edema (CME) being the leading cause of blindness. Anti-TNF, especially adalimumab (ADA) and infliximab (IFX), have demonstrated efficacy as first-line biologic agents in BD-related uveitis [1,2]. Moreover, the anti-IL6R tocilizumab (TCZ) has shown excellent results in highly refractory BD-uveitis and noninfectious uveitic CME [3-6].

Objectives: To compare the efficacy of ADA vs IFX vs TCZ in patients with refractory CME due to BD.

Methods: Observational multicenter study of patients with BD-associated CME refractory to conventional and/or biological immunosuppressive drugs. From a cohort of 177 patients treated with anti-TNF and 14 patients treated with TCZ, we selected those with CME at baseline. CME was defined as macular thickness > 300µm (measured by optic coherence tomography). We analyzed in the 3 groups of treatment (ADA, IFX, TCZ) from baseline up to 4 years the evolution of macular thickness (main outcome) and best-corrected visual acuity (BCVA). Differences between basal and final follow-up were evaluated. Multivariable linear regression was used to assess the differences between the 3 groups.

Results: A total of 49 patients were included. ADA was used in 25 patients (40 eyes with CME), IFX in 15 (21 eyes with CME) and TCZ in 9 (11 eyes with CME). No statistically significant baseline differences were observed between the 3 groups (Table) except for previous anti-TNF therapy, which was used only in patients treated with TCZ (5 patients received ADA, 1 received IFX and 2 received both ADA and IFX, in different times). Most patients from all groups had received several conventional immunosuppressive drugs. Biological therapy was used in monotherapy or combined with azathioprine (n=10, 5 and 1 in ADA, IFX and TCZ group, respectively), cyclosporine A (n=10, 5 and 1) or methotrexate (n=4, 2 and 3). Macular thickness progressively decreased in the 3 groups, with no signs of CME after 1 year of treatment. Similarly, BCVA improvement and inflammatory ocular remission was reached in all groups (Figure).

Table 1. Demographic and clinical characteristics of 49 patients with cystoid macular edema due to Behçet's disease receiving ADA, IFX or TCZ.

	ADA (n=25)	IFX (n=15)	TCZ (n=9)
Eyes with cystoid macular edema, n	40	21	11
Age, years	41 ± 11	38 ± 9	43 ± 16
Sex, men/women	12/13	7/8	5/4
HLA-B51 +, n	19	10	6
Duration of uveitis before anti-TNF/ anti-IL6R, months	30 [12-82]	15 [8-60]	32 [24-144]
Ocular features at start of anti-TNF/anti-IL6R			
Macular thickness, µm	432 ± 118	483 ± 126	417 ± 113
Visual acuity, BCVA	0.4 ± 0.2	0.3 ± 0.2	0.2 ± 0.2
Tyndall, inflammation grade	2 [1-3]	1 [0-1.5]	1 [0-1.5]
Vitritis, inflammation grade	2.5 [1.5-3]	1 [0-2]	2 [1-2]
Previous treatment, n			
Oral glucocorticoids // i.v. pulse methylprednisolone	18 // 13	4 // 9	7 // 8
MTX // CsA // AZA	13 // 22 // 14	8 // 13 // 8	8 // 6 // 2
ADA // IFX	0 // 0	0 // 0	7 // 3
Prednisone dosage at start of anti-TNF/anti-IL6R, mg/day	45 [30-60]	30 [20-60]	30 [30-30]
Combined treatment, n			
CsA // AZA // MTX	10 // 10 // 4	5 // 5 // 2	1 // 1 // 3

Data are presented as mean ± SD or median [IQR] when data were not normally distributed. ADA, adalimumab; AZA, azathioprine; CsA, cyclosporine A; MTX, methotrexate; IFX, infliximab; TCZ, tocilizumab.

Figure 1. Evolution of ocular parameters in 49 patients with cystoid macular edema due to Behçet's disease receiving ADA, IFX or TCZ.

Conclusion: Refractory CME associated to BD's uveitis can be effectively treated with ADA, IFX or TCZ. Moreover, TCZ is effective in patients resistant to anti-TNF therapy.

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