

Emerging GI Therapies

Written by Maria Vinall

Tofa-Burmester_Table1

	Months 0-3			Months 3-6			
	PBO n=132	5 mg BID n=133	10 mg BID n=134	PBO→5 n=66	PBO→10 n=66	5 mg BID n=133	0 mg BID n=134
Patients with AE n (%)	75 (56.8)	71 (53.4)	76 (56.7)	24 (36.4)	28 (42.4)	57 (42.9)	58 (43.3)
Patients with SAE n (%)	6 (4.5)	2 (1.5)	2 (1.5)	3 (4.5)	2 (3.0)	5 (3.8)	6 (4.5)
Patients with SEI n (%)	0	0	0	1 (1.5)	0	2 (1.6)	2 (1.4)

No opportunistic infections or cases of TB were observed; AE=adverse event; SAE=serious adverse event; SIE=serious infection event.

Tofa-Burmester_Table2

	Months 3			Month 6			
	PBO	5 mg BID	10 mg BID	PBO→5	PBO→10	5 mg BID	0 mg BID
LS Mean Change from Baseline							
Neutrophil count, 10 ³ /mm ³	0.13	-0.93***	-0.81***	-0.77*	-0.69*	-0.73***	-0.77***
Hemoglobin, g/dL	-0.10	0.11	0.01	0.11	0.03	0.16	-0.02
% LDL-C change from baseline	-0.31	11.14***	11.71***	9.58**	16.24***	11.80***	10.39***
% HDL-C change from baseline	0.03	13.38***	15.25***	14.20***	17.33***	16.42***	17.97***
Serum creatinine (mg/dL)	0.05	0.04	0.05	0.04	0.06	0.05	0.06*
Confirmed Incidence n (%)	n=118	n=116	n=124	n=50	n=48	n=100	n=102
Neutropenia 500-1499 cells/mm ³	0	1 (<1.0%)	0	0	0	0	1 (<1.0%)
Decreased hemoglobin (-1.0 to -3.0 g/dL)	12 (10.2%)	9 (7.8%)	16 (12.9%)	4 (8.0%)	5 (10.4%)	5 (5.0)	15 (14.7%)

*p≤0.05; **p<0.001; ***p<0.0001 versus PBO at Month 3 (unadjusted); versus baseline at Month 6 (unadjusted); HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol.

Peer-Reviewed
Highlights from the

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75th Annual Scientific
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Table 1. Tofa Wallenjaupt

	Tofacitinib all doses	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Background DMARDs	Monotherapy
Hemoglobin, n (%)	n=3219	n=1319	n=1900	n=2017	n=1202
≥2 g/dL decrease from baseline or hemoglobin <8 g/dL	81 (2.5)	54 (4.1)	27 (1.4)	43 (2.1)	38 (3.2)
Neutropenia, n (%)	n=3219	n=1319	n=1900	n=2017	n=1202
Mild [1500-1999 cells/mm³]	92 (2.9)	55 (4.2)	37 (1.9)	47 (2.3)	45 (3.7)
Moderate [1000-1499 cells/mm³] to severe [500-999 cells/mm³]	16 (0.5)	8 (0.6)	8 (0.4)	9 (0.4)	7 (0.6)
Potential life-threatening [<500 cells/mm³]	0	0	0	0	0
Aminotransferases, n (%)	n=3183	n=1314	n=1869	n=1989	n=1194
AST>3x ULN	40 (1.3)	23 (1.8)	17 (0.9)	29 (1.5)	11 (0.9)
ALT>3x ULN	73 (2.3)	42 (3.2)	31 (1.7)	47 (2.4)	26 (2.2)
Serum creatinine, n (%)	n=3227	n=1321	n=1906	n=2019	n=1208
>50% increase from baseline	60 (1.9)	30 (2.3)	30 (1.6)	29 (1.4)	31 (2.6)

ALT=alanine aminotransferase; AST=aspartate aminotransferase; BID=twice daily; DMARD=disease-modifying antirheumatic drug; ULN=upper limit of normal.

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