

ONLINE ONLY APPENDIX

Failure to Preserve beta-cell function with Mycophenolate Mofetil and Daclizumab Combined Therapy in patients with new onset Type 1 Diabetes

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This Online Only Appendix presents supplemental material not contained in the published manuscript.

Figure A1: Enrollment, Randomization and Follow-up of Study Participants.

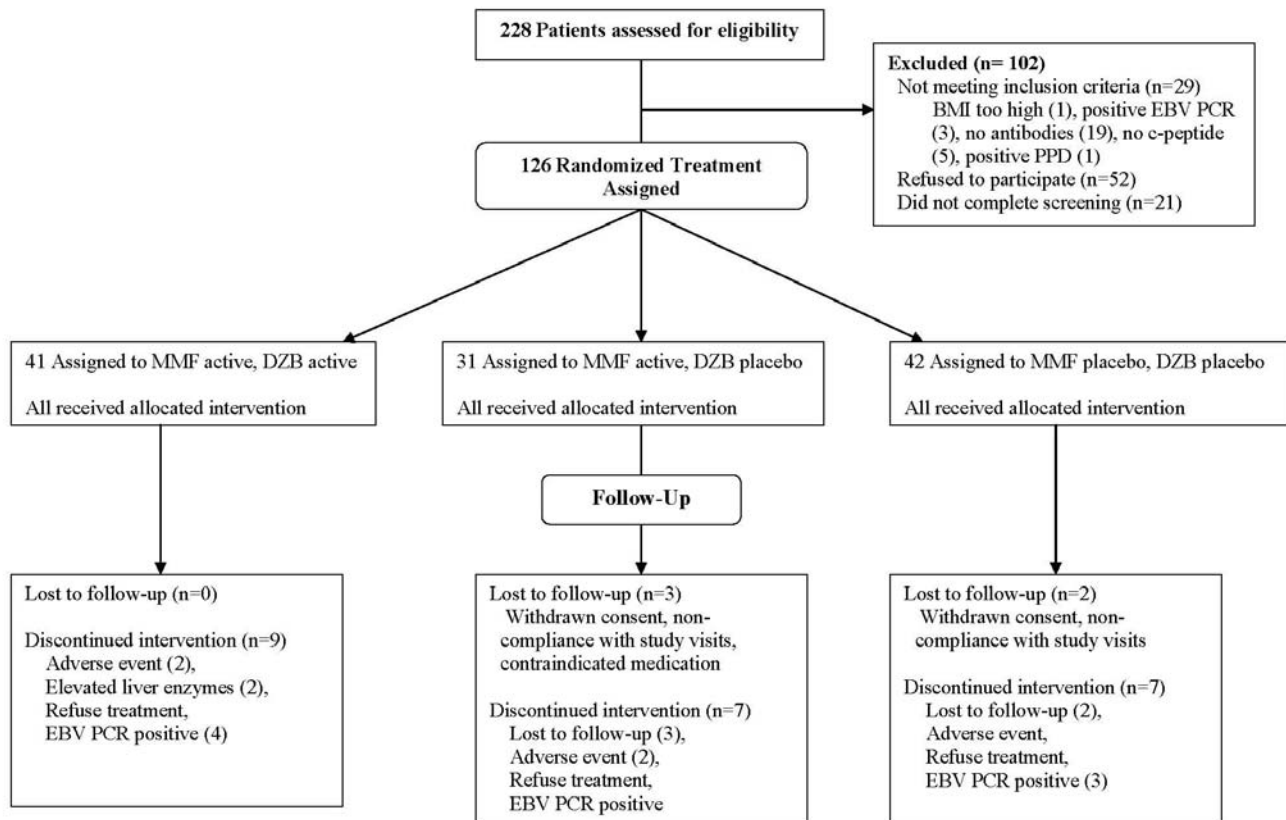


Table A1. Summary of Grade 2+ Adverse Events of Interest by Treatment Group. Only events that occurred in 2 or more subjects within a treatment group are shown.

Event	MMF+DZB (N=41)		MMF-alone (N=31)		Placebo Control (N=42)		p-value*
	# Events	# (%) Subjects w/ Event	# Events	# (%) Subjects w/ Event	# Events	# (%) Subjects w/ Event	
Infection	59	26 (63.4)	40	17 (54.8)	47	24 (57.1)	0.765
Conjunctivitis	0	0 (0)	1	1 (3.2)	4	4 (9.5)	0.075
Elevated EBV viral load**	7	5 (12.2)	9	1 (3.2)	3	2 (4.8)	0.344
HSV, GU	1	1 (2.4)	2	1 (3.2)	0	0 (0)	0.530
HSV, oral	5	4 (9.8)	4	3 (9.7)	1	1 (2.4)	0.307
Sinusitis	3	3 (7.3)	2	2 (6.4)	5	1 (2.4)	0.579
Sore throat	13	10 (24.4)	7	5 (16.1)	12	11 (26.2)	0.613
URI	19	11 (26.8)	8	7 (22.6)	16	11 (26.2)	0.927
UTI	2	2 (4.9)	2	1 (3.2)	1	1 (2.4)	0.836
Wart	2	2 (4.9)	0	0 (0)	1	1 (2.4)	0.631
GI Toxicity	13	7 (17.1)	12	9 (29.0)	12	9 (21.4)	0.487
Diarrhea	7	6 (14.6)	5	4 (12.9)	5	5 (11.9)	0.941
Emesis	5	4 (9.8)	6	5 (16.1)	2	2 (4.8)	0.222
Nausea	1	1 (2.4)	0	0 (0)	3	3 (7.1)	0.450
Hematologic	9	7 (17.1)	14	9 (29.0)	9	6 (14.3)	0.288
Leukopenia	1	1 (2.4)	4	3 (9.7)	0	0 (0)	0.064
Lymphopenia	0	0 (0)	2	2 (6.4)	0	0 (0)	0.072
Neutropenia	8	7 (17.1)	8	6 (19.4)	9	6 (14.3)	0.860
Miscellaneous	45	22 (53.7)	25	10 (32.3)	29	16 (38.1)	0.147
Cough	6	6 (14.6)	1	1 (3.2)	2	2 (4.8)	0.187
Elevated liver enzymes	7	4 (9.8)	0	0 (0)	0	0 (0)	0.13
Headache	4	4 (9.8)	5	1 (3.2)	2	2 (4.8)	0.551
Hyperglycemia	4	3 (7.3)	3	3 (9.7)	4	3 (7.1)	0.914
Hypoglycemia	19	11 (26.8)	13	7 (22.6)	18	8 (19.1)	0.692
Pain	2	2 (4.9)	1	1 (3.2)	1	1 (2.4)	0.836

Mood alteration	3	2 (4.9)	2	2 (6.4)	2	2 (4.8)	1.000
Serious	19	14 (34.2)	9	5 (16.1)	3	3 (7.1)	0.007
Cataract	2	1 (2.4)	0	0 (0)	0	0 (0)	0.632
Elevated liver enzymes	2	2 (4.9)	0	0 (0)	0	0 (0)	0.200
Hyperglycemia	1	1 (2.4)	0	0 (0)	2	2 (4.8)	0.778
Neutropenia	3	3 (7.3)	1	1 (3.2)	1	1 (2.4)	0.530

* p-value is based on two-sided Fisher's exact test

** > 10,000 DNA copies/ml

Six additional serious adverse events occurred in the DZB alone group (emesis, fracture, hypoglycemia, 2 neutropenia, and poor diabetes control) not included in the table above.