Diabetes TrialNet

MMF-DZB Study ELIGIBILITY AND RANDOMIZATION FORM

Form MMF03 October 01, 2005

Page 1 of 3

Selecting 15.	Site Number:		Screening ID:		First 3 Letters of First Name:	
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Complete this form during the Baseline visit (Week 0) immediately prior to randomization, <u>or</u> when a screened patient is determined to be ineligible to participate in this study.

A. FORM COMPLETION INFORMATION

1. Date form completed: $-\frac{1}{MM}$	$\frac{1}{DD}$ $\frac{1}{Y}$	YYY
B. INCLUSION CRITERIA		
1. Patient is within 3-months of diagnosis of type 1 diabetes based on ADA criteria (FPG ≥ 126 mg/dl or NFPG ≥ 200 mg/dl)?	Y	N
2. Patient is between 12 and 35 years of age?	Y	N
3. Patient has stimulated C-peptide levels ≥ 0.2 pmol/ml?	Y	N
4. Patient is willing to be randomized to treatment group?	Y	N
5. Patient has completed the 4-hour MMTT and all screening and baseline procedures?	Y	N
6. Patient has either detectable anti-GAD, anti-ICA512/IA-2, insulin autoantibodies (drawn within one-week of start of insulin therapy), or islet cell autoantibodies?	Y	N
7. Patient is willing to attend all scheduled follow-up visits at the designated clinic (unforeseen events withstanding)?	Y	N
8. Patient is willing to comply with intensive diabetes management?	Y	N
C. EXCLUSION CRITERIA		
1. Patient is sexually active and refuses to use an effective form of birth control?	Y	N
2. Patient is a female with reproductive potential who refuses to undergo pregnancy testing during the course of the MMF/DZB study? (<i>If male, answer No</i>)	Y	N
3. Patient is a female with reproductive potential who refuses to promptly report possible or confirmed pregnancies during the course of the MMF/DZB study? (<i>If male, answer No</i>)	Y	N
4. Patient is a female who is currently pregnant or less than 3 months postpartum? (<i>If male, answer No</i>)	Y	N
5. Patient is a female who is currently nursing or within 6 weeks of having completed nursing? (<i>If male, answer No</i>)	Y	N
6. Patient anticipates becoming pregnant, or fathering a child, during the study?	Y	N
7. Patient has complicating medical issues that would interfere with blood drawing or monitoring	g? Y	N
8. Patient has body mass index greater than 95 th percentile for age and gender?	Y	N
9. Patient has serologic evidence of HIV infection?	Y	N
10. Patient has serologic evidence of Hepatitis B or C infection?	Y	N
11. Patient has abnormal liver function tests?	Y	N
12. Patient has a history of leukopenia and/or neutropenia?	Y	N
13. Patient has a history of chronic peptic ulcer disease, erosive esophagitis, chronic inflammator bowel disease and/or chronic colonic disease?	Y	N
14. Patient has a positive PPD test result?	Y	N
15. Patient has had any live vaccinations in the preceding 6 weeks?	Y	N
16. Patient requires chronic use of steroids or other immunosuppressive agents for other conditions?	Y	N

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).

MMF-DZB Study Form MMF03 **Diabetes** ELIGIBILITY AND RANDOMIZATION FORM October 01, 2005 TrialNet Page 2 of 3 First 3 Letters of First Name: Site Number: Screening ID: STOP AND DOUBLE CHECK ELIGIBILITY Double check sections B and C. To randomize a participant, you must have Answered YES to every inclusion criteria **AND** Answered NO to every exclusion criteria AND Completed all Baseline assessments (including **all** sections of the Baseline Form (**MMF02**)) satisfactorily IF NOT ELIGIBLE, STOP HERE. D. RANDOMIZATION 1. Was the participant randomized? IF YES. a. Date of randomization: DD b. Randomization number: IF NO.

IF NO, STOP HERE

c. Explain:

E. DACLIZUMAB ADMINISTRATION

1.	Was t	he participant	given hi	s/her fi	rst IV	infusion	(DZB	or DZB	placebo)	at this s	tudy	visit?
		IF YES,										

Y N

a. Dose of DZB or DZB placebo infused:

___ __

b. Affix second part of label from DZB or DZB placebo infusion kit administered to the participant:



IF NO,

c. Explain:

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).

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MMF-DZB Study ELIGIBILITY AND RANDOMIZATION FORM

Form MMF03

October 01, 2005 Page 3 of 3

Site Number:	Screening ID:	 First 3 Letters of First Name:	
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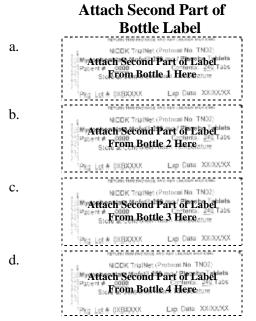
F. DISPENSATION OF MYCOPHENOLATE MOFETIL

Instructions:

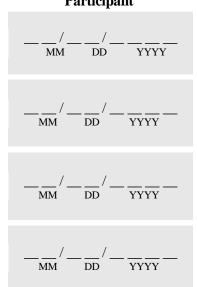
- (1) The participant should take the first dose of the study medication in the clinic before leaving.
- (2) The Study Coordinator should write today's date on the label of the bottle (in the space provided).
- (3) The participant should continue taking the study medication, per the instructions on the bottle, until it is empty (unless instructed differently by Study Coordinator).
- (4) When the last capsule is taken from the bottle, the participant should write the date on the label of the bottle (in the space provided).
- (5) The participant should begin taking capsules from the second bottle at the next dosing time after completing the first bottle.
- (6) The participant will write the date on the label of the new capsule bottle (in the space provided).
- (7) The participant should take medication as prescribed from this capsule bottle until he/she returns to the study clinic to receive refill bottles (unless instructed differently by the Study Coordinator).
- (8) Have the participant write the date the last capsule was taken from this bottle (in the space provided).

1. Total daily dose of study medication prescribed following this clinic visit:								
2. Frequency of dosing prescribed:		Once per day		BID	\square_3	mg TID		
3. Record the Randomization Number used to dispense study medication:								

4. Labels and dates of study medication bottles dispensed to the participant at this study visit:







Initials (first, middle, last) of person completing this form: $\frac{1}{F} = \frac{1}{M} = \frac{1}{L}$

Date form completed: