

Site Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_ First 3 Letters of First Name: \_\_\_\_\_

**Complete this form during the Baseline visit (Week 0) immediately prior to randomization, or when a screened patient is determined to be ineligible to participate in this study.**

**A. FORM COMPLETION INFORMATION**

1. Date form completed:

__	__	/	__	__	/	__	__	__	__
MM			DD			YYYY			

**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? (If male, answer No)                         | 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? (If male, answer No) | Y | N |
| 4. Patient is a female who is currently pregnant or less than 3 months postpartum? (If male, answer No)  | Y | N |
| 5. Patient is a female who is currently nursing or within 6 weeks of having completed nursing? (If male, answer No)  | 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?  | Y | N |
| 8. Patient has body mass index greater than 95 <sup>th</sup> 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 inflammatory 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).*

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**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? Y N

IF YES,

a. Date of randomization:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
MM DD YYYY

b. Randomization number:

\_\_\_\_\_  
\_\_\_\_\_

IF NO,

c. Explain:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**IF NO, STOP HERE**

**E. DACLIZUMAB ADMINISTRATION**

1. Was the participant given his/her first IV infusion (DZB or DZB placebo) at this study visit? Y N

IF YES,

a. Dose of DZB or DZB placebo infused:

\_\_\_\_\_  
mg

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



IF NO,

c. Explain:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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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: \_\_\_\_\_ mg
2. Frequency of dosing prescribed:  1 Once per day  2 BID  3 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:

**Attach Second Part of  
Bottle Label**

**1. Date Bottle Given to  
Participant**

<p>a.</p> <div style="border: 1px dashed black; padding: 5px; width: fit-content;"> <p style="font-size: small;">NICDK TrialNet (Protocol No. TNO2) Mycophenolate Mofetil Capsules, 250 mg Patient # 0000      250 Tabs Site: _____ Signature: _____ Exp. Lot #: 0XBXXXX      Exp. Date: XX/XX/XX</p> <p style="text-align: center;"><b>Attach Second Part of Label From Bottle 1 Here</b></p> </div>	<p>____/____/____ MM      DD      YYYY</p>
<p>b.</p> <div style="border: 1px dashed black; padding: 5px; width: fit-content;"> <p style="font-size: small;">NICDK TrialNet (Protocol No. TNO2) Mycophenolate Mofetil Capsules, 250 mg Patient # 0000      250 Tabs Site: _____ Signature: _____ Exp. Lot #: 0XBXXXX      Exp. Date: XX/XX/XX</p> <p style="text-align: center;"><b>Attach Second Part of Label From Bottle 2 Here</b></p> </div>	<p>____/____/____ MM      DD      YYYY</p>
<p>c.</p> <div style="border: 1px dashed black; padding: 5px; width: fit-content;"> <p style="font-size: small;">NICDK TrialNet (Protocol No. TNO2) Mycophenolate Mofetil Capsules, 250 mg Patient # 0000      250 Tabs Site: _____ Signature: _____ Exp. Lot #: 0XBXXXX      Exp. Date: XX/XX/XX</p> <p style="text-align: center;"><b>Attach Second Part of Label From Bottle 3 Here</b></p> </div>	<p>____/____/____ MM      DD      YYYY</p>
<p>d.</p> <div style="border: 1px dashed black; padding: 5px; width: fit-content;"> <p style="font-size: small;">NICDK TrialNet (Protocol No. TNO2) Mycophenolate Mofetil Capsules, 250 mg Patient # 0000      250 Tabs Site: _____ Signature: _____ Exp. Lot #: 0XBXXXX      Exp. Date: XX/XX/XX</p> <p style="text-align: center;"><b>Attach Second Part of Label From Bottle 4 Here</b></p> </div>	<p>____/____/____ MM      DD      YYYY</p>

**Initials (first, middle, last) of person completing this form:** \_\_\_\_\_  
F M L

**Date form completed:** \_\_\_\_\_  
MM      DD      YYYY

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