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 95th 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).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

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**

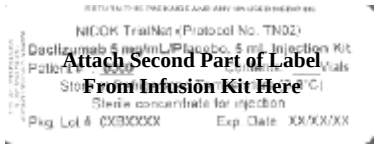
E. DACLIZUMAB ADMINISTRATION

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:



Attach Second Part of Label From Infusion Kit Here

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).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

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**
a.	 **Attach Second Part of Label From Bottle 1 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
b.	 **Attach Second Part of Label From Bottle 2 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
c.	 **Attach Second Part of Label From Bottle 3 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY
d.	 **Attach Second Part of Label From Bottle 4 Here**	__ __ / __ __ / __ __ __ __ MM DD YYYY

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

Date form completed: __ __ / __ __ / __ __ __ __ MM DD YYYY

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).*