Protocol # TN10 - Anti-CD3 Prevention

Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			

Eligibility

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * Date

Interviewer User ID: *

Eligibility Information

A. INCLUSION CRITERIA

1. Subject is a relative of a proband with T1DM?* Yes No

2. Subject has signed written informed consent for participation* Yes No

If yes, date consent was obtained:

3. If <18 yo, subject has an abnormal glucose tolerance by OGTT within 7 weeks of baseline visit:* Yes No

a. Fasting plasma glucose ≥110 mg/dL, and < 126 mg/dL **-AND/OR-**
b. 2-hour plasma glucose ≥140 mg/dL, and < 200 mg/dL **-AND/OR-**
c. 30, 60, or 90 minute value on OGTT ≥ 200 mg/dL

4. Subject has at least two diabetes related autoantibodies confirmed to be present on two occasions. The autoantibodies that will be confirmed are anti-GAD65, anti-ICA512, anti-insulin (MIAA), ZnT8 and/or ICA. Confirmation of 2 positive autoantibodies must occur within six months prior to study drug administration but the confirmation does not have to involve the same 2 autoantibodies.* Yes No

5. Subject weighs at least 26 kg at randomization?* Yes No

Please enter the participant's Baseline Visit weight:* kg

6. Subject is willing and medically acceptable to postpone live vaccine immunizations for one year after treatment?* Yes No

7. Subject is willing to forego other forms of experimental treatment during the study?* Yes No

B. EXCLUSION CRITERIA

1. Subject has diabetes?*	Yes No
2. If < 18 yo, subject has a screening random plasma glucose > 200mg/dL*	Yes No
3. Subject has Lymphopenia (< 1000 lymphocytes/µL)?*	Yes No
4. Subject has Neutropenia (< 1500 PMN/ µL)?*	Yes No
5. Subject has Thrombocytopenia (< 150,000 platelets/ µL)?*	Yes No
6. Subject has Anemia (Hgb < 10 grams/deciliter [g/dL])?*	Yes No
7. Subject has total bilirubin > 1.5 x upper limit of normal (ULN)?*	Yes No
7a. Subjects with the presumptive diagnosis of Gilbert's syndrome may be eligible provided they have no other causes leading to hyperbilirubinemia. Are there any other causes leading to hyperbilirubinemia other than a diagnosis of Gilbert's syndrome?*	Yes No
8. Subject has AST or ALT > 1.5 x ULN?*	Yes No
9. Subject has INR > 0.1 above the upper limit of normal at the Center's laboratory.*	Yes No
10. Subject has a chronic active infection other than localized skin infections.*	Yes No
11. Subject has a positive PPD test result.*	Yes No
12. Subject has had a vaccination with a live virus within 8 weeks of randomization.*	Yes No
13. Subject has had a vaccination with a killed virus within 4 weeks of randomization.*	Yes No
14. Subject has had a history of infectious mononucleosis within the 3 months prior to enrollment.*	Yes No
15. Subject has laboratory or clinical evidence of acute infection with EBV or CMV.*	Yes No
16. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection.*	Yes No
17. Subject has chronic use of steroids or other immunosuppressive agents.*	Yes No
18. Subject has a history of asthma or atopic disease requiring chronic treatment.*	Yes No
19. Subject has untreated hypothyroidism or Graves' disease at	

randomization.*	Yes No
20. Subject is currently using non-insulin pharmaceuticals to affect glycemic control.*	Yes No
21. Subject has had prior OKT®3 treatment or other anti-CD3 treatment.*	Yes No
22. Subject has had prior administration of a monoclonal antibody within the previous 1 year before randomization.*	Yes No
23. Subject is currently participating or has had previous participation in any type of therapeutic drug or vaccine clinical trial within the last 12 weeks before randomization.*	Yes No
24. Subject has any condition that, in the opinion of the investigator, would interfere with the study conduct or the safety of the subject.*	Yes No
25. Subject is sexually active and refuses to use an effective form of birth control.*	Yes No
26. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study.*	Yes No
27. Subject is not willing to avoid pregnancy (if male, in any partners) for at least one year from randomization?*	Yes No

If FEMALE, answer the following questions (28-31):

28. Subject has reproductive potential and refuses to undergo pregnancy testing during the course of study.*	Yes No
29. Subject is currently pregnant or less than three months postpartum.*	Yes No
30. Subject is currently lactating?*	Yes No
31. Subject refused or did not complete the pregnancy test at this visit.*	Yes No

Eligibility Committee Review

Answer the following question **ONLY** if the participant has not met eligibility requirements and has undergone Eligibility Committee review; otherwise, leave blank.

Subject is eligible per eligibility committee	Yes No

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