Protocol # TN10 - Anti-CD3 Prevention

Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			
Randomization ID:			
Treatment Assign Date:		Treatment Start Date:	

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. Subject has an abnormal glucose tolerance by OGTT confirmed 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. Subject has an OGTT with:

a. Fasting plasma glucose ≥ 126 mg/dL -**AND/OR-***	Yes No
b. 2-hour plasma glucose ≥ 200 mg/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
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

C. DATE OF BIRTH

Subject's date of birth: *

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

Participant is ELIGIBLE for the study according to the Inclusion/Exclusion criteria. Prior to randomization, ensure the site PI has reviewed all central laboratory test results and has confirmed eligibility.

Please contact the TN10 Anti-CD3 Prevention CRA at the Coordinating Center for any questions regarding the Inclusion/Exclusion Criteria.

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