

Site Number:  
Date of Visit:  
Person Completing Form:

Participant ID:  
Participant Letters:

**A. INCLUSION CRITERIA\***

1. Subject is a relative of a proband with T1DM?

Y  N

2. Subject has signed written informed consent for participation  
If yes, date consent was obtained:

Y  N

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR

3a. If  $\geq 18$ yo, subject has an abnormal glucose tolerance by OGTT confirmed within 7 weeks of baseline visit:

Y  N

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

Y  N

3b. If  $< 18$  yo, subject has an abnormal glucose tolerance by OGTT within 7 weeks of baseline visit:

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

Y  N

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 the previous six months but the confirmation does not have to involve the same 2 autoantibodies.

Y  N

5. Subject weighs at least 26 kg at randomization?

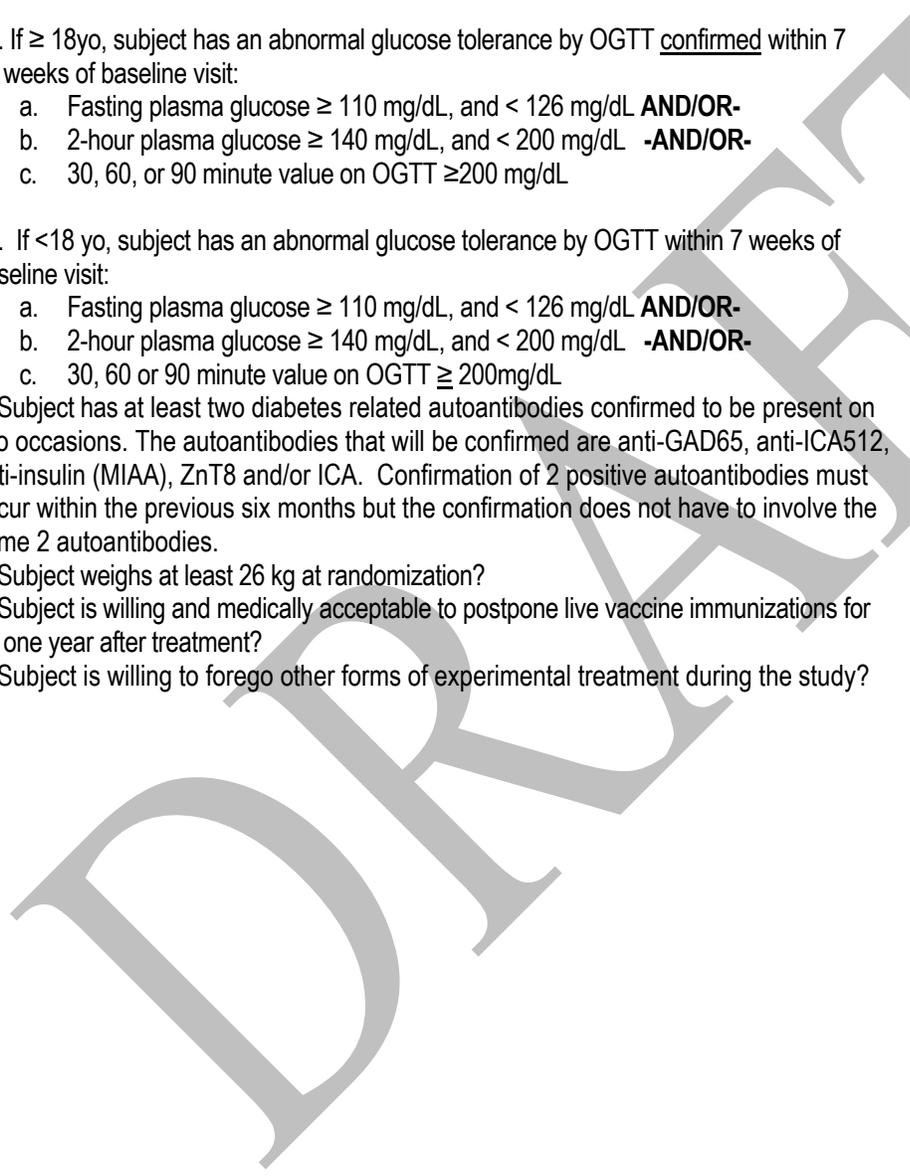
Y  N

6. Subject is willing and medically acceptable to postpone live vaccine immunizations for one year after treatment?

Y  N

7. Subject is willing to forego other forms of experimental treatment during the study?

Y  N



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**B. EXCLUSION CRITERIA\***

- 1. Subject has diabetes?  Y  N
- 2a. If  $\geq 18$  yo, subject has an OGTT with:
  - a. Fasting plasma glucose  $\geq 126$  mg/dL **-AND/OR-**  Y  N
  - b. 2-hour plasma glucose  $\geq 200$  mg/dL  Y  N
- 2b. If  $< 18$  yo, subject has a screening random plasma glucose  $\geq 200$ mg/dL.3. Subject has Lymphopenia ( $< 1000$  lymphocytes/ $\mu$ L)?  Y  N
- 4. Subject has Neutropenia ( $< 1500$  PMN/  $\mu$ L)?  Y  N
- 5. Subject has Thrombocytopenia ( $< 150,000$  platelets/  $\mu$ L)?  Y  N
- 6. Subject has Anemia (Hgb  $< 10$  grams/deciliter [g/dL])?  Y  N
- 7. Subject has total bilirubin  $> 1.5$  x upper limit of normal (ULN)?  Y  N
- 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?  Y  N
- 8. Subject has AST or ALT  $> 1.5$  x ULN?  Y  N
- 9. Subject has INR  $> 0.1$  above the upper limit of normal at the Center's laboratory?  Y  N
- 10. Subject has a chronic active infection other than localized skin infections.  Y  N
- 11. Subject has a positive PPD test result.  Y  N
- 12. Subject has had a vaccination with a live virus within 8 weeks of randomization.  Y  N
- 13. Subject has had a vaccination with a killed virus within 4 weeks of randomization.  Y  N
- 14. Subject has had a history of infectious mononucleosis within the 3 months prior to enrollment.  Y  N
- 15. Subject has laboratory or clinical evidence of acute infection with EBV or CMV.  Y  N
- 16. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection.  Y  N
- 17. Subject has chronic use of steroids or other immunosuppressive agents.  Y  N
- 18. Subject has a history of asthma or atopic disease requiring chronic treatment.  Y  N
- 19. Subject has untreated hypothyroidism or Graves' disease at randomization.  Y  N
- 20. Subject is currently using non-insulin pharmaceuticals to affect glycemic control  Y  N
- 21. Subject has had prior OKT@3 treatment or other anti-CD3 treatment.  Y  N
- 22. Subject has had prior administration of a monoclonal antibody within the previous 1 year before randomization.  Y  N
- 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  Y  N
- 24. Subject has any condition that, in the opinion of the investigator, would interfere with the study conduct or the safety of the subject.  Y  N
- 25. Subject is sexually active and refuses to use an effective form of birth control.  Y  N
- 26. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study.  Y  N
- 27. Subject is not willing to avoid pregnancy (if male, in any partners) for at least one year from randomization?  Y  N

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

- 28. Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study.  Y  N
- 29. Subject is currently pregnant or less than three months postpartum.  Y  N
- 30. Subject is currently lactating?  Y  N
- 31. Subject refused or did not complete the pregnancy test at this visit  Y  N

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**C. Date of Birth**

Subject's Date of Birth:

\_\_\_/\_\_\_/\_\_\_  
DAY MONTH YEAR

**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

Y  N

DRAFT