

Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

A. INCLUSION CRITERIA

1. Subject is between 6 and 45 years of age (inclusive)?
2. Subject is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria?
3. Subject has at least one diabetes-related autoantibody present?
4. Subject has stimulated C-peptide levels ≥ 0.2 pmol/ml?
5. Subject has not had any live immunizations in the preceding month?
6. Subject is willing to forgo live vaccinations during the 12 months of treatment and for an additional 3 months?
7. Subject is willing to comply with intensive diabetes management?
8. Subject weighs at least 20 kg (44 lb) at study entry?
9. Subject has signed written informed intervention consent for participation

If yes, date consent was obtained:

If yes, was permission given for samples of the participant's blood to be stored for other tests?

If yes: ☐ with DNA ☐ without DNA (this answer will not affect eligibility)

[illegible]

B. EXCLUSION CRITERIA

1. Subject is immunodeficient or has clinically significant chronic lymphopenia?
2. Subject has an active infection?
3. Subject has a positive PPD test result?
4. Subject is currently using medications known to influence glucose tolerance?
5. Subject requires use of other immunosuppressive agents?
6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection?
7. Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk (including pre-existing cardiac disease, COPD, neurological or blood count abnormalities such as lymphopenia, leucopenia or thrombocytopenia)?
8. Subject has a history of malignancies?
9. Subject is currently using non-insulin pharmaceuticals to affect glycemic control?
10. Subject is currently participating in another type 1 diabetes treatment study?

[illegible]

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11. Subject is sexually active and refuses to use an effective form of birth control?
12. Subject has reproductive potential and refuses to undergo pregnancy testing and/or promptly report possible or confirmed pregnancies during the course of the study?
13. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study?
14. Subject is currently pregnant?
15. Subject is currently breastfeeding?
16. Subject anticipates becoming pregnant?
17. Subject refused or did not complete the pregnancy test at this visit?

[illegible]