

Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

A. INCLUSION CRITERIA

- | | | |
|---|-------------------------|-------------------------|
| 1. Subject is between 16 and 45 years of age (inclusive)? | <input type="radio"/> Y | <input type="radio"/> N |
| 2. Subject is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria? | <input type="radio"/> Y | <input type="radio"/> N |
| 3. Subject has stimulated C-peptide levels ≥ 0.2 pmol/ml? | <input type="radio"/> Y | <input type="radio"/> N |
| 4. Subject has detectable GAD65 autoantibodies? | <input type="radio"/> Y | <input type="radio"/> N |
| 5. Subject has not had any vaccinations in the preceding month? | <input type="radio"/> Y | <input type="radio"/> N |
| 6. Subject is willing to comply with intensive diabetes management? | <input type="radio"/> Y | <input type="radio"/> N |
| 7. Subject is willing to be randomized to either group? | <input type="radio"/> Y | <input type="radio"/> N |
| 8. Subject weighs at least 20 kg (44 lb) at study entry? | <input type="radio"/> Y | <input type="radio"/> N |
| 9. Subject is willing to forgo immunizations for 100 days after first injection? | <input type="radio"/> Y | <input type="radio"/> N |
| 10. Subject has signed written informed intervention consent for participation | <input type="radio"/> Y | <input type="radio"/> N |

If yes, date consent was obtained:

_	_	_	_	_	_	_	_	_	_
DAY		MONTH		YEAR					
<input type="radio"/> Y	<input type="radio"/> N								

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

If yes: with DNA without DNA

B. EXCLUSION CRITERIA

- | | | |
|--|-------------------------|-------------------------|
| 1. Subject is taking any medications that are known to influence glucose tolerance? | <input type="radio"/> Y | <input type="radio"/> N |
| 2. Subject requires chronic use of systemic steroids or other immunosuppressive agents for other conditions? | <input type="radio"/> Y | <input type="radio"/> N |
| 3. Subject has a history of malignancies? | <input type="radio"/> Y | <input type="radio"/> N |
| 4. Subject is currently using non-insulin pharmaceuticals to affect glycemic control? | <input type="radio"/> Y | <input type="radio"/> N |
| 5. Subject has acute or chronic complicating medical issues that in the opinion of the investigator would interfere with study conduct or cause increased risk including neurological abnormalities? | <input type="radio"/> Y | <input type="radio"/> N |
| 6. Subject has abnormal laboratory tests that in the opinion of the investigator would interfere with study conduct? | <input type="radio"/> Y | <input type="radio"/> N |
| 7. Subject has a history of epilepsy, significant head trauma or cerebrovascular accident or clinical features of continuous motor unit activity in proximal muscles? | <input type="radio"/> Y | <input type="radio"/> N |
| 8. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection? | <input type="radio"/> Y | <input type="radio"/> N |
| 9. Subject has an active infection or positive PPD test result? | <input type="radio"/> Y | <input type="radio"/> N |

If FEMALE, answer the following questions (10-15):

- | | | |
|---|-------------------------|-------------------------|
| 10. Subject is sexually active and refuses to use an effective form of birth control? | <input type="radio"/> Y | <input type="radio"/> N |
| 11. Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study? | <input type="radio"/> Y | <input type="radio"/> N |
| 12. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study? | <input type="radio"/> Y | <input type="radio"/> N |
| 13. Subject is currently pregnant or less than three months postpartum? | <input type="radio"/> Y | <input type="radio"/> N |
| 14. Subject anticipates becoming pregnant within 24 months after first injection? | <input type="radio"/> Y | <input type="radio"/> N |
| 15. Subject refused or did not complete the pregnancy test at this visit? | <input type="radio"/> Y | <input type="radio"/> N |