

Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

A. INCLUSION CRITERIA

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|--|---|-------------------------|--------------------------------|-----------|----------------------|
| 1. Subject is between 6 and 45 years of age (inclusive)? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 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 | <input type="radio"/> Not Done | | |
| 3. Subject has at least one diabetes-related autoantibody present? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 4. Subject has stimulated C-peptide levels \geq 0.2 pmol/ml? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 5. Subject has not had any live immunizations in the preceding month? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 6. Subject is willing to forgo live vaccinations during the 12 months of treatment and for an additional 3 months? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 7. Subject is willing to comply with intensive diabetes management? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 8. Subject weighs at least 20 kg (44 lb) at study entry? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| 9. Subject has signed written informed intervention consent for participation | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| If yes, date consent was obtained: | <table border="0" style="margin-left: 20px;"> <tr> <td style="text-align: center;">_ / _ / _</td> </tr> <tr> <td style="text-align: center;">DAY MONTH YEAR</td> </tr> </table> | | | _ / _ / _ | DAY MONTH YEAR |
| _ / _ / _ | | | | | |
| DAY MONTH YEAR | | | | | |
| If yes, was permission given for samples of the participant's blood to be stored for other tests? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done | | |
| If yes: <input type="checkbox"/> with DNA <input type="checkbox"/> without DNA (this answer will not affect eligibility) | | | | | |

B. EXCLUSION CRITERIA

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|--|-------------------------|-------------------------|--------------------------------|
| 1. Subject is immunodeficient or has clinically significant chronic lymphopenia? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 2. Subject has an active infection? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 3. Subject has a positive PPD test result? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 4. Subject is currently using medications known to influence glucose tolerance? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 5. Subject requires use of other immunosuppressive agents? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 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)? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 8. Subject has a history of malignancies? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 9. Subject is currently using non-insulin pharmaceuticals to affect glycemic control? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 10. Subject is currently participating in another type 1 diabetes treatment study? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |

