

Site Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_

Participant Letters: \_\_\_\_\_

**Complete this form any time BEFORE RANDOMIZATION. Use this form to record a Subject's ineligibility or withdrawal from the study.**

**A. DATE**

1. Date screening discontinued:

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

**B. REASON FOR STUDY INELIGIBILITY**

Mark the reason(s) for discontinuing the screening process: *(check all that apply)*

- |  |  |
|--|--|
| 1. <input type="checkbox"/> 1 Subject does not have at least one diabetes-related autoantibody present   | 14. <input type="checkbox"/> 1 Subject has history of malignancies   |
| 2. <input type="checkbox"/> 1 Subject is not within 3-months (100 days) of diagnosis of type 1 diabetes  | 15. <input type="checkbox"/> 1 Subject requires use of non-insulin pharmaceuticals that affect glycemic control or influence glucose tolerance |
| 3. <input type="checkbox"/> 1 Subject is not between the ages of 6 and 45 years  | 16. <input type="checkbox"/> 1 Subject has serologic evidence of HIV, Hep B, or Hep C infection  |
| 4. <input type="checkbox"/> 1 Subject has complicating medical issues that would interfere with the study conduct or cause increased risk                          | 17. <input type="checkbox"/> 1 Subject has history of immunodeficiency or lymphopenia  |
| 5. <input type="checkbox"/> 1 Subject does not have stimulated C-peptide levels $\geq 0.2$ pmol/ml   | 18. <input type="checkbox"/> 1 Subject withdrew consent  |
| 6. <input type="checkbox"/> 1 Subject is female with reproductive potential and is not willing to avoid pregnancy.   | 19. <input type="checkbox"/> 1 Subject is currently participating in another type 1 diabetes treatment study                                   |
| 7. <input type="checkbox"/> 1 Subject weighs less than 20 kg (44 lb)   | 20. <input type="checkbox"/> 1 Other   |
| 8. <input type="checkbox"/> 1 Subject is not willing to forgo live vaccinations during treatment and for at least 3 months after the last dose of study medication | If OTHER, a. Specify:  |
| 9. <input type="checkbox"/> 1 Subject is not at least three months from last live immunization received  | _____  |
| 10. <input type="checkbox"/> 1 Subject is currently pregnant or lactating  | _____  |
| 11. <input type="checkbox"/> 1 Subject has an active infection or positive PPD test  | _____  |
| 12. <input type="checkbox"/> 1 Subject is not willing to comply with intensive diabetes management   |  |
| 13. <input type="checkbox"/> 1 Subject requires use of other immunosuppressive agents  |  |

**Initials (first, middle, last) of person completing this form:**

\_\_\_\_ F M L

**Date form completed:**

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

*On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "\*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*