

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)*

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

If OTHER, a. Specify:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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).*