

Site Number:
Date of Visit:
Person Completing Form:

Participant 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):*

<input type="checkbox"/>	Subject has diabetes.
<input type="checkbox"/>	Subject is ≥18yo and has an OGTT with: a. Fasting plasma glucose ≥ 126 mg/dL AND/OR b. 2-hour plasma glucose ≥ 200 mg/dL
<input type="checkbox"/>	Subject is ≥18yo and has an OGTT with: a. Fasting plasma glucose < 110 mg/dL AND b. 2-hour plasma glucose < 140 mg/dL AND c. 30, 60, or 90 minute value on OGTT < 200 mg/dL
<input type="checkbox"/>	Subject is <18yo and has a screening random glucose ≥ 200mg/dL
<input type="checkbox"/>	Subject has Lymphopenia (< 1000 lymphocytes/μL)
<input type="checkbox"/>	Subject has Neutropenia (< 1500 PMN/ μL)
<input type="checkbox"/>	Subject has Thrombocytopenia (< 150,000 platelets/ μL)
<input type="checkbox"/>	Subject has Anemia (Hgb < 10 grams/deciliter [g/dL])
<input type="checkbox"/>	Subject has total bilirubin > 1.5 x upper limit of normal (ULN).
<input type="checkbox"/>	Subject has AST or ALT > 1.5 x ULN.
<input type="checkbox"/>	Subject has INR > 0.1 above the upper limit of normal at the Center's laboratory.
<input type="checkbox"/>	Subject has a chronic active infection other than localized skin infections.
<input type="checkbox"/>	Subject has a positive PPD test result.
<input type="checkbox"/>	Subject has had a vaccination with a live virus within 8 weeks of randomization.
<input type="checkbox"/>	Subject has had a vaccination with a killed virus within 4 weeks of randomization.
<input type="checkbox"/>	Subject has had a history of infectious mononucleosis within the 3 months prior to enrollment.
<input type="checkbox"/>	Subject has laboratory or clinical evidence of acute infection with EBV or CMV.
<input type="checkbox"/>	Subject has serologic evidence of current or past HIV, Hepatitis B or C infection.
<input type="checkbox"/>	Subject has chronic use of steroids or other immunosuppressive agents.
<input type="checkbox"/>	Subject has a history of asthma or atopic disease requiring chronic treatment.
<input type="checkbox"/>	Subject has untreated hypothyroidism or Graves' disease at randomization.
<input type="checkbox"/>	Subject is currently using non-insulin pharmaceuticals to affect glycemic control.
<input type="checkbox"/>	Subject has had prior OKT®3 treatment or other anti-CD3 treatment.
<input type="checkbox"/>	Subject has had prior administration of a monoclonal antibody within the previous 1 year before randomization.
<input type="checkbox"/>	Subject is currently participating or previously participated in a therapeutic drug or vaccine clinical trial within the last 12 weeks.
<input type="checkbox"/>	Subject has a condition, in the opinion of the investigator, that would interfere with the study conduct or the safety of the subject.
<input type="checkbox"/>	Subject is sexually active and refuses to use an effective form of birth control.
<input type="checkbox"/>	Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study.
<input type="checkbox"/>	Subject is not willing to avoid pregnancy (if male, in any partners) for at least one year from randomization.

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If female:

	Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study.
	Subject is currently pregnant or less than three months postpartum.
	Subject is currently lactating.
	Subject refused or did not complete the pregnancy test at this visit.