

[REDACTED]	Date of Visit:
Dr. [REDACTED]	Subject ID:

Follow Up Visits

Date of Visit: _____

- Week 4
 Week 8
 Week 12
 Week 18
 Week 24
 Week 30
 Week 36
 Week 42
 Week 48
 Week 54
 Week 60
 Week 66
 Week 72
 Week 78
 Week 84
 Week 90
 Week 96

- Adverse Events
- Concomitant Medications
- Validated Investigator's Assessment (vIGA)
- Eczema Area Severity Index (EASI)
- Tanner Staging (if applicable)
- TB Risk Assessment Form/ TB test (Only on Week 48)
- Chest X-ray (Only on Week 48)
- Vital Signs
- Physical Exam (Except week 8)
- 12 Lead ECG (Only on Week 48)
- Urinalysis
- Urine pregnancy test (if applicable)
- Blood Draw
- PK Samples (If applicable)
- Dispense Study Drug
- Dispense Home Urine Pregnancy Tests (if applicable)
- ClinCard
- Scheduling
- Requisition

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Adverse Events

Was adverse events chart reviewed? Yes No

Concomitant Medications

Was con meds chart reviewed? Yes No

Validated global Assessment (vIGA)

Was the assessment done? (separate form): Yes No

Eczema Area and Sensitivity Index (EASI)

Was the assessment done? (separate form): Yes No

Tanner Staging (Weeks 24, 48, and 72 Only)

Was the assessment done? (separate form): Yes No

TB Risk Assessment Form (Only on Week 48)

Was the Risk Assessment Form completed? (separate form): Yes No

Chest X-ray (only if applicable per TB Risk Assessment Form)

Completed: Date/Time: _____ N/A

Vital Signs

Blood Pressure: _____/_____ mmHg

Pulse: _____ beats/min

Respiratory Rate: _____ breaths/min

Temperature: _____ F C

Weight: _____ lb kg

Height: _____ in cm

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Physical Exam

(Except Week 8)

Date: ____/____/____

Time: ____:____

Body System	Result	Abnormality
General Appearance	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Head, Neck, Ears, Nose, Throat, Eyes	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Dermatologic	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Cardiovascular	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Respiratory	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Abdomen	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Neurological	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Musculoskeletal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Extremities	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Lymph Nodes	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	
Other (specify):	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, clinically significant <input type="checkbox"/> Not Done significant <input type="checkbox"/> Abnormal, not clinically significant	

PI Signature: _____ Date: _____

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12-Lead ECG (Only on Week 48)

Date of ECG: ____/____/____ Time of ECG: ____:____
dd mmm yyyy hh mm

Investigator's Interpretation:

- Normal
- Abnormal, clinically significant
- Abnormal, not clinically significant
- Not evaluable

Abnormal Findings:

- | | | |
|--|--|--|
| <input type="checkbox"/> Abnormal rhythm | <input type="checkbox"/> Left Ventricular hypertrophy | <input type="checkbox"/> T wave abnormality |
| <input type="checkbox"/> Abnormal conduction | <input type="checkbox"/> Right Ventricular hypertrophy | <input type="checkbox"/> U wave abnormality |
| <input type="checkbox"/> Axis QRS >+120 | <input type="checkbox"/> Q wave abnormality | <input type="checkbox"/> QTcF prolongation |
| <input type="checkbox"/> Axis QRS < -30 | <input type="checkbox"/> ST segment depressed > +1mm | <input type="checkbox"/> Other abnormality, specify: |
| <input type="checkbox"/> Axis indeterminate | <input type="checkbox"/> ST segment elevated > =1mm | |

If QTcF prolongation, QTcF = _____ msec (M: >430MSEC; F: >450MSEC)

If QTcF prolongation, baseline = _____ msec (prior to drug exposure)

Urinalysis

Was the urinalysis performed? Yes No

Time performed: _____:_____

PREGNANCY TEST – IF APPLICABLE

Was Pregnancy Test Performed? YES NO N/A

If Yes: Collection Date: ____/____/____
dd mmm yyyy

Result: Positive Negative

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Test Type: Serum Urine

If No: specify Post-menopausal Surgically Sterile

Blood Draw

(TB Quantiferons Only on Week 48)

Was the blood draw performed? Yes No

Time performed: _____:_____

PK Sampling

(If dose is modified based on analysis of data from Part 2, sample will be collected prior to dosing on visit day and at subsequent visit.)

(Sample will not be collected when dose is changed due to change in subject's weight.)

Was the blood draw performed? Yes No

Time performed: _____:_____

Drug Return

Where used kits returned? Yes No

If yes, what kits were returned? _____

Drug Dispense & Dosing Review

Formulation: tablet Solution

Date & Time of second to last dose: _____

Date & Time of last dose: _____

Was study drug dispensed and dosing reviewed? Yes No

Was there a change is patient dosing? Yes No

Dispense Home Urine Pregnancy Tests

(females of childbearing potential only)

Was the pregnancy tests dispensed? Yes N/A

ClinCard Form

Was a clincard form filled out and clincard given? Yes No

Scheduling

Was the next visit scheduled? Yes No

Requisition Form

Was the requisition form filled out? Yes No