

Blank PDF

79635322MMY3002 Version 1.02 06MAR2026 - All Forms

Generated On: 06 Mar 2026 12:08:14

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Subject

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please save the form and the subject number will be automatically added to the 'Subject' field

Subject

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Date of Visit

Generated On: 06 Mar 2026 12:08:14 (GMT)

Did this visit occur? Yes ☐
No ☐

Subject's Status Continuing ☐
Discontinuing Study ☐

Visit Start Date _____

Type of Contact Audio-Videoconferencing ☐
Home Visit ☐
Site Visit ☐
Telephone Call ☐

Reason this visit did not occur Adverse Event ☐
Natural Disaster, Major ☐
Disruption or Pandemic ☐
Subject / Caregiver Unavailable ☐
Other ☐

If 'Adverse Event,' select the primary corresponding AE log line, start date, and term _____

If Other, specify _____

Planned visit date _____

Project Name: 79635322MMY3002

Form: Date of Visit (Unscheduled)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Visit Start Date	
Type of Contact	Audio-Videoconferencing ☐
	Home Visit ☐
	Site Visit ☐
	Telephone Call ☐

Project Name: 79635322MMY3002

Form: Cycle Delay

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was Day 1 of the cycle delayed? Yes ☐
No ☐

What was the reason the cycle was delayed? Adverse Event ☐
Other ☐

If Reason was Adverse Event, choose the corresponding AE log
line(s), start date(s), and term(s)

 AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

If Other, Specify

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Next Cycle Selection

Generated On: 06 Mar 2026 12:08:14 (GMT)

Does the subject continue to the next treatment cycle?

Yes ☐

No ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Next Cycle Selection (LTE)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Does the subject continue to the next LTE phase treatment cycle?

Yes ☐

No ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Next Visit Selection

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were additional administrations of study drug performed to handle
repeat step-up dosing per protocol?

Yes ☐

No ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Unscheduled Assessments

Generated On: 06 Mar 2026 12:08:14 (GMT)

Vital Signs	
Pregnancy Test	
ECG Results	
Local Hematology (Unscheduled)	
Local Chemistry (Unscheduled)	
Local Hematology_Coagulation Tests (Uns)	
Diagnostic and Safety Monitoring Procedures	
Arterial Blood Gases	
Serology (Unscheduled)/Additional Serology Follow-up	
ICE score (Unscheduled)	
ECOG Performance Status	
Central Laboratory Pharmacokinetics Blood Sample	
Cytokine Profile (Local)	
Bone Marrow Aspirate Sampling for Central Cytogenetics (FISH)	
Local Cytogenetic Testing (FISH)	
Unscheduled Local Immunoglobulines (related to Hypogammaglobulinemia)	
ePRO Completion Status	
Central Laboratory Pharmacokinetics Blood Sample	
Local Efficacy Lab Results - Serum	
Local Efficacy Lab Results - Urinalysis	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Disease Evaluation Date of Visit

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was this visit completed? Yes ☐
No ☐

Visit date _____

Planned visit date _____

Reason this visit did not occur Adverse Event ☐

Natural Disaster, Major ☐

Disruption or Pandemic ☐

Subject / Caregiver Unavailable ☐

Other ☐

If 'Adverse Event,' select the primary corresponding AE log line,
start date, and term _____

If 'Other,' Specify _____

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Disease Evaluation Assessments

Generated On: 06 Mar 2026 12:08:14 (GMT)

Local Efficacy Lab Results - Serum (only in case central lab results are not available)	
Local Efficacy Lab Results - Urinalysis (only in case central lab results are not available)	
Bone Marrow for Morphology	
Bone Marrow for Immunohistochemistry / Flow Cytometry	
Bone Marrow Aspirate Sampling for MRD	
Bone Marrow Aspirate Sampling for Molecular Markers	
Lytic Bone Lesion Assessment	
Soft Tissue Plasmacytomas Assessment	
New Soft Tissue Plasmacytomas	
Central Efficacy Lab - Serum	
Central Efficacy Lab - Urinalysis	

Project Name: 79635322MMY3002

Form: Demographics

Generated On: 06 Mar 2026 12:08:14 (GMT)

INFORMED CONSENT

What was the date of the signature on informed consent? _____

PROTOCOL DATE

What is the protocol date the subject consented to at study start? _____

DEMOGRAPHICS

What is the subject's age? _____

Age unit

Hours ☐

Days ☐

Weeks ☐

Months ☐

Years ☒

Sex assigned at birth

Female ☐

Male ☐

Unknown ☐

Intersex ☐

What is the subject's childbearing potential?

Of Childbearing Potential ☐

Permanently Sterilized ☐

Postmenopausal ☐

Premenarchal ☐

Not Applicable ☐

What is the ethnicity of the subject?

Hispanic or Latino ☐

Not Hispanic or Latino ☐

Not Reported ☐

Unknown ☐

What is the race of the subject (*Check all that apply*)

American Indian or Alaska Native _____

Asian _____

Black or African American _____

Native Hawaiian or other Pacific Islander _____

White _____

Not reported _____

Unknown _____

If subject was re-screened, specify below:

Previous Subject ID _____

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Inclusion/Exclusion Criteria

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were all eligibility criteria met?	Yes ☐
	No ☐

If No, enter below information about criteria not satisfied/met (click Add New Log Line to enter more than one criterion)	Exclusion ☐
	Inclusion ☐

What was the category of the criterion?

Criterion ID _____

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: Randomization

Generated On: 06 Mar 2026 12:08:14 (GMT)

What was the date of randomization?	
Treatment Arm	Treatment Arm A ☐
	(JNJ-79635322)
	Treatment Arm B (Teclistamab) ☐

Project Name: 79635322MMY3002

Form: Consents / Withdrawal of Consents

Generated On: 06 Mar 2026 12:08:14 (GMT)

Type	
Consent Given	Yes ☐ No ☐
Date of Consent Signature	
Date Consent Withdrawn	

Project Name: 79635322MMY3002

Form: Consent for Participation in Long-term Extension Phase

Generated On: 06 Mar 2026 12:08:14 (GMT)

Phase	Long-term Extension Phase	☒
Did the subject agree to participate?	Yes	☐
	No	☐
Consent Signature Date		

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: General Medical History

Generated On: 06 Mar 2026 12:08:14 (GMT)

Has the subject had any medical conditions or events? Yes ☐
If 'Yes', add a log line for each abnormality. No ☐

What is the verbatim term for the medical history condition/event? _____

Start Date _____

Is the medical condition or event ongoing as of Screening? Yes ☐
No ☐

End Date _____

Toxicity Grade 1 ☐
2 ☐
3 ☐
4 ☐

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: Prior Cancer-Related Surgery / Procedure

Generated On: 06 Mar 2026 12:08:14 (GMT)

Has the subject undergone any prior surgery/procedure for Multiple Myeloma ?	Yes ☐
	No ☐

Surgery or Procedure	Kyphoplasty	☐
	Vertebroplasty	☐
	Orthopedic Surgery	☐
	Autologous Transplant	☐
	Allogeneic Transplant	☐
	Other	☐

If Other, Specify	
-------------------	--

Start Date	
------------	--

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: Prior Radiotherapy (MMY)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Has the subject had prior radiotherapy?	Yes ☐
	No ☐

Anatomical Location	Bones Foot ☐
	Bones Hand ☐
	Brain ☐
	Clavicle ☐
	Coccyx ☐
	Femur ☐
	Fibula ☐
	Humerus ☐
	Mandible ☐
	Maxilla ☐
	Patella ☐
	Pelvis ☐
	Radius ☐
	Rib ☐
	Sacrum ☐
	Scapula ☐
	Skin Abdominal ☐
	Skin Arm ☐
	Skin Head ☐
	Skin Leg ☐
	Skin Trunk ☐
	Skin Thorax ☐
	Skull ☐
	Sternum ☐
	Spinal Cord ☐
	Temporal bone ☐
	Tibia ☐
	Ulna ☐
	Cervical Vertebra ☐
	Lumbar Vertebra ☐
	Sacral Vertebra ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Prior Radiotherapy (MMY)

Generated On: 06 Mar 2026 12:08:14 (GMT)

		Thoracic Vertebra	☐
		Other	☐
If Other, Specify			
Total Cumulative Dose		Fixed Unit: Gray	
Start Date			
End Date			
Indication		Bone Lesion Related Pain	☐
		Soft Tissue Plasmacytoma	☐
		Other	☐
		Pathological fracture	☐
		Spinal Cord Compression	☐
		Stabilization of Lytic Bone Lesion	☐
If Other, Specify			

Project Name: 79635322MMY3002

Form: Prior Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any prior systemic therapies taken Multiple Myeloma? Yes ☐
No ☐

Line of Therapy Number 1 ☐
2 ☐
3 ☐

Best Response Stringent Complete Response ☐
Complete Response ☐
Very Good Partial Response ☐
Partial Response ☐
Minimal Response ☐
Stable Disease ☐
Progressive Disease ☐
Not Evaluable ☐
Unknown ☐

Line of Therapy (transplant info) Yes ☐
Was this **line of therapy** transplant related? No ☐

If transplant related, choose the primary corresponding log line(s),
start date(s), and Procedure(s)
PR log line, start date, and procedure _____
PR log line, start date, and procedure _____
PR log line, start date, and procedure _____

Line of Therapy (progression/relapse info) Yes ☐
Did subject progress/relapse on or after this **line of therapy**? No ☐
Unknown ☐

If Yes, Progression/Relapse Date _____
Line of Therapy Number _____
Medication or Therapy

Belantamab mafodotin-blmf ☐
(Blenrep)
Bendamustine (Belrapzo, ☐
Bendeka, Treanda)
Bortezomib (Velcade) ☐
Busulfan (Busulfex, Myleran, ☐
PMS-Busulfan)
Ciltacabtagene autoleucel ☐
(Carvykti)

Project Name: 79635322MMY3002

Form: Prior Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

-
- Carfilzomib (Kyprolis) ☐
- Cisplatin (Platinol) ☐
- Corticosteroids (dexamethasone, prednisone, prednisolone, methylprednisolone) ☐
- Cyclophosphamide (Procytox) ☐
- Daratumumab (Darzalex, Darzalex Faspro) ☐
- Doxorubicin (Adriamycin, Myocet, Doxil, Lipodox, Caelyx, Taro-doxorubicin liposomal) ☐
- Elranatamab (Elrexio)** Note: Not permitted in this study due to exclusion criteria for BCMA-targeted bispecific antibody therapies ☐
- Etoposide (Vepesid, Etopophos) ☐
- Elotuzamab (Empliciti) ☐
- Idecabtagene vicleucel (Abecma, Ide-cel) ☐
- Isatuximab (Sarclisa) ☐
- Ixazomib (Ninlaro) ☐
- Lenalidomide (Revlimid) ☐
- Linvoseltamab (Lynozyfic) ☐
- Melflufen (Melphalan flufenamide) ☐
- Melphalan (Alkeran, Evomela, Taro-Melphalan) ☐
- Panobinostat (Farydak) ☐
- Pomalidomide (pomalyst) ☐
- Selinexor (Xpovio) ☐
- Talquetamab (Talvey) ☐
- Teclistamab (Tecvayli)** Note: Not permitted in this study due to exclusion criteria for BCMA-targeted bispecific antibody therapies ☐
- Thalidomide (Thalomid) ☐
- Venetoclax (Venclexta, Venclyxto) ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Prior Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Vincristine (Vincasar pFS,
Marqibo) ☐
Other ☐

Start Date _____

End Date _____

Dose _____

Dose Unit ☐ Milligram
☐ Milligram per Kilogram
☐ mg per Square Meter
☐ $\times 10^6$ CAR-positive viable T
cells/kg
☐ $\times 10^8$ CAR-positive viable T
cells
Other ☐

If Other, Specify _____

Frequency ☐ Once
☐ 4 Times Per Week
☐ Every Two Weeks
☐ Every Three Weeks
☐ Every Four Weeks
☐ Monthly
☐ Twice Per Month
☐ Every Six Months
☐ Daily
☐ Twice Daily
☐ Three Times Daily
☐ Four Times Daily
☐ Every Other Day
☐ Every Week
☐ 2 Times Per Week
☐ 3 Times Per Week
☐ Other
☐ Unknown

If Other, Specify _____

Number of Cycles _____

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Prior Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Route	Intramuscular	☐
	Intravenous	☐
	Oral	☐
	Parenteral	☐
	Subcutaneous	☐
	Transdermal	☐
	Unknown	☐
	Other	☐

If Other, Specify	
Did the subject receive any other lines of prior systemic therapies?	Yes ☐
(Click 'yes' to create a new form to report additional lines of prior systemic therapies)	No ☐

Project Name: 79635322MMY3002

Form: Baseline ICE score

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date	
Total ICE Score	0 ☐
	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6 ☐
	7 ☐
	8 ☐
	9 ☐
	10 ☐
If total ICE score is >0 and <10, provide the detailed individual scores	0 ☐
Orientation (Orientation to year, month, city, hospital)	1 ☐
Score	2 ☐
	3 ☐
	4 ☐
	Not Done ☐
Naming (Name 3 objects e.g., point to clock, pen, button)	0 ☐
Score	1 ☐
	2 ☐
	3 ☐
	Not Done ☐
Following simple commands (e.g. , show me 2 fingers or close your eyes and stick out your tongue)	0 ☐
Score	1 ☐
	Not Done ☐
Writing (Ability to write a standard sentence (e.g., our national bird is the bald eagle))	0 ☐
Score	1 ☐
	Not Done ☐
Attention (Count backwards from 100 by ten)	0 ☐
Score	1 ☐
	Not Done ☐

Project Name: 79635322MMY3002

Form: Baseline ICE score

Generated On: 06 Mar 2026 12:08:14 (GMT)

For total ICE score >0 and <10 and/or for the individual score assessment(s) that were 'not done', specify reason	Adverse Event ☐
	Other ☐

If reason is Adverse Event, choose the corresponding	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date and term	
AE log line, start date, and term	
AE log line, start date, and term	
If Other, Specify	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Baseline Soft Tissue Plasmacytoma Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

Did the subject have a history of Plasmacytomas? Yes ☐
No ☐

Was a baseline assessment performed by imaging, physical exam or both? Yes ☐
No ☐

If 'No', provide the reason _____
Method CT Scan ☐
PET/CT Scan ☐
MRI ☐
Physical Examination ☐
Spiral CT Scan ☐

Body Part Whole Body ☐
Other ☐

If Other, specify _____

Date _____

Are there any plasmacytomas present at baseline? Yes ☐
No ☐

If the answer is Yes, record data on the Soft Tissue Plasmacytoma form.

Project Name: 79635322MMY3002

Form: Soft Tissue Plasmacytomas Assessment (Screening)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lesion Identifier	EP01	☐
	EP02	☐
	EP03	☐
	EP04	☐
	EP05	☐
	EP06	☐
	EP07	☐
	EP08	☐
	EP09	☐
	EP10	☐
Type of Plasmacytoma	Bone Related Soft Tissue Plasmacytoma	☐
	Extramedullary Soft Tissue Plasmacytoma	☐
Anatomical Location	Adrenal Gland	☐
	Clavicle	☐
	Central Nervous System	☐
	Femur	☐
	Humerus	☐
	Kidney	☐
	Liver	☐
	Lung	☐
	Mandible	☐
	Maxilla	☐
	Pancreas	☐
	Pelvis	☐
	Ribs	☐
	Scapula	☐
	Skin	☐
	Skull	☐
	Spleen	☐
	Sternum	☐
	Subcutaneous	☐
	Temporal Bone	☐

Project Name: 79635322MMY3002

Form: Soft Tissue Plasmacytomas Assessment (Screening)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Testis	☐
	Tibia	☐
	Chest Wall	☐
	Cervical Vertebra	☐
	Lumbar Vertebra	☐
	Sacral Vertebra	☐
	Thoracic Vertebra	☐
	Other	☐
	Larynx	☐
	Lymph Node	☐

If Other, Specify _____

Sub-location _____

Was Pathological Proof Obtained? Yes ☐

No ☐

TUMOR ASSESSMENT INFO:

Date of Assessment _____

Method of assessment _____

CT Scan ☐

PET/CT Scan ☐

Diffusion Weighted MRI
(DWI-MRI) ☐

Bidimensional Measurement 1 Fixed Unit: mm

Bidimensional Measurement 2 Fixed Unit: mm

Comments _____

Project Name: 79635322MMY3002

Form: Soft Tissue Plasmacytomas Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lesion Identifier	EP01	☐
	EP02	☐
	EP03	☐
	EP04	☐
	EP05	☐
	EP06	☐
	EP07	☐
	EP08	☐
	EP09	☐
	EP10	☐
Type of Plasmacytoma	Bone Related Soft Tissue Plasmacytoma	☐
	Extramedullary Soft Tissue Plasmacytoma	☐
Anatomical Location	Adrenal Gland	☐
	Clavicle	☐
	Central Nervous System	☐
	Femur	☐
	Humerus	☐
	Kidney	☐
	Liver	☐
	Lung	☐
	Mandible	☐
	Maxilla	☐
	Pancreas	☐
	Pelvis	☐
	Ribs	☐
	Scapula	☐
	Skin	☐
	Skull	☐
	Spleen	☐
	Sternum	☐
	Subcutaneous	☐
	Temporal Bone	☐

Project Name: 79635322MMY3002

Form: Soft Tissue Plasmacytomas Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Testis	☐
	Tibia	☐
	Chest Wall	☐
	Cervical Vertebra	☐
	Lumbar Vertebra	☐
	Sacral Vertebra	☐
	Thoracic Vertebra	☐
	Other	☐
	Larynx	☐
	Lymph Node	☐

If Other, Specify _____

Sub-location _____

TUMOR ASSESSMENT INFO:

Date of Assessment _____

Not Done _____

Reason not done _____

Method of assessment	CT Scan	☐
	PET/CT Scan	☐
	Diffusion Weighted MRI (DWI-MRI)	☐

Has the lesion completely disappeared (0 x 0 mm)? Yes ☐

No ☐

Bidimensional Measurement 1 Fixed Unit: mm

Present, but too small to measure _____

Bidimensional Measurement 2 Fixed Unit: mm

Present, but too small to measure _____

Not Evaluable _____

Reason Not Evaluable _____

Fixed Unit: mm

If the plasmacytoma split, specify the bidimensional measurements of the second part

Bidimensional Measurement 1 _____

Project Name: 79635322MMY3002

Form: Soft Tissue Plasmacytomas Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

Bidimensional Measurement 2		Fixed Unit: mm
Comments		

Project Name: 79635322MMY3002

Form: Baseline Lytic Bone Lesion Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

Number of lytic bone lesions	None	☐
	1-3	☐
	4-10	☐
	More than 10	☐

Description of Findings _____

Please report details on the lytic bone lesion assessments

Date of Assessment _____

Method of Assessment	CT Scan	☐
	PET/CT Scan	☐
	Diffusion Weighted MRI (DWI-MRI)	☐

Body Regions Imaged	Whole Body	☐
	Other	☐

If Other, (check all that apply)	
Skull	_____
Spine	_____
Thorax	_____
Pelvis	_____
Long Bones and Extremities	_____

Anatomic location of lytic bone lesions identified (check all that apply)	
Skull	_____
Ribs	_____
Vertebrae	_____
Pelvis	_____
Humerus	_____
Femur	_____
Other	_____
If Vertebrae, Specify	_____
If Ribs, Specify	_____
If Other, Specify	_____

Project Name: 79635322MMY3002

Form: New Soft Tissue Plasmacytomas

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lesion Identifier	NST01	☐
	NST02	☐
	NST03	☐
	NST04	☐
	NST05	☐
	NST06	☐
	NST07	☐
	NST08	☐
	NST09	☐
	NST10	☐
Type of Plasmacytoma	Bone Related Soft Tissue Plasmacytoma	☐
	Extramedullary Soft Tissue Plasmacytoma	☐
Anatomical Location	Adrenal Gland	☐
	Clavicle	☐
	Central Nervous System	☐
	Femur	☐
	Humerus	☐
	Kidney	☐
	Liver	☐
	Lung	☐
	Mandible	☐
	Maxilla	☐
	Pancreas	☐
	Pelvis	☐
	Ribs	☐
	Scapula	☐
	Skin	☐
	Skull	☐
	Spleen	☐
	Sternum	☐
	Subcutaneous	☐
	Temporal Bone	☐

Project Name: 79635322MMY3002

Form: New Soft Tissue Plasmacytomas

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Testis	☐
	Tibia	☐
	Chest Wall	☐
	Cervical Vertebra	☐
	Lumbar Vertebra	☐
	Sacral Vertebra	☐
	Thoracic Vertebra	☐
	Other	☐
	Larynx	☐
	Lymph Node	☐

If Other, Specify _____

Sub-location _____

TUMOR ASSESSMENT INFO:

Date of Assessment _____

Method of assessment	CT Scan	☐
	PET/CT Scan	☐
	Diffusion Weighted MRI (DWI-MRI)	☐

Bidimensional Measurement 1	Fixed Unit: mm
-----------------------------	----------------

Bidimensional Measurement 2	Fixed Unit: mm
-----------------------------	----------------

Comments _____

Project Name: 79635322MMY3002

Form: Temperature Log

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please add a logline for every temperature measurement	
Date	
Time	
Temperature	C F
Comments	

Project Name: 79635322MMY3002

Form: Vital Signs

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were vital signs performed?	Yes ☐
	No ☐

Was the collection date the same as the visit date?	Yes ☐
	No ☐

Date

If Yes is answered for the 'Were vital signs performed?' question, save the form to make the rows visible and enterable (Not applicable for Unscheduled visits).

Time

Test	Height ☐
	Weight ☐
	Temperature ☐
	Systolic Blood Pressure ☐
	Diastolic Blood Pressure ☐
	Pulse Rate ☐
	Respiratory Rate ☐
	Oxygen Saturation ☐

Result

Unit

Not Done

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Local Hematology

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:

Was the sample collected? Yes ☐

No ☐

If Yes, was the collection date the same as the visit date? Yes ☐

No ☐

Collection Date

Collection Time

White blood cell (WBC) count or Leukocytes

Lymphocytes (abs)

Neutrophils (abs)

Hemoglobin

Platelet Count or Platelets

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Local Chemistry

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:

Panel	CHEMISTRY
-------	-----------

Was the sample collected?	Yes ☐
	No ☐

Was the collection date the same as the visit date?	Yes ☐
	No ☐

Collection Date	
-----------------	--

Collection Time	
-----------------	--

Sodium	
--------	--

Potassium	
-----------	--

Creatinine	
------------	--

Total Bilirubin	
-----------------	--

Aspartate Aminotransferase (AST)	
----------------------------------	--

Alanine Aminotransferase (ALT)	
--------------------------------	--

Gamma-Glutamyltransferase (GGT)	
---------------------------------	--

Alkaline Phosphatase (ALP)	
----------------------------	--

Lactic Acid Dehydrogenase (LDH)	
---------------------------------	--

Urate or Uric Acid	
--------------------	--

Calcium	
---------	--

Phosphate	
-----------	--

Albumin	
---------	--

Report at least one of the following tests	
---	--

Total Lipase	
--------------	--

Total Amylase	
---------------	--

Only to be entered in case of congenital Gilbert's disease	
---	--

Direct Bilirubin or Conjugated Bilirubin	
--	--

Project Name: 79635322MMY3002

Form: Local Hematology (Unscheduled)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:	
Collection Date (Derived field)	
White blood cell (WBC) count or Leukocytes	
Lymphocytes (abs)	
Neutrophils (abs)	
Hemoglobin	
Platelet Count or Platelets	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Local Chemistry (Unscheduled)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:

Panel	CHEMISTRY
Collection Date (Derived date)	
Sodium	
Potassium	
Creatinine	
Total Bilirubin	
Aspartate Aminotransferase (AST)	
Alanine Aminotransferase (ALT)	
Gamma-Glutamyltransferase (GGT)	
Alkaline Phosphatase (ALP)	
Lactic Acid Dehydrogenase (LDH)	
Urate or Uric Acid	
Calcium	
Phosphate	
Albumin	
C Reactive Protein (CRP)	
Ferritin	
Blood Brain Natriuretic Peptide OR B-Type Natriuretic Peptide	
Report at least one of the following tests	
Total Lipase	
Total Amylase	
Only to be entered in case of congenital Gilbert's disease	
Direct Bilirubin or Conjugated Bilirubin	
Beta-2-microglobulin	
Beta-2-microglobulin Unit	mg/L
	ng/mL
	ug/mL

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Local Hematology_Coagulation Tests

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:

Was the sample collected? Yes ☐

No ☐

If Yes, was the collection date the same as the visit date? Yes ☐

No ☐

Collection Date

Coagulation

Activated Partial Thromboplastin Time (aPTT)

Fibrinogen

Report at least one of the following tests

Prothrombin Intl. Normalized Ratio (INR)

Plasma Prothrombin Time (sec)

Project Name: 79635322MMY3002

Form: Local Hematology_Coagulation Tests (Uns)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Lab Name:

Collection Date (Derived field)	
---------------------------------	--

Coagulation

Activated Partial Thromboplastin Time (aPTT)	
--	--

Fibrinogen	
------------	--

Prothrombin Intl. Normalized Ratio (INR)	
--	--

Plasma Prothrombin Time (sec)	
-------------------------------	--

Project Name: 79635322MMY3002

Form: Serology

Generated On: 06 Mar 2026 12:08:14 (GMT)

Panel	SEROLOGY
Was the sample collected?	Yes ☐ No ☐
If Yes, was the collection date the same as the visit date?	Yes ☐ No ☐
Collection Date _____	
HCV	Negative ☐
Hepatitis C Virus Antibody	Positive ☐
Hepatitis C PCR measurements (only to be collected for participants where HCV antibody is Positive)	
Collection Date _____	
Hepatitis C Virus RNA	Negative ☐ Positive ☐
HBV	Yes ☐
Known history of prior HBV vaccination	No ☐ Unknown ☐
Hepatitis B Virus Surface Antibody	Negative ☐ Positive ☐
Hepatitis B Virus Surface Antigen	Negative ☐ Positive ☐
Hepatitis B Virus Core Antibody	Negative ☐ Positive ☐
Hepatitis B PCR measurements (only to be collected for participants where Hepatitis B surface Antibody OR Hepatitis B Core antibody are positive)	
Collection Date _____	
Hepatitis B Virus DNA	Negative ☐ Positive ☐
HIV related information is only required for participants with known HIV or a history of HIV antibody positivity	
Collection Date _____	
HIV viral load	Fixed Unit: copies/mL

Project Name: 79635322MMY3002

Form: Serology

Generated On: 06 Mar 2026 12:08:14 (GMT)

CD4 Count	Fixed Unit: cells/mm3
-----------	-----------------------

Project Name: 79635322MMY3002

Form: Serology (Unscheduled)/Additional Serology Follow-up

Generated On: 06 Mar 2026 12:08:14 (GMT)

Panel	SEROLOGY
Collection Date (Derived field)	
HCV	Negative ☐
Hepatitis C Virus Antibody	Positive ☐
Hepatitis C Virus RNA	Negative ☐
	Positive ☐
HBV	Yes ☐
Known history of prior HBV vaccination	No ☐
	Unknown ☐
Hepatitis B Virus Surface Antibody	Negative ☐
	Positive ☐
Hepatitis B Virus Surface Antigen	Negative ☐
	Positive ☐
Hepatitis B Virus Core Antibody	Negative ☐
	Positive ☐
Hepatitis B Virus DNA	Negative ☐
	Positive ☐
HIV related information is only required for participants with known HIV or a history of HIV antibody positivity	
HIV viral load	Fixed Unit: copies/mL
CD4 Count	Fixed Unit: cells/mm3

Project Name: 79635322MMY3002

Form: ECG Results

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the ECG performed? Yes ☐
No ☐

Was the collection date the same as the visit date? Yes ☐
No ☐

Method 12 Lead Standard ☐

ECG Date _____

ECG Time _____

Overall Interpretation Normal ☐
Abnormal ☐
Not Evaluable ☐

If Abnormal, Specify _____

If Abnormal, Clinically Significant? Yes ☐
No ☐

If Clinically Significant is Yes

If Medical History Condition, choose the corresponding Medical

History log line(s) and term(s)

MH log line and term _____

MH log line and term _____

MH log line and term _____

MH log line and term _____

MH log line and term _____

MH log line and term _____

If Adverse Event, choose the primary corresponding AE log

line(s), start date(s), and term(s)

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

Was another unscheduled ECG performed on this same day? Yes ☐
No ☐

Project Name: 79635322MMY3002

Form: Pregnancy Test

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the sample collected?	Yes	☐
	No	☐
	Not Applicable	☐
Was the collection date the same as the visit date?	Yes	☐
	No	☐
Specimen Type	Serum	☐
	Urine	☐
Collection Date		
Pregnancy Test Result	Positive	☐
	Negative	☐
	Borderline	☐
	Invalid	☐
Panel (Derived field)		

Project Name: 79635322MMY3002

Form: ePro Completion Status

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any Clinical Outcome Assessments missed at this visit? Yes ☐
No ☐

Assessment Name MySIm-Q ☒
EORTC QLQ-C30 ☐
EQ-5D-5L ☐
PGI-S ☐
EORTC IL46 ☐

Indicate Missed Assessment

If the assessment was missed, reason Site Forgot ☐
Subject Forgot ☐
Subject too ill ☐
Subject refused ☐
Technical failure ☐
Other ☐

If Other, Specify

Assessment Name MySIm-Q ☐
EORTC QLQ-C30 ☒
EQ-5D-5L ☐
PGI-S ☐
EORTC IL46 ☐

Indicate Missed Assessment

If the assessment was missed, reason Site Forgot ☐
Subject Forgot ☐
Subject too ill ☐
Subject refused ☐
Technical failure ☐
Other ☐

If Other, Specify

Assessment Name MySIm-Q ☐
EORTC QLQ-C30 ☐
EQ-5D-5L ☒
PGI-S ☐

Project Name: 79635322MMY3002

Form: ePro Completion Status

Generated On: 06 Mar 2026 12:08:14 (GMT)

EORTC IL46 ☐

Indicate Missed Assessment

If the assessment was missed, reason

- Site Forgot ☐
- Subject Forgot ☐
- Subject too ill ☐
- Subject refused ☐
- Technical failure ☐
- Other ☐

If Other, Specify

Assessment Name

- MySIm-Q ☐
- EORTC QLQ-C30 ☐
- EQ-5D-5L ☐
- PGI-S ☒
- EORTC IL46 ☐

Indicate Missed Assessment

If the assessment was missed, reason

- Site Forgot ☐
- Subject Forgot ☐
- Subject too ill ☐
- Subject refused ☐
- Technical failure ☐
- Other ☐

If Other, Specify

Assessment Name

- MySIm-Q ☐
- EORTC QLQ-C30 ☐
- EQ-5D-5L ☐
- PGI-S ☐
- EORTC IL46 ☒

Indicate Missed Assessment

If the assessment was missed, reason

- Site Forgot ☐
- Subject Forgot ☐
- Subject too ill ☐
- Subject refused ☐

Project Name: 79635322MMY3002

Form: ePro Completion Status

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Technical failure	☐
	Other	☐
If Other, Specify _____		

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: ECOG Performance Status

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the questionnaire completed? Yes ☐
No ☐

Reason Not Done Site did not administer or other ☐
site staff error
Subject did not attend visit/could ☐
not be contacted
Subject refused ☐
Subject too ill ☐
Technical failure ☐
Other ☐

If Other, specify _____

Was the collection date the same as the visit date? Yes ☐
No ☐

Collection Date _____

Grade 0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐

Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55

Project Name: 79635322MMY3002

Form: Local Efficacy Lab Results - Serum

Generated On: 06 Mar 2026 12:08:14 (GMT)

Only to be completed if no central lab sample was provided

Was the serum sample collected? Yes ☐
No ☐

If no, specify reason _____

Collection Date _____

Total M-protein _____

Units g/L ☐
g/dL ☐
mg/L ☐

Beta-2-microglobulin _____

Beta-2-microglobulin Unit mg/L ☐
ng/mL ☐
ug/mL ☐

Immunofixation result Negative ☐

Isotype 1 IgG ☐
IgG kappa ☐
IgG lambda ☐
IgA ☐
IgA kappa ☐
IgA lambda ☐
Kappa light chain free ☐
Lambda light chain free ☐
IgD ☐
IgD kappa ☐
IgD lambda ☐
IgE ☐
IgE kappa ☐
IgE lambda ☐
IgM ☐
IgM kappa ☐
IgM lambda ☐

Isotype 2 (If bi-allelic/multiple isotypes are detected) Negative ☐
IgG ☐

Project Name: 79635322MMY3002

Form: Local Efficacy Lab Results - Serum

Generated On: 06 Mar 2026 12:08:14 (GMT)

	IgG kappa	
	IgG lambda	
	IgA	
	IgA kappa	
	IgA lambda	
	Kappa light chain free	
	Lambda light chain free	
	IgD	
	IgD kappa	
	IgD lambda	
	IgE	
	IgE kappa	
	IgE lambda	
	IgM	
	IgM kappa	
	IgM lambda	

Free Light Chain

Kappa Light Chain, Free *(The field allows to enter numbers, period and < , > , <=> ; < and >=> ; symbols)*

Kappa Light Chain, Free Unit	mg/L	
	mg/dL	

Lambda Light Chain, Free *(The field allows to enter numbers, period and < , > , <=> ; < and >=> ; symbols)*

Lambda Light Chain, Free Unit	mg/L	
	mg/dL	

Free Kappa/Free Lambda Ratio *(The field allows to enter numbers, period and < , > , <=> ; < and >=> ; symbols)*

--	--	----------------------

Project Name: 79635322MMY3002

Form: Local Efficacy Lab Results - Urinalysis

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the 24-hour urine sample collected? Yes ☐
No ☐

If no, specify reason _____

Collection Start Date _____

Collection Start Time _____

Collection End Date _____

Collection End Time _____

Total M-protein _____

Units g/24h ☐
g/d ☐
mg/24h ☐

Immunofixation result

Isotype 1

Negative ☐IgG ☐IgG kappa ☐IgG lambda ☐IgA ☐IgA kappa ☐IgA lambda ☐Kappa light chain free ☐Lambda light chain free ☐IgD ☐IgD kappa ☐IgD lambda ☐IgE ☐IgE kappa ☐IgE lambda ☐IgM ☐IgM kappa ☐IgM lambda ☐

Isotype 2 (If bi-allelic/multiple isotypes are detected)

Negative ☐IgG ☐IgG kappa ☐IgG lambda ☐

Project Name: 79635322MMY3002

Form: Local Efficacy Lab Results - Urinalysis

Generated On: 06 Mar 2026 12:08:14 (GMT)

	IgA	☐
	IgA kappa	☐
	IgA lambda	☐
	Kappa light chain free	☐
	Lambda light chain free	☐
	IgD	☐
	IgD kappa	☐
	IgD lambda	☐
	IgE	☐
	IgE kappa	☐
	IgE lambda	☐
	IgM	☐
	IgM kappa	☐
	IgM lambda	☐

Project Name: 79635322MMY3002

Form: Local Cytogenetic Testing (FISH)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Sample collection date

Method

FISH ☒

Specimen Type

Bone Marrow ☒

If Bone Marrow, specify original specimen collection method

Aspirate ☐Biopsy ☐

Protocol Relevant Cytogenetic Abnormalities

gain(1q) ☒amp(1q) ☐t(4;14) ☐t(14;16) ☐del(17p) ☐t(14;20) ☐del(1p32) ☐

Number of cells analyzed

Result

Not Tested ☐Not Evaluable ☐Detected ☐Not Detected ☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities

gain(1q) ☐amp(1q) ☒t(4;14) ☐t(14;16) ☐del(17p) ☐t(14;20) ☐del(1p32) ☐

Number of cells analyzed

Result

Not Tested ☐Not Evaluable ☐Detected ☐Not Detected ☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities

gain(1q) ☐

Project Name: 79635322MMY3002

Form: Local Cytogenetic Testing (FISH)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	amp(1q)	☐
	t(4;14)	☒
	t(14;16)	☐
	del(17p)	☐
	t(14;20)	☐
	del(1p32)	☐

Number of cells analyzed

Result	Not Tested	☐
	Not Evaluable	☐
	Detected	☐
	Not Detected	☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities	gain(1q)	☐
	amp(1q)	☐
	t(4;14)	☐
	t(14;16)	☒
	del(17p)	☐
	t(14;20)	☐
	del(1p32)	☐

Number of cells analyzed

Result	Not Tested	☐
	Not Evaluable	☐
	Detected	☐
	Not Detected	☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities	gain(1q)	☐
	amp(1q)	☐
	t(4;14)	☐
	t(14;16)	☐
	del(17p)	☒
	t(14;20)	☐
	del(1p32)	☐

Project Name: 79635322MMY3002

Form: Local Cytogenetic Testing (FISH)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Number of cells analyzed

Result

Not Tested ☐Not Evaluable ☐Detected ☐Not Detected ☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities

gain(1q) ☐amp(1q) ☐t(4;14) ☐t(14;16) ☐del(17p) ☐t(14;20) ☒del(1p32) ☐

Number of cells analyzed

Result

Not Tested ☐Not Evaluable ☐Detected ☐Not Detected ☐

If Detected, specify % of abnormal cells

Protocol Relevant Cytogenetic Abnormalities

gain(1q) ☐amp(1q) ☐t(4;14) ☐t(14;16) ☐del(17p) ☐t(14;20) ☐del(1p32) ☒

Number of cells analyzed

Result

Not Tested ☐Not Evaluable ☐Detected ☐Not Detected ☐

If Detected, specify % of abnormal cells

Project Name: 79635322MMY3002

Form: Bone Marrow for Morphology

Generated On: 06 Mar 2026 12:08:14 (GMT)

Sample Collection Method	Bone Marrow Biopsy	☒
	Bone Marrow Aspirate	☐
Was the sample collected?	Yes	☐
	No	☐
Collection Date		
Plasma Cells	Fixed Unit: %	

Sample Collection Method	Bone Marrow Biopsy	☐
	Bone Marrow Aspirate	☒
Was the sample collected?	Yes	☐
	No	☐
Collection Date		
Plasma Cells	Fixed Unit: %	

Project Name: 79635322MMY3002**Form:** Bone Marrow for Immunohistochemistry / Flow Cytometry**Generated On:** 06 Mar 2026 12:08:14 (GMT)

Collection Date	
Method of Assessment	Immunohistochemistry ☐
	Flow Cytometry ☐
Number of plasma cells examined	
Are clonal/abnormal plasma cells identified?	Positive ☐
	Negative ☐
	Indeterminate ☐
If Indeterminate, clarify result	
Kappa/Lambda Ratio	Fixed Unit: ratio
Kappa/Lambda Ratio (descriptive)	Abnormal ☐
	Normal ☐
	Indeterminate ☐
If Indeterminate, clarify result	
Markers used (Check all that apply)	
CD38	
CD138	
CD19	
CD45	
CD56	
Kappa	
Lambda	
Other	
If Other, Specify	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Central Laboratory Pharmacokinetics and Immunogenicity Blood Sample

Generated On: 06 Mar 2026 12:08:14 (GMT)

Specimen Type	Serum	☒
Purpose of Sample	PHARMACOKINETICS AND IMMUNOGENICITY	☒
Was the sample collected?	Yes	☐
	No	☐
Comment		

Project Name: 79635322MMY3002

Form: Central Efficacy Lab - Serum

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the sample collected?	Yes ☐
	No ☐
What was the reason not done?	

Project Name: 79635322MMY3002

Form: Central Efficacy Lab - Urinalysis

Generated On: 06 Mar 2026 12:08:14 (GMT)

Panel	URINALYSIS
Was the sample collected?	Yes ☐
	No ☐
What was the reason not done?	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Arterial Blood Gases

Generated On: 06 Mar 2026 12:08:14 (GMT)

Date	
Time	
Oxygen Saturation	Fixed Unit: %
pH	
pCO2	
pCO2 Unit	mmHg ☐ kPa ☐
pO2	
pO2 Unit	mmHg ☐ kPa ☐
Bicarbonate	
Bicarbonate Unit	mEq/L ☐ mmol/L ☐
Base excess	
Base excess Unit	mEq/L ☐ mmol/L ☐

Project Name: 79635322MMY3002

Form: Unscheduled Local Immunoglobulines (related to Hypogammaglobulinemia)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date (Derived field)

IgG

Unit

g/L g/dL mg/L mg/dL mg/mL umol/L IU/mL

IgM

Unit

g/L g/dL mg/L mg/dL mg/mL umol/L IU/mL

IgA

Unit

g/L g/dL mg/L mg/dL mg/mL umol/L IU/mL

IgD

Unit

g/L g/dL mg/L mg/dL mg/mL umol/L IU/mL

Project Name: 79635322MMY3002

Form: Unscheduled Local Immunoglobulines (related to Hypogammaglobulinemia)

Generated On: 06 Mar 2026 12:08:14 (GMT)

IgE	
Unit	g/L g/dL mg/L mg/dL mg/mL umol/L IU/mL

Project Name: 79635322MMY3002

Form: Bone Marrow Aspirate Sampling for MRD

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was a bone marrow aspirate for MRD collected?	Yes ☐
	No ☐

Reason not done	
Comment (if needed)	

Project Name: 79635322MMY3002

Form: Bone Marrow Aspirate Sampling for Molecular Markers

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was a bone marrow aspirate for Molecular Markers collected?	Yes ☐
	No ☐
Reason not done	
Comment (if needed)	

Project Name: 79635322MMY3002

Form: Bone Marrow Aspirate Sampling for Central Cytogenetics (FISH)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was a bone marrow aspirate for Cytogenetics (FISH) collected?	Yes ☐
	No ☐
Reason not done	
Comment (if needed)	

Project Name: 79635322MMY3002

Form: Lytic Bone Lesion Assessment

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was there an increase in the total number of lytic bone lesions since the baseline assessment? Yes ☐
No ☐

Was there a definite increase in the size of the lytic bone lesions since the baseline assessment? Yes ☐
No ☐

Description of Findings

Please report details on the lytic bone lesion assessments

Date of assessment

Method of Assessment

CT Scan ☐PET/CT Scan ☐Diffusion Weighted MRI
(DWI-MRI) ☐

Body Regions Imaged

Whole Body ☐Other ☐

If Other, (check all that apply)

Skull

Spine

Thorax

Pelvis

Long Bones and Extremities

Anatomic location of lytic bone lesions identified (check all that apply)

Skull

Ribs

If Ribs, Specify

Vertebrae

If Vertebrae, Specify

Pelvis

Humerus

Femur

Other

If Other, Specify

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date

Collection Time

Specimen

Serum ☐

Cerebrospinal Fluid ☐

Plasma ☐

Was this assessment repeated at the same date? (click 'yes' to create a new form to report additional cytokine measurements)

Yes ☐

No ☐

Test

Tumor Necrosis Factor Alpha ☒

Interferon Gamma ☐

Interleukin 6 ☐

Interleukin 1 Beta ☐

Interleukin 2 ☐

Interleukin 2 Receptor ☐

Interleukin 4 ☐

Interleukin 5 ☐

Interleukin 8 ☐

Interleukin 10 ☐

Interleukin 12 ☐

Interleukin 13 ☐

Interleukin 15 ☐

Interleukin 17 ☐

GM-CSF ☐

MCP1 ☐

Result

Unit

pg/mL ☐

ng/mL ☐

U/mL ☐

Test

Tumor Necrosis Factor Alpha ☐

Interferon Gamma ☒

Interleukin 6 ☐

Interleukin 1 Beta ☐

Interleukin 2 ☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interleukin 2 Receptor	
	Interleukin 4	
	Interleukin 5	
	Interleukin 8	
	Interleukin 10	
	Interleukin 12	
	Interleukin 13	
	Interleukin 15	
	Interleukin 17	
	GM-CSF	
	MCP1	

Result	
Unit	pg/mL
	ng/mL
	U/mL

Test	Tumor Necrosis Factor Alpha	
	Interferon Gamma	
	Interleukin 6	<input checked="" type="text"/>
	Interleukin 1 Beta	
	Interleukin 2	
	Interleukin 2 Receptor	
	Interleukin 4	
	Interleukin 5	
	Interleukin 8	
	Interleukin 10	
	Interleukin 12	
	Interleukin 13	
	Interleukin 15	
	Interleukin 17	
	GM-CSF	
	MCP1	

Result	
Unit	pg/mL

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	ng/mL	☐
	U/mL	☐
Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☒
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☒
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☒
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☒
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result	
Unit	pg/mL☐ ng/mL☐ U/mL☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☒
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	MCP1	☐
--	------	--------------------------

Result	
--------	--

Unit	pg/mL	☐
------	-------	--------------------------

ng/mL	☐
-------	--------------------------

U/mL	☐
------	--------------------------

Test	Tumor Necrosis Factor Alpha	☐
------	-----------------------------	--------------------------

Interferon Gamma	☐
------------------	--------------------------

Interleukin 6	☐
---------------	--------------------------

Interleukin 1 Beta	☐
--------------------	--------------------------

Interleukin 2	☐
---------------	--------------------------

Interleukin 2 Receptor	☐
------------------------	--------------------------

Interleukin 4	☐
---------------	--------------------------

Interleukin 5	☐
---------------	--------------------------

Interleukin 8	☒
---------------	-------------------------------------

Interleukin 10	☐
----------------	--------------------------

Interleukin 12	☐
----------------	--------------------------

Interleukin 13	☐
----------------	--------------------------

Interleukin 15	☐
----------------	--------------------------

Interleukin 17	☐
----------------	--------------------------

GM-CSF	☐
--------	--------------------------

MCP1	☐
------	--------------------------

Result	
--------	--

Unit	pg/mL	☐
------	-------	--------------------------

ng/mL	☐
-------	--------------------------

U/mL	☐
------	--------------------------

Test	Tumor Necrosis Factor Alpha	☐
------	-----------------------------	--------------------------

Interferon Gamma	☐
------------------	--------------------------

Interleukin 6	☐
---------------	--------------------------

Interleukin 1 Beta	☐
--------------------	--------------------------

Interleukin 2	☐
---------------	--------------------------

Interleukin 2 Receptor	☐
------------------------	--------------------------

Interleukin 4	☐
---------------	--------------------------

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☒
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☒
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☒
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result

Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☒
	Interleukin 17	☐
	GM-CSF	☐
	MCP1	☐

Result	
Unit	pg/mL ☐
	ng/mL ☐
	U/mL ☐

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☒
	GM-CSF	☐
	MCP1	☐

Result	
Unit	pg/mL ☐
	ng/mL ☐
	U/mL ☐

Test	Tumor Necrosis Factor Alpha	☐
------	-----------------------------	--------------------------

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐
	GM-CSF	☒
	MCP1	☐

Result	
Unit	☐ pg/mL
	☐ ng/mL
	☐ U/mL

Test	Tumor Necrosis Factor Alpha	☐
	Interferon Gamma	☐
	Interleukin 6	☐
	Interleukin 1 Beta	☐
	Interleukin 2	☐
	Interleukin 2 Receptor	☐
	Interleukin 4	☐
	Interleukin 5	☐
	Interleukin 8	☐
	Interleukin 10	☐
	Interleukin 12	☐
	Interleukin 13	☐
	Interleukin 15	☐
	Interleukin 17	☐

Project Name: 79635322MMY3002

Form: Cytokine Profile (Local)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	GM-CSF	☐
	MCP1	☒
Result		
Unit	pg/mL	☐
	ng/mL	☐
	U/mL	☐

Date of Initial Diagnosis	
---------------------------	--

Project Name: 79635322MMY3002

Form: Diagnostic and Safety Monitoring Procedures

Generated On: 06 Mar 2026 12:08:14 (GMT)

Date of Assessment	
Time of Assessment	
Type of Assessment	Culture ☐ Histopathology/ Cytology ☐ Flow Cytometry ☐ Imaging Assessment ☐ Other ☐
Type if Other, specify	
If Culture, specify pathogen tested	
If Culture, Histopathology, Cytology or Flow Cytometry, select Specimen Type	Blood ☐ Bone Marrow ☐ CSF ☐ Mucus ☐ Pericardial Fluid ☐ Peritoneal Fluid ☐ Pleural Fluid ☐ Sputum ☐ Stool ☐ Swab ☐ Tissue ☐ Urine ☐ Other ☐
If Other, Specify	
If Imaging Assessment, provide Method	Angiography ☐ Bronchoscopy ☐ CT angiography ☐ CT Scan ☐ Dopamine Transporter Scan ☐ EEG ☐ EMG ☐ Endoscopy ☐ Fundoscopy ☐ Magnetic resonance angiography ☐

Project Name: 79635322MMY3002

Form: Diagnostic and Safety Monitoring Procedures

Generated On: 06 Mar 2026 12:08:14 (GMT)

	MRI ☐
	Nerve Conduction Studies ☐
	PET Scan ☐
	Ultrasound ☐
	V/Q Scan ☐
	X-ray ☐
If Imaging Assessment, provide location	
	Abdomen ☐
	Bone ☐
	Brain ☐
	Chest ☐
	Eye ☐
	Gastrointestinal ☐
	Head ☐
	Heart ☐
	Kidney ☐
	Liver ☐
	Lower Extremities ☐
	Lung ☐
	Lymph Node ☐
	Neck ☐
	Pelvis ☐
	Spleen ☐
	Upper Extremities ☐
	Whole Body ☐
	Other ☐
If Other, Specify _____	
Findings _____	
Findings (Continued) _____	
Were the findings/diagnosis considered an Adverse Event?	
	Yes ☐
	No ☐
If Yes, choose the corresponding AE log line, start date, and term	
AE log line, start date, and term _____	
AE log line, start date, and term _____	

Project Name: 79635322MMY3002

Form: Diagnostic and Safety Monitoring Procedures

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were additional diagnostic or safety monitoring procedures performed at this visit?	Yes ☐
	No ☐

Project Name: 79635322MMY3002

Form: Disease Progression

Generated On: 06 Mar 2026 12:08:14 (GMT)

Date of Initial Disease Progression	
Date of Confirmation of Disease Progression by Repeat Investigation	
Progression Diagnosis Based on (please check all that apply)	
≥25% increase in the level of serum monoclonal paraprotein, which must also be an absolute increase of at least 5 g/L (500 mg/dL) and confirmed on a repeat investigation	
≥25% increase in 24-hour urine monoclonal paraprotein, which must also be an absolute increase of at least 200 mg/24 h and confirmed on a repeat investigation	
Definite increase in the size of existing lytic bone lesions	
Definite increase in the size of existing soft tissue plasmacytomas	
Development of new bone lesions	
Development of new soft tissue plasmacytomas	
Difference of ≥ 25% increase between involved and uninvolved FLC levels, absolute increase must be > 10 mg/dL	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Drug Expiry Information

Generated On: 06 Mar 2026 12:08:14 (GMT)

Did the subject take all investigational medication within the expiry
timeframe?

Yes ☐

No ☐

**If No, add a log line for each treatment label Identifier used after
the expiration date**

Treatment Label ID

Expiration Date

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: ICE score (Unscheduled)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was the Total ICE Score performed? Yes ☐
No ☐

If 'No', provide the reason Patient under general sedation ☐
Other ☐

If Other, Specify _____

Collection Date (Derived field) _____

Collection Time _____

Total ICE Score 0 ☐

1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 ☐

If total ICE score is 0, provide the reason Patient is awake, but unable to speak or follow commands (i.e., global aphasia) ☐
Patient is unarousable and unable to perform the ICE assessment ☐

If Total ICE Score = 0, consider to enter an ICANS event on the Adverse Events form.

If total ICE score is >0 and <10, provide the detailed individual scores 0 ☐

Orientation (Orientation to year, month, city, hospital) 1 ☐Score 2 ☐3 ☐4 ☐Not Done ☐

Naming (Name 3 objects e.g., point to clock, pen, button) 0 ☐
Score 1 ☐

2 ☐3 ☐

Project Name: 79635322MMY3002

Form: ICE score (Unscheduled)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Not Done	☐
Following simple commands (e.g. , show me 2 fingers or close your eyes and stick out your tongue)	0	☐
Score	1	☐
	Not Done	☐
Writing (Ability to write a standard sentence (e.g., our national bird is the bald eagle))	0	☐
Score	1	☐
	Not Done	☐
Attention (Count backwards from 100 by ten)	0	☐
Score	1	☐
	Not Done	☐
For total ICE score >0 and <10 and/or for the individual score assessments that were 'not done', specify reason	Adverse Event	☐
	Other	☐
If reason is Adverse Event, choose the corresponding		
AE log line, start date, and term		
AE log line, start date, and term		
AE log line, start date and term		
AE log line, start date, and term		
AE log line, start date, and term		
If Other, Specify		
Was this assessment repeated during the visit?	Yes	☐
	No	☐

Project Name: 79635322MMY3002

Form: Limitation on Retention of Samples

Generated On: 06 Mar 2026 12:08:14 (GMT)

Do the local or country regulations supersede the sample retention requirements specified in the protocol?	Yes ☐
	No ☐

Specify the storage limit	Fixed Unit: Years
	0 ☐
	1 ☐
	2 ☐
	3 ☐
	5 ☐
	10 ☐
	15 ☐
	Other ☐

If storage limit is 'Other', specify the number of years the samples may be stored

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Medical Encounters (Inpatient/Outpatient)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Did the subject require any medical encounters other than those mandated per trial protocol? Yes ☐
No ☐

Start Date _____

Is the medical encounter still ongoing? _____

End Date _____

Reason for the medical encounter _____

Adverse Event ☐
Mandated per institutional guidance for study drug administration or follow-up ☐
Investigator Decision ☐
Other ☐

Choose the corresponding AE log line, start date, and term

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

AE log line, start date, and term _____

If Other, Specify _____

Type of medical encounter _____

Emergency Room ☐
Home Care ☐
Hospice/Palliative Care Unit ☐
Hospital Inpatient Department ☐
Hospital Outpatient Department ☐
Intensive Care Unit ☐
Laboratory Department ☐
Long Term Care Facility ☐
Medical Practitioner Office ☐
Rehabilitation Center ☐

Frequency of Visits _____

Twice daily ☐
Daily ☐
Every Other Day ☐
Twice Weekly ☐
Weekly ☐
Every Three Weeks ☐

Project Name: 79635322MMY3002

Form: Medical Encounters (Inpatient/Outpatient)

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Every Three Months	☐
	Every Four Months	☐
	Other	☐
	Unknown	☐
Type of Practitioner	Cardiologist	☐
	Dermatologist	☐
	Gastroenterologist	☐
	General Practitioner	☐
	Hematologist	☐
	Hepatologist	☐
	Infectious Disease Specialist	☐
	Internal Medicine	☐
	Nephrologist	☐
	Nurse	☐
	Oncologist	☐
	Pediatrician	☐
	Physiotherapist	☐
	Psychologist	☐
	Psychiatrist	☐
	Pulmonologist	☐
	Radiologist	☐
	Respiratory Physiotherapist	☐
	Study Physician	☐
	Social Worker	☐
	Surgeon	☐
	Urologist	☐
	Other	☐

If Other, Specify

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: Oxygen Supplementation (for CRS events)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Was supplemental oxygen administered to the subject? Yes ☐
No ☐

Start Date _____

Start Time _____

End Time _____

Is the supplemental oxygen still ongoing at end of trial? Yes ☐
No ☐

End Date _____

Choose the corresponding AE log line(s), start date(s), and term(s) for which this therapy is indicated

AE log line, start date and term _____

AE log line, start date and term _____

AE log line, start date and term _____

AE log line, start date and term _____

AE log line, start date and term _____

Oxygen requirement and delivery method (Select only 1 option out of the three sections below)

If low flow, specify

Nasal Cannula (less than or equal to 6 L/min) _____

Blow By _____

If high flow, specify

Nasal Cannula (> 6 L/min) _____

Face mask _____

Nonrebreather mask _____

Venturi mask _____

If positive pressure, specify

CPAP (Continuous positive airway pressure) _____

BiPAP (Bi-level positive airway pressure) _____

Intubation/ Mechanical Ventilation _____

FiO₂ _____ Less than 40% ☐

Greater than or equal to 40% ☐

Project Name: 79635322MMY3002

Form: Evaluation of Response (IMWG Criteria)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Date of Procedure for Disease Response	
Disease Response	Stringent Complete Response☐ Complete Response☐ Very Good Partial Response☐ Partial Response☐ Minimal Response☐ Stable Disease☐ Progressive Disease☐ Not Applicable☐ Not Evaluable☐
If Not Evaluable, specify	

Project Name: 79635322MMY3002

Form: Pre-Treatment Medications

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any pre-treatment medications administered? Yes ☐
No ☐

Medication or Therapy _____

Dose _____

Dose Unit _____ Gram ☐

Microgram ☐

Milligram ☐

Milligram per Kilogram ☐

Milliliter ☐

Other ☐

If Other, Specify _____

Frequency _____ Once ☐

Other ☐

If Other, Specify _____

Route _____ Intravenous ☐

Oral ☐

Unknown ☐

Other ☐

If Other, Specify _____

Start Date _____

Start Time _____

Project Name: 79635322MMY3002

Form: Study Drug Injection Administration for JNJ-79635322

Generated On: 06 Mar 2026 12:08:14 (GMT)

Start Date

What was the prescribed dose level?

5 ☐100 ☐

Action taken prior to the injection start

Step-Up Dose (or Repeat
Step-Up Dose) ☐Treatment Dose ☐Dose Reduced Compared To
Prior Injection ☐Injection Delayed Within The
Cycle ☐Injection Skipped (And Not
Made Up) ☐Study Drug Permanently
Discontinued ☐Schedule Change ☐

If schedule change, specify new dosing frequency

Once ☐Infrequent ☐As Necessary ☐Continue ☐Daily ☐Twice Daily ☐Three Times Daily ☐Four Times Daily ☐Every Other Day ☐Weekly ☐Twice Weekly ☐Three Times Weekly ☐Four Times Weekly ☐Every Two Weeks ☐Every Four Weeks ☐Monthly ☐Twice Per Month ☐Every Three Months ☐Thrice ☐Every Thirty Minutes ☐

Project Name: 79635322MMY3002

Form: Study Drug Injection Administration for JNJ-79635322

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Every Two Months ☐
	Every Six Months ☐
	Unknown ☐
	Other ☐

If Action Taken was not 'Step-Up Dose (or Repeat Step-Up Dose)' or 'Treatment Dose', specify

What was the reason for the action taken prior to injection start?

Adverse Event ☐

Other ☐

If Adverse Event, choose the corresponding AE log line, start date, and term

AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	

If Other, Specify

Total number of syringes administered

1 ☐
 2 ☐
 3 ☐
 4 ☐
 5 ☐

What is the treatment label identifier?

If second medkit was used, specify second treatment label identifier

If third medkit was used, specify third treatment label identifier

If fourth medkit was used, specify fourth treatment label identifier

How did you monitor the subject after this administration?

Inpatient ☐
 Outpatient ☐

Syringe Number

What was the volume administered from this syringe? Fixed Unit: Milliliter

Actual Start Time of injection of this syringe

What was the anatomical location of the administration?

Upper Right Abdominal ☐
 Upper Left Abdominal ☐
 Lower Right Abdominal ☐
 Lower Left Abdominal ☐
 Upper Right Arm ☐

Project Name: 79635322MMY3002

Form: Study Drug Injection Administration for JNJ-79635322

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Upper Left Arm	☐
	Right Thigh	☐
	Left Thigh	☐
	Other	☐
If Other, Specify _____		

Project Name: 79635322MMY3002

Form: Study Drug Injection Administration for Teclistamab

Generated On: 06 Mar 2026 12:08:14 (GMT)

Start Date

What was the prescribed dose level?

Fixed Unit: mg/kg

0.06 ☐0.3 ☐1.5 ☐

Action taken prior to the injection start

If schedule change, specify new dosing frequency

Once ☐Infrequent ☐As Necessary ☐Continue ☐Daily ☐Twice Daily ☐Three Times Daily ☐Four Times Daily ☐Every Other Day ☐Weekly ☐Twice Weekly ☐Three Times Weekly ☐Four Times Weekly ☐Every Two Weeks ☒Every Four Weeks ☐Monthly ☐Twice Per Month ☐Every Three Months ☐Thrice ☐Every Thirty Minutes ☐Every Two Months ☐Every Six Months ☐Unknown ☐Other ☐If Action Taken was not 'Step-Up Dose (or Repeat Step-Up Dose)'
or 'Treatment Dose', specifyAdverse Event ☐

What was the reason for the action taken prior to injection start?

Change from Weekly to Q2W
due to complete response as per
protocol ☐

Project Name: 79635322MMY3002

Form: Study Drug Injection Administration for Teclistamab

Generated On: 06 Mar 2026 12:08:14 (GMT)

		Other ☐
If Adverse Event, choose the corresponding AE log line, start date, and term		
AE log line, start date, and term		
AE log line, start date, and term		
AE log line, start date, and term		
AE log line, start date, and term		
If Other, Specify		
Total number of syringes administered		1 ☐
		2 ☐
		3 ☐
		4 ☐
		5 ☐
What is the treatment label identifier?		
Route		Subcutaneous ☒
Syringe Number		
What was the volume administered from this syringe?		Fixed Unit: Milliliter
Actual Start Time of injection of this syringe		
What was the anatomical location of the administration?	Upper Right Abdominal	☐
	Upper Left Abdominal	☐
	Lower Right Abdominal	☐
	Lower Left Abdominal	☐
	Upper Right Arm	☐
	Upper Left Arm	☐
	Right Thigh	☐
	Left Thigh	☐
	Other	☐
If Other, Specify		

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Additional Administration of JNJ-79635322 for Repeat Step-up Dosing

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were additional administrations of JNJ-79635322 performed to
handle repeat step-up dosing per protocol?

Yes ☐

No ☐

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Additional Administration of Teclistamab for Repeat Step-up Dosing

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were additional administrations of Teclistamab performed to handle
repeat step-up dosing per protocol?

Yes ☐

No ☐

Project Name: 79635322MMY3002

Form: Post-Treatment Medications

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were post-medications given? Yes ☐
No ☐

Medication or Therapy _____

Dose _____

Dose Unit _____ Gram ☐

Milligram ☐

Other ☐

If Other, Specify _____

Frequency _____ Once ☐

Daily ☐

Twice Daily ☐

Three Times Daily ☐

Four Times Daily ☐

Unknown ☐

Other ☐

If Other, Specify _____

Route _____ Intravenous ☐

Oral ☐

Unknown ☐

Other ☐

If Other, Specify _____

Start Date _____

Start Time _____

End Date _____

End Time _____

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

Day #	Day 2	☒
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☐
Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☒
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☐
Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☒
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☐

Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☒
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☐

Inpatient/Outpatient	In-Patient	☐
----------------------	------------	-----------------------

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

Out-Patient ☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☒
	Day 7 ☐
	Day 8 ☐
	Day 9 ☐
	Day 10 ☐
	Day 11 ☐
	Day 12 ☐
	Day 13 ☐
	Day 14 ☐

Inpatient/Outpatient

In-Patient ☐
Out-Patient ☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ☒
	Day 8 ☐
	Day 9 ☐
	Day 10 ☐
	Day 11 ☐
	Day 12 ☐
	Day 13 ☐
	Day 14 ☐

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

Inpatient/Outpatient	In-Patient ☐
	Out-Patient ☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	Day 8 ☒
	Day 9 ☐
	Day 10 ☐
	Day 11 ☐
	Day 12 ☐
	Day 13 ☐
	Day 14 ☐

Inpatient/Outpatient	In-Patient ☐
	Out-Patient ☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	Day 8 ☐
	Day 9 ☒
	Day 10 ☐
	Day 11 ☐
	Day 12 ☐
	Day 13 ☐

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Day 14	☐
Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☒
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☐

Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☒
	Day 12	☐

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Day 13	☐
	Day 14	☐
Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☒
	Day 13	☐
	Day 14	☐

Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐

Project Name: 79635322MMY3002

Form: Hospitalization follow-up after study drug administration

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Day 12	☐
	Day 13	☒
	Day 14	☐

Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Day #	Day 2	☐
	Day 3	☐
	Day 4	☐
	Day 5	☐
	Day 6	☐
	Day 7	☐
	Day 8	☐
	Day 9	☐
	Day 10	☐
	Day 11	☐
	Day 12	☐
	Day 13	☐
	Day 14	☒

Inpatient/Outpatient	In-Patient	☐
	Out-Patient	☐

If Inpatient, choose the corresponding Medical Encounters log line,
start date, and term

Project Name: 79635322MMY3002

Form: Subsequent Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any subsequent systemic therapies taken? Yes ☐
No ☐

Line of Therapy (general info) 1 ☐
Line of Therapy Number 2 ☐
3 ☐

Start Date _____

End Date _____

Ongoing at the end of the study _____

Best Response Stringent Complete Response ☐
Complete Response ☐
Very Good Partial Response ☐
Partial Response ☐
Minimal Response ☐
Stable Disease ☐
Progressive Disease ☐
Not Evaluable ☐
Unknown ☐

If Unknown, please specify Responder ☐
Non Responder ☐
Unknown ☐

Regimen (Transplant info) Yes ☐
Was this conditioning regimen for cell transplant? No ☐

Transplantation Date _____

Did subject progress/relapse on or after this regimen? Yes ☐
No ☐
Unknown ☐

If Yes, specify date and type of progression (check all that apply)
Progression/Relapse Date _____

Clinical Progression _____

Radiographic Progression _____

Line of Therapy Number _____

Medication or Therapy _____

Initial Dose Level _____

Project Name: 79635322MMY3002

Form: Subsequent Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Dose Level Unit	Milligram	☐
	Milligram per Kilogram	☐
	Milligram per Square Meter	☐
	Gram	☐
	International Units	☐
	Microgram	☐
	Milliliter	☐
	x10 ⁶ CAR-positive viable T cells/kg	☐
	x10 ⁸ CAR-positive viable T cells	☐
	x10 ⁶ CAR-positive viable T cells	☐
	Other	☐

If Other, Specify

Frequency	Once	☐
	Daily	☐
	Twice Daily	☐
	Three Times Daily	☐
	Four Times Daily	☐
	Every Other Day	☐
	Every Week	☐
	2 Times Per Week	☐
	3 Times Per Week	☐
	4 Times Per Week	☐
	Every Two Weeks	☐
	Every Three Weeks	☐
	Every Four Weeks	☐
	Monthly	☐
	Twice Per Month	☐
	Every Six Months	☐
	Other	☐
	Unknown	☐

If Other, Specify

Number of Cycles

Project Name: 79635322MMY3002

Form: Subsequent Systemic Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Route	Intramuscular	☐
	Intravenous	☐
	Oral	☐
	Subcutaneous	☐
	Transdermal	☐
	Not Applicable	☐
	Unknown	☐
	Other	☐

If Other, Specify	
<i>After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable</i>	Yes ☐
Did the subject receive any other lines of subsequent systemic therapies? (Click 'yes' to create a new form to report additional lines of subsequent systemic therapies)	No ☐

Project Name: 79635322MMY3002

Form: Adverse Events/Serious AEs

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any adverse events experienced? Yes ☐
No ☐

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

What is the adverse event term?

Derived AE term for coding purposes

Any queries raised on this field should be addressed by updating the AE term and/or the AE event type.

Specify the event type

Local injection site reaction to Study Drug ☐
Systemic administration related reaction to Study Drug ☐
CRS ☐
ICANS ☐
New Malignancy ☐
None of the above ☐

Start Date

Start Time

End Date

End Time

Toxicity Grade

1 ☐
2 ☐
3 ☐
4 ☐
5 ☐

Action Taken with JNJ-79635322

Drug Interrupted ☐
Dose Not Changed ☐
Drug Withdrawn ☐
Not Applicable ☐
Unknown ☐

Action Taken with Teclistamab

Drug Interrupted ☐
Dose Not Changed ☐
Drug Withdrawn ☐
Not Applicable ☐
Unknown ☐

Project Name: 79635322MMY3002

Form: Adverse Events/Serious AEs

Generated On: 06 Mar 2026 12:08:14 (GMT)

Concomitant or additional therapy given for this adverse event?	Yes ☐
	No ☐
	Unknown ☐
Relationship to JNJ-79635322	Not Related ☐
	Related ☐
Relationship to Teclistamab	Not Related ☐
	Related ☐
Outcome	Fatal ☐
	Not Recovered or Not Resolved ☐
	Recovered or Resolved ☐
	Recovered or Resolved with Sequelae ☐
	Recovering or Resolving ☐
	Unknown ☐
If Not recovered or Not resolved, has the event stabilized?	Yes ☐
	No ☐
	Unknown ☐
If yes, date of stabilization	
Is the adverse event serious?	Yes ☐
	No ☐
Case ID (To generate a NEW case, keep empty. To link this case to another one, select an existing CASE ID)	
Date Investigator/Investigational Staff became aware of SAE?	
Is SAE related to any trial procedure not including study agent therapy? If yes, specify the specific trial procedure in the narrative	Yes ☐
	No ☐
Congenital Anomaly or Birth Defect	Yes ☐
	No ☐
Persistent or significant disability/incapacity	Yes ☐
	No ☐
Death	Yes ☐
	No ☐
Hospitalization (initial hospitalization or prolonged an ongoing hospitalization)	Yes ☐

Project Name: 79635322MMY3002

Form: Adverse Events/Serious AEs

Generated On: 06 Mar 2026 12:08:14 (GMT)

	No	☐
Life Threatening	Yes	☐
	No	☐
Other Medically Important Event	Yes	☐
	No	☐
Other Medically Important Event Specification		
Is the SAE an infection?	Yes	☐
	No	☐
<i>The following information should be completed ONLY if the SAE is an infection</i>	Yes	☐
	No	☐
Is the infection opportunistic?	Unknown	☐
Is the pathogen known?	Yes	☐
	No	☐
	Unknown	☐
In case of Yes, Pathogen		
Identification method		
Pathogen Type	Bacterial	☐
	Fungal	☐
	Parasitic	☐
	Prion	☐
	Protozoal	☐
	Viral	☐
If viral, is the infection new or reactivated?	New	☐
	Reactivation	☐
Is the infection localized or disseminated?	Disseminated (Generalized)	☐
	Localized	☐

Project Name: 79635322MMY3002

Form: Symptomatic Worsening of Multiple Myeloma

Generated On: 06 Mar 2026 12:08:14 (GMT)

Has the subject experienced any new or worsened symptoms associated with multiple myeloma? Yes ☐
No ☐

Start date of symptom _____

Symptom _____ Bone Pain ☐
Pathological Fracture ☐
Fatigue ☐
Renal Impairment ☐
Infection ☐
Fever ☐
Malaise ☐
Thromboembolic Event ☐
Dyspnea ☐
Weight Loss ☐
Hyperviscosity Syndrome ☐
Bleeding ☐
Other ☐

If Other, Specify _____

Toxicity Grade 2 ☐
3 ☐
4 ☐

Has the symptom led to an intervention? Yes ☐
No ☐

Interventions (Check all that apply)

Systemic anti-cancer therapy _____

Transfusions _____

Therapeutic procedures _____

Type of Therapeutic procedure _____ Plasmapheresis ☐
Stem Cell Transplantation ☐
Kyphoplasty ☐
Vertebroplasty ☐
Other surgical interventions ☐
Other therapeutic procedure ☐

Radiation _____

Project Name: 79635322MMY3002

Form: Symptomatic Worsening of Multiple Myeloma

Generated On: 06 Mar 2026 12:08:14 (GMT)

Supportive Medicinal therapies	
Type of supportive medicinal therapy	
<i>(Check all that apply)</i></br>Antibiotics	
Antiemetics	
Bisphosphonates	
Corticosteroids	
Erythropoietin Stimulating Agents (ESAs)	
Hydration	
IVIGs	
Neuropathy Supportive Care	
Opioids	
Non-Opioid analgesics	
Other Medicinal therapy	

Project Name: 79635322MMY3002

Form: Symptoms of Cytokine Release Syndrome (CRS)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Adverse Event Term (Derived field)	
Start Date (Derived)	
AE Logline (Derived)	
Symptom	Fever ☐
	Hypoxia ☐
	Hypotension ☐
	Other ☐
If Other, specify	
Derived symptom field for coding purposes	
<i>Any queries raised on this field should be addressed by updating the symptoms reported under 'Other, specify' field.</i>	
Start date	
Start time	
End date	
End time	
Was Symptom ongoing at end of reporting period	Yes ☐
	No ☐
Toxicity grade	1 ☐
	2 ☐
	3 ☐
	4 ☐

Project Name: 79635322MMY3002

Form: Symptoms of ICANS

Generated On: 06 Mar 2026 12:08:14 (GMT)

ICANS grading assessment per ASTCT

Date of ICANS grading assessment _____

Neurotoxicity Domains

ICE score: Report on the separate ICE score form

Level of consciousness

Awakens Spontaneously ☐

Awakens to voice ☐

Awakens only to tactile stimulus ☐

Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, stupor or coma ☐

Seizures

Not Applicable ☐

Any clinical seizure focal or general that resolves rapidly, non-convulsive seizures on EEG that resolve with intervention ☐

Life-threatening prolonged seizures (longer than 5 min) or repetitive clinical or electrical seizures without return to baseline in between ☐

Motor findings

Not Applicable ☐

Deep focal motor weakness such as hemiparesis or paraparesis ☐

Raised ICP/Cerebral edema

Not Applicable ☐

Focal/local edema on neuroimaging ☐

Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's Triad ☐

Adverse Event Term (Derived field) _____

Start DATE (Derived) _____

AE logline (Derived) _____

Were symptoms of ICANS observed? Yes ☐

No ☐

Symptom _____

Start date _____

Start time _____

Project Name: 79635322MMY3002

Form: Symptoms of ICANS

Generated On: 06 Mar 2026 12:08:14 (GMT)

End date	
End time	
Ongoing at end of reporting period	Yes ☐
	No ☐
Toxicity grade	1 ☐
	2 ☐
	3 ☐
	4 ☐

Project Name: 79635322MMY3002

Form: Additional data on New Malignancies (reported as AE)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Adverse Event Term (Derived field)	
Start Date (Derived)	
AE Logline (Derived)	
Type of Malignancy Diagnosis	Recurrent Prior Diagnosed Malignancy ☐
	Second Primary Malignancy ☐
Choose the corresponding MH log line and term	
Was confirmation by pathology diagnosis obtained?	Yes ☐
	No ☐
Date of pathology diagnosis	
Stage of the Disease	0 ☐
	I ☐
	II ☐
	III ☐
	IV ☐
	Not Applicable ☐
	Unknown ☐

Project Name: 79635322MMY3002

Form: New Malignancies (observed after AE reporting period)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Diagnosis			
Diagnosis Date			
Type of Malignancy Diagnosis	Recurrent Prior Diagnosed Malignancy	☐	
	Second Primary Malignancy	☐	
Choose the corresponding MH log line and term			
Was confirmation by pathology diagnosis obtained?	Yes	☐	
	No	☐	
Date of pathology diagnosis			
Stage of the Disease	0	☐	
	I	☐	
	II	☐	
	III	☐	
	IV	☐	
	Not Applicable	☐	
	Unknown	☐	
Treatment summary, relevant to new malignancy only (check all that apply)			
Systemic Therapy	☐		
If Systemic Therapy is checked, specify regimen			
Regimen			
Curative Surgery	☐		
Curative Radiotherapy	☐		
Palliative Supportive Care	☐		
No Treatment Started	☐		
Unknown	☐		
Outcome	Fatal	☐	
	Recovered/Resolved	☐	
	Not Recovered/Not Resolved	☐	
Comments			

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Survival Data

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date

Survival status

Alive ☐

Dead ☐

Unknown ☐

Last date known to be alive

Was any new malignancy diagnosed since last visit?

Yes ☐

No ☐

Unknown ☐

If yes, report the malignancy on the New Malignancies form under the Screening to end of study folder.

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Death Information

Generated On: 06 Mar 2026 12:08:14 (GMT)

Death Date	
What was the primary cause of death?	Adverse Event ☐
	Progressive Disease ☐
	Other ☐
Choose the corresponding AE log line, start date, and term	
If Other, Specify	
Was an autopsy performed?	Yes ☐
	No ☐
	Unknown ☐

Project Name: 79635322MMY3002

Form: Concomitant Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any medication(s)/therapy(ies) taken? Yes ☐
No ☐

After clicking 'Save and Add' or 'Add' to add new rows, click SAVE to make the new rows enterable.

Medication or Therapy	
Indication	Adverse Event ☐
	Medical History ☐
	Prophylaxis ☐
	Therapeutic or Diagnostic ☐
	Procedure ☐
	Trial Indication - Multiple ☐
	Myeloma ☐
	Other ☐

Choose the primary corresponding AE log line(s), start date(s), and term(s)

AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	

Choose the primary corresponding MH log line(s) and term(s)

MH log line and term	
MH log line and term	
MH log line and term	
MH log line and term	
MH log line and term	

Choose the primary corresponding Procedure's log line, start date, and procedure

If indication is 'Prophylaxis' or 'Other', specify	
Dose	

Dose Unit	Application ☐
	Capsule ☐
	Drop ☐
	Fingertip ☐
	Gram ☐
	Implant ☐
	International Unit ☐

Project Name: 79635322MMY3002

Form: Concomitant Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Liter	☐
	L/min	☐
	Milliequivalent	☐
	Microgram	☐
	Microliter	☐
	Milligram	☐
	Milligram per Kilogram	☐
	Milligram per Square Meter	☐
	Milliliter	☐
	Patch	☐
	Puff	☐
	Sachet	☐
	Spray	☐
	Tablespoon	☐
	Tablet	☐
	Teaspoon	☐
	ug/kg/min	☐
	ug/min	☐
	Unit	☐
	Vial	☐
	Other	☐
Dose Form	Aerosol	☐
	Capsule	☐
	Cream	☐
	Delayed Release Capsule	☐
	Delayed Release Tablet	☐
	Extended Release Capsule	☐
	Extended Release Tablet	☐
	For Solution	☐
	For Suspension	☐
	Gel	☐
	Granule	☐
	Implant	☐

Project Name: 79635322MMY3002

Form: Concomitant Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Inhalant	☐
	Injectable	☐
	Liquid	☐
	Lotion	☐
	Mouthwash	☐
	Ointment	☐
	Patch	☐
	Powder	☐
	Shampoo	☐
	Solution	☐
	Soap	☐
	Spray	☐
	Suppository	☐
	Suspension	☐
	Syrup	☐
	Tablet	☐
	Tape	☐
	Unassigned	☐
	Not Applicable	☐
	Unknown	☐
Route	Auricular	☐
	Inhalation	☐
	Intra-Articular	☐
	Intralesional	☐
	Intramuscular	☐
	Intrathecal	☐
	Intravenous	☐
	Nasal	☐
	Nasogastric	☐
	Ophthalmic	☐
	Oral	☐
	Parenteral	☐
	Rectal	☐

Project Name: 79635322MMY3002

Form: Concomitant Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Retrobulbar	☐
	Subcutaneous	☐
	Sublingual	☐
	Topical	☐
	Transdermal	☐
	Not Applicable	☐
	Unknown	☐
	Other	☐
Frequency	Once	☐
	Infrequent	☐
	As Necessary	☐
	Continue	☐
	Daily	☐
	Twice Daily	☐
	Three Times Daily	☐
	Four Times Daily	☐
	Every Other Day	☐
	Weekly	☐
	Twice Weekly	☐
	Three Times Weekly	☐
	Four Times Weekly	☐
	Every Two Weeks	☐
	Every Four Weeks	☐
	Monthly	☐
	Twice Per Month	☐
	Every Three Months	☐
	Thrice	☐
	Every Thirty Minutes	☐
	Every Two Months	☐
	Every Six Months	☐
	Unknown	☐
	Other	☐

Start Date

Project Name: 79635322MMY3002

Form: Concomitant Therapy

Generated On: 06 Mar 2026 12:08:14 (GMT)

If Start Date is entirely or partially unknown:		Yes ☐
Was the medication/therapy taken prior to the study?		No ☐
End Date		
Is the medication/therapy still ongoing?		

Project Name: 79635322MMY3002

Form: Protocol Amendment Implementation

Generated On: 06 Mar 2026 12:08:14 (GMT)

Protocol Version	
What was the date of informed consent obtained?	

Project Name: 79635322MMY3002

Form: Therapeutic/Surgical Procedures

Generated On: 06 Mar 2026 12:08:14 (GMT)

Therapeutic / Surgical Procedure	
Indication	Adverse Event ☐
	Medical History ☐
	Prophylaxis ☐
	Other ☐
If indication is 'Adverse Event,' choose the corresponding AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
AE log line, start date, and term	
If indication is 'Medical History,' choose the corresponding MH log line and term	
MH log line and term	
MH log line and term	
MH log line and term	
MH log line and term	
MH log line and term	
If Prophylaxis or Other, Specify	
Start Date	
End Date	
Was this procedure/surgery planned before entry into the study?	Yes ☐
	No ☐

Project Name: 79635322MMY3002

Form: Transfusions

Generated On: 06 Mar 2026 12:08:14 (GMT)

Were any transfusions given? Yes ☐
No ☐

Start Date

Type of Transfusion

Whole Blood ☐
Packed Red Blood Cells ☐
Fresh Frozen Plasma ☐
Platelets ☐
Other Transfusion ☐

If Other, specify

Number of units

Fixed Unit: U

Total Volume Transfused

Fixed Unit: Milliliter

Indication

Adverse Event ☐
Medical History ☐
Surgical Procedure ☐
Trial Indication ☐
Other ☐

If indication is 'Adverse Event,' choose the corresponding AE log
line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

If Indication is 'Surgical Procedure,' choose the primary
corresponding PR log line, start date, and procedure

If Other, Specify

Project Name: 79635322MMY3002

Form: Treatment Disposition (End of treatment)

Generated On: 06 Mar 2026 12:08:14 (GMT)

Treatment Disposition Date

What was the subject's primary reason for treatment discontinuation/completion?

Completed Treatment Period per Protocol ☐Adverse Event ☐Complete Response/ Remission ☐Lost to Follow-Up ☐Natural Disaster or Major Disruption ☐Non-Compliance with Study Drug ☐Pandemic ☐Physician Decision ☐Pregnancy ☐Progressive Disease ☐Protocol Deviation ☐Reached Maximum Total Dose ☐Site Terminated by Sponsor ☐Study Terminated by Sponsor ☐Withdrawal of Consent from study treatment ☐Other ☐

Choose the corresponding AE log line(s), start date(s), and term(s)

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

If Other, Specify

If Protocol Deviation, Specify

If Withdrawal of Consent from study treatment, Specify

If Physician Decision, Specify

If Pregnancy, Pregnancy Due Date

Project Name: 79635322MMY3002

Form: Trial Disposition (Completion/ Discontinuation)

Generated On: 06 Mar 2026 12:08:14 (GMT)

This form should only be completed at End of Data Collection

What was the subject's status? (Derived field)

Completed ☐Discontinued ☐Screen Failure ☐

Disposition Date _____

What was the subject's primary reason for screen failure?

Adverse Event ☐Death ☐Failure to Meet Eligibility ☐Criteria ☐Lost to Follow-Up ☐Natural Disaster or Major ☐Disruption ☐Pandemic ☐Pregnancy ☐Progressive Disease ☐Site Terminated by Sponsor ☐Study Terminated by Sponsor ☐Subject Met Eligibility Criteria ☐But Was Not Needed ☐Withdrawal of Consent ☐Other ☐What was the subject's primary reason for trial
discontinuation/completion?Death ☐Lost to Follow-Up ☐Natural Disaster or Major ☐Disruption ☐Pandemic ☐Site Terminated by Sponsor ☐Study Terminated by Sponsor ☐Withdrawal of Consent ☐

Choose corresponding AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

AE log line, start date, and term

If Other, Specify

Project Name: 79635322MMY3002

Form: Trial Disposition (Completion/ Discontinuation)

Generated On: 06 Mar 2026 12:08:14 (GMT)

If Withdrawal of Consent, select the reason	Enrolling in another study	☐
	Lack of Improvement	☐
	Lack of Transportation	☐
	Loss of Informant/Caregiver	☐
	Moving	☐
	Scheduling Difficulties	☐
	Study Tests Too Hard	☐
	To pursue alternative treatment	☐
	Other	☐

If Other, Specify	
-------------------	--

Project Name: 79635322MMY3002

Form: Comments

Generated On: 06 Mar 2026 12:08:14 (GMT)

Indicate the form to which the comment applies	
Indicate the visit to which the comment applies (if applicable)	
Comment	

Project Name: 79635322MMY3002

Form: Subject Site Switch

Generated On: 06 Mar 2026 12:08:14 (GMT)

Provide new Site ID	
Date subject started at new site	

Project Name: 79635322MMY3002

Form: Integrated Medication Kit Accountability Information-ACT_5mg

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please do not add log records manually. Any manually added records will be removed.

Drug Dispensed

Date Assigned

Assigned treatment label ID

Dispensed Status

Dispensed ☐

Dispensed In Error ☐

Not Dispensed ☐

If 'Not Dispensed', provide reason

Medical Decision ☐

Medication Kit not available or
damaged ☐

Study medication discontinued ☐

Visit skipped or administration
skipped ☐

Other Medication kit dispensed
in error ☐

Date Dispensed

Amount Dispensed

Units

Project Name: 79635322MMY3002

Form: Integrated Medication Kit Accountability Information-ACT_100mg

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please do not add log records manually. Any manually added records will be removed.

Treatment

Drug DispensedDate Assigned

Assigned treatment label ID

Dispensed Status

Dispensed ☐Dispensed In Error ☐Not Dispensed ☐

If 'Not Dispensed', provide reason

Medical Decision ☐Medication Kit not available or
damaged ☐Study medication discontinued ☐Visit skipped or administration
skipped ☐Other Medication kit dispensed
in error ☐Date Dispensed

Amount Dispensed

Units

Project Name: 79635322MMY3002

Form: Integrated Medication Kit Accountability Information- Teclistamab_ACT_30mg

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please do not add log records manually. Any manually added records will be removed.

Treatment

Drug DispensedDate Assigned

Assigned treatment label ID

Dispensed Status

Dispensed ☐Dispensed In Error ☐Not Dispensed ☐

If 'Not Dispensed', provide reason

Medical Decision ☐Medication Kit not available or
damaged ☐Study medication discontinued ☐Visit skipped or administration
skipped ☐Other Medication kit dispensed
in error ☐Date Dispensed

Amount Dispensed

Units

Project Name: 79635322MMY3002

Form: Integrated Medication Kit Accountability Information- Teclistamab_ACT_150mg

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please do not add log records manually. Any manually added records will be removed.

Treatment

Drug DispensedDate Assigned

Assigned treatment label ID

Dispensed Status

Dispensed ☐Dispensed In Error ☐Not Dispensed ☐

If 'Not Dispensed', provide reason

Medical Decision ☐Medication Kit not available or
damaged ☐Study medication discontinued ☐Visit skipped or administration
skipped ☐Other Medication kit dispensed
in error ☐Date Dispensed

Amount Dispensed

Units

Project Name: 79635322MMY3002

Form: Acknowledgement Reporting Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

CASE ID #	
Adverse Event Term(s)	
Date Safety Case created	
Version	
Date report received by Safety System	
Status	
Date of acknowledgement	
Error	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Periodic Investigator's EDC Review Acknowledgement

Generated On: 06 Mar 2026 12:08:14 (GMT)

As the investigator, I have ensured the accuracy, completeness, and
timeliness of the data reported to the sponsor in the CRFs.

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Relevant Additional Drug Therapies

Generated On: 06 Mar 2026 12:08:14 (GMT)

Please report only relevant concomitant medications discontinued $\geq$ 15 days prior to start of event

Relevant Past Medication or Therapy	
Relevant Indication	
Start Date	
End Date	
Select to include in Safety Case	1
Case ID	

Project Name: 79635322MMY3002**Form:** Relevant information Selection**Generated On:** 06 Mar 2026 12:08:14 (GMT)

Indicate all the forms that contain relevant information for this safety case. By completing the relevant form, the information can be submitted together with the safety case information. The submission of the safety case needs to be completed on the Safety Reporting Form after all information is captured and within 24 hours of knowledge of the safety case information.

Are relevant *Additional Drug Therapies* available for this safety case? Yes ☐

Are relevant *Tests* available for this safety case? Yes ☐

Are relevant *Procedures* available for this safety case? Yes ☐

Are relevant *Local Laboratory Data* available for this safety case? Yes ☐

Project Name: 79635322MMY3002

Form: Relevant Local Laboratory

Generated On: 06 Mar 2026 12:08:14 (GMT)

Select the applicable category	
Select the applicable test	

Project Name: 79635322MMY3002

Form: Relevant Local Laboratory Data

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date	
Test	
Result	
Unit	
Normal Lower Range	
Normal Higher Range	
Select to include in Safety Case	
Case ID	
Source Form Name	
Source Folder Names	

Project Name: 79635322MMY3002

Form: Relevant Procedures

Generated On: 06 Mar 2026 12:08:14 (GMT)

Relevant Therapeutic or Diagnostic Procedure	
Findings	
Procedure Date	
Select to include in Safety Case	1
Case ID	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Relevant Study Medication

Generated On: 06 Mar 2026 12:08:14 (GMT)

On Relevant Study Medication form, fields with label (Site Entry) need to be entered by the Site.

Do not inactivate the form if the Safety Report Form is still Active.

Relevant study agent	JNJ-79635322	☐
	TECLISTAMAB	☐
	SUBJECT NOT DOSED	☐
	SUBJECT DOSED AFTER SAE	☐
	ONSET DATE	☐
	EDC DATA ENTRY	☐
	INCOMPLETE	☐
Date of first dose of study agent		
Time of first dose of study agent		
Date of most recent dose of study agent prior to start of Safety Case		
(Site Entry)		
Time of most recent dose of study agent prior to start of Safety Case		
(Site Entry)		
Dose (Site Entry)		
Dose Unit (Site Entry)	Capsule	☐
	Gram	☐
	Implant	☐
	International Unit	☐
	Liter	☐
	Medical Drop	☐
	Microgram	☐
	Milligram	☐
	Milligram Equivalent	☐
	Milligram per Kilogram	☐
	Milligram per Square Meter	☐
	Milliliter	☐
	Patch	☐
	Puff	☐
	Sachet	☐
	Spray	☐

Project Name: 79635322MMY3002

Form: Relevant Study Medication

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Tablet	☐
	Tablespoon	☐
	Teaspoon	☐
	Vial	☐
	Milliliter per Hour	☐

Dose Text (Site Entry)

Dose Frequency (Site Entry)

	Once	☐
	Infrequent	☐
	As Necessary	☐
	Continue	☐
	Daily	☐
	Twice Daily	☐
	Three Times Daily	☐
	Four Times Daily	☐
	Every Other Day	☐
	Weekly	☐
	Twice Weekly	☐
	Three Times Weekly	☐
	Four Times Weekly	☐
	Every Two Weeks	☐
	Every Four Weeks	☐
	Monthly	☐
	Twice Per Month	☐
	Every Three Months	☐
	Thrice	☐
	Every Thirty Minutes	☐
	Every Two Months	☐
	Every Six Months	☐
	Unknown	☐
	Other	☐

Route

	Auricular	☐
	Inhalation	☐
	Intralesional	☐

Project Name: 79635322MMY3002

Form: Relevant Study Medication

Generated On: 06 Mar 2026 12:08:14 (GMT)

	Intramuscular	☐
	Intrathecal	☐
	Intravenous	☐
	Nasal	☐
	Nasogastric	☐
	Ophthalmic	☐
	Oral	☐
	Parenteral	☐
	Rectal	☐
	Retrobulbar	☐
	Subcutaneous	☐
	Sublingual	☐
	Topical	☐
	Transdermal	☐
	Not Applicable	☐
	Unknown	☐
	Other	☐
	Intracolonic	☐

Dose Form

Action taken with study agent (Site Entry)	Drug Interrupted	☐
	Dose Not Changed	☐
	Drug Withdrawn	☐
	Not Applicable	☐
	Unknown	☐

Did Reaction Recur on Readministration? (Site Entry)	Yes	☐
	No	☐
	Unknown	☐

Batch/lot Number available? (Site Entry)	Yes	☐
	No	☐

Batch/lot Number (Site Entry)

Indication (Site Entry)	Trial Indication - Multiple Myeloma	☐
-------------------------	-------------------------------------	--------------------------

Select to include in Safety Case

Project Name: 79635322MMY3002

Form: Relevant Study Medication

Generated On: 06 Mar 2026 12:08:14 (GMT)

Case ID	
Source Form Name	

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Relevant Tests

Generated On: 06 Mar 2026 12:08:14 (GMT)

Collection Date	
Relevant Test	
Result	
Unit	
Normal Higher Range	
(Optional) Normal Lower Range	
Select to include in Safety Case	1
Case ID	

Project Name: 79635322MMY3002

Form: Safety Report Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

CASE ID #

Adverse event terms included in safety case

Date Safety case (CASEID) created in eDC

Time Safety case (CASEID) created in eDC

UTC Date Safety case (CASEID) created in eDC

UTC Time Safety case (CASEID) created in eDC

Case Seriousness Roll-up

Serious adverse event? Yes ☐
No ☐

Was event a congenital anomaly or birth defect? Yes ☐
No ☐

Event Required Inpatient hospitalization or Prolongation of Existing Hospitalization? Yes ☐
No ☐

Did the event result in persistent or significant disability or incapacity? Yes ☐
No ☐

Was the event life threatening? Yes ☐
No ☐

Was this an 'Other medically important condition?' Yes ☐
No ☐

Did the event result in death? Yes ☐
No ☐

Additional subject information

Date of Death (dd-MMM-yyyy)

Was an autopsy performed? Yes ☐
No ☐
Unknown ☐

Age at onset of event

Age unit Hours ☐
Days ☐
Weeks ☐
Months ☐
Years ☐

Project Name: 79635322MMY3002

Form: Safety Report Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

Weight at onset of SAE (kg)

Height at onset of SAE (cm)

INVESTIGATOR'S NARRATIVE

SGINVNAR While it is not necessary to repeat all information that is already available in the Safety Report Form and Relevant Forms, it is important that the Narrative provides an understandable, full medical story of the event/patient's experience, presented in logical time-sequence. Therefore, please describe the event in sufficient detail that enables a safety physician to perform a medical assessment of the case. E.g. (but not limited to):

- Signs & Symptoms
- Risk Factors
- Investigations and Supporting Diagnostics
- Differential Diagnosis
- Course of Events
- Treatment for Event / Response to Treatment
- Suspected Causes
- Product Quality Complaint? (If yes, please complete TV-FRM-03237: Product Quality Complaint Form)

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

INVESTIGATOR'S NARRATIVE (Continued)

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Project Name: 79635322MMY3002

Form: Safety Report Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Project Name: 79635322MMY3002

Form: Safety Report Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

Use this field to add additional information to the Narrative.

Do NOT include any Personally identifiable information (e.g. Name, Initials,...) in the Narrative

Mapped Narrative, auto populated.

No action required.

Mapped Narrative, auto populated.

No action required.

Submit Safety Case

Trial Phase

Open-label phase of
multi-phased trial ☐

Blinded phase of multi-phased
trial ☐

Was blind broken?

Yes ☐

No ☐

If event required hospitalization or prolonged hospitalization specify
admission date

Hospital discharge date

Reason for Downgrade **(Select only if event is downgraded)**

Event has been downgraded from
a Serious to a Non Serious Event ☐

Event has been downgraded from
a Non-Serious Event requiring
rapid reporting to a Non-Serious
Event which does not require
rapid reporting ☐

Event was reported in error (did
not occur for this patient) or
Event was reported in error and
will be deleted ☐

Other ☐

Specify

79635322MMY3002 Version 1.02 06MAR2026: All Forms

Project Name: 79635322MMY3002

Form: Safety Report Form

Generated On: 06 Mar 2026 12:08:14 (GMT)

**CHECK BOX AND CLICK SAVE TO SUBMIT EVENT TO
SPONSOR.**

**IF THIS BOX IS NOT CHECKED ANY DATA WHICH HAS
BEEN ENTERED AND SAVED WILL BE AUTOMATICALLY
TRANSMITTED TO SPONSOR 12 HOURS AFTER SAVING.**
