










		Study Period	Screening	Pre-Treatment [d]			Treatment and Safety Follow Up																	ET	
		Study Week	-10 to -7	-6 to -1			1				2		3	4	6	8	10	12	18	24	36	48/ES			
		Study Day (Visit Window)			-10 to -4	-7 to 1	1	2	4 or 5	7±1	11±1	14±2	21±2	28±2	42±2	56±2	70±2	84±3	126±7	168±7	252±7	336±7			
Label	Collection	Testing		Apheresis	Pre-Infusion	Biopsy																			
ADA	 7.0 mL SST	Serum sample for ADA			X									X		X		X	X			X	X		
Exploratory Markers - Serum	 4.0 mL SST	Serum sample for exploratory markers	X		X			X		X		X	X	X	X	X	X	X	X	X	X	X	X		
PBMC (collection) [b]	 10.0 mL NaHep	PBMC for Cellular Immunogenicity, Exploratory Biomarkers, RCL	X(x2) Ex2		X (x4) Cx1 Ex2 Rx1			X(x2) Ex2	X(x2) Ex2	X(x2) Ex2	X(x2) Ex2	X(x2) Ex2	X (x3) Cx1 Ex2	X(x2) Ex2	X (x3) Cx1 Ex2	X(x2) Ex2	X (x3) Cx1 Ex1 Rx1	X(x2) Ex2	X (x3) Ex2 Rx1	X(x2) Ex2	X (x3) Cx1 Ex1 Rx1	X (x2) Cx1 Ex1			
PK ddPCR	 3.0 mL K2EDTA	Blood sample for PK(ddPCR)			X			X[a]	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Exploratory Markers - Plasma [c]	 4.0 mL K2EDTA	Plasma sample for exploratory markers	X		X(x2)			X		X		X	X	X	X	X	X	X	X	X	X	X			
FFPE Skin Biopsy (Lesional & Peri-lesional) [e]	 6mm Punch and petri dish	X (optional) Lesional			X Lesional									X Lesional				X Lesional				X Lesional			
					X (Optional) peri-lesional						X (Optional) peri-lesional			X (Optional) peri-lesional			X (Optional) peri-lesional								
Footnotes														Order of Draw											
General Note: Samples collected outside the listed scheduled visits should use the Unscheduled Visit forms provided at the back of the requisition binder.																									
[a] The PK sample collected on study Day 2 should be collected at approximately the same time of day that the infusion of study drug took place on study Day 1 (+/- 1 hour). An unscheduled PK sample should be collected as soon as possible after a suspected infusion related reaction adverse event.																									
[b] 4 tubes will be collected at Pre-Treatment. 3 tubes will be collected at Day 28, Day 56, Day 84, Day 168 and Day 336. For all other visits only 2 tubes will be collected. X = total, C = Cellular Immunogenicity, E = exploratory biomarkers, R = RCL, number of tubes for each collection designated for each visit as outlined in protocol SOA.																									
[c] 2 tubes will be collected at Pre-Treatment. For all other visits only 1 tube will be collected.																									
[d] The Pre-Treatment visit samples may be redrawn any number of times. For redraws of the Pre-Treatment visit samples please use the Pre-Treatment Reassessment Visit forms in the back of the requisition binder next to the Unscheduled Visit forms.																									
[e] Mandatory lesional biopsies should be collected at Pre-treatment, Week 4, and Week 12 visits. An additional optional lesional biopsy may be collected during the screening period, and optional peri-lesional biopsies may also be collected at Pre-treatment, Week 4, and Week 12. The Pretreatment skin biopsy (6-mm punch biopsy) is to be performed after the pre-infusion confirmation of eligibility, up to 7 days before study drug administration. During treatment and follow-up the skin biopsy can be performed at or up to 7 days after the scheduled assessment visit. For patients who discontinue the study prior to Week 12, a skin biopsy at ET is optional. Please photograph the lesion that is to be biopsied according to the instruction provided in the biopsy manual. Please refer to the Biopsy Manual for further information.																									

Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
ADA		Fill tube completely with blood.	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		Immediately after collection, gently invert tubes 5 times.			
		Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical. The SST tube should NOT be refrigerated prior to centrifugation.			
		Within 60 minutes of collection, centrifuge at 1,800- 2,200xg (RCF not RPM) for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers.			
		Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL cryovials and divide the remaining serum between the other 2 x 2.0mL cryovials, leaving a small amount on top of the separator gel. Discard the collection tube.			
		Store at ≤-20°C until shipping			
	7.0 mL SST	Ship cryovials to MRL frozen in weekly batches.			
Exploratory markers - Serum		Fill tube completely with blood.	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		Immediately after collection, gently invert tubes 5 times.			
		Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical. The SST tube should NOT be refrigerated prior to centrifugation.			
		Within 60 minutes of collection, centrifuge at 1,800- 2,200xg (RCF not RPM) for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers.			
		Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL cryovials and divide the remaining serum between the other 2 x 2.0mL cryovials, leaving a small amount on top of the separator gel. Discard the collection tube.			
		Store at ≤-20°C until shipping			
	4.0 mL SST	Ship cryovials to MRL frozen in weekly batches.			
PBMC (collection)		Fill all tubes completely with blood.	None	Ship to MRL ambient on day of collection	
		Gently invert 8-10 times to avoid clotting.			
		Do NOT Centrifuge. Do NOT open tube.			
		Ship tube to MRL ambient on day of collection			
Exploratory markers - Plasma		Fill all tubes completely.	4 or 8 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		Mix tubes after collection by gently inverting 8-10 times and immediately place on wet ice.			
		Within 60 minutes of collection, centrifuge at 4°C at 1800g - 2200g (RCF not RPM) for 10-15 minutes.			
		Using a transfer pipette, aliquot 0.5 mL of plasma into each of 4(8 for Pre-Treatment) x 2.0 mL cryovials and freeze until shipment.			
		Store at ≤-20°C until shipping			
		Ship cryovials to MRL frozen in weekly batches.			
PK ddPCR		Fill tube completely as a partial fill results in over anticoagulation, impacting results of testing.	2 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		Mix tube immediately after collection, gently inverting 8-10 times			
		Do NOT Centrifuge.			
		Using a pipette, divide blood equally between 2 separate aliquots			
		Freeze immediately on dry ice and keep at ≤-70°C until shipping.			
		Ship cryovials to MRL frozen in weekly batches.			
	3.0 mL K2EDTA				
FFPE Skin Biopsy Lesional and Peri-lesional	6mm Punch and petri dish	See biopsy manual for instruction	2x 20.0 mL tube	Ship to Mosaic Refrigerated (4C) day of collection	DO NOT SEND TO MRL