



		Study Period	Screening	Pre-Treatment [d]								Safety Fo	ollow Up								ET
		Study Week	-8 to -7	-6 to -1			1		:	2	3	4	6	8	10	12	18	24	36	48/ES	
		Study Day (Visit Window)		Apheresis Pre-infusion -10 to -4	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			'																
ADA	7 mL SST	Serum sample for ADA		x								x		x		x				х	х
Exploratory Markers - Serum	7.0 mL SST	Serum sample for exploratory markers		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(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	x
Exploratory Markers - Plasma [c]	4.0 mL K2EDTA	Plasma sample for exploratory markers	х	X(x2)		x		х		x	x	x	x	x	x	x	x	x	x	x	x
				Footnotes								Order of Draw									
[a] The PK sample colle		uld be collected at app	roximately th	use the Unscheduled Vi e same time of day that the							eduled PK				→		4		0		
[b] 4 tubes will be co	ollected at Pre-Treatme	ent. 3 tubes will be co	llected at D	ay 28, Day 56, Day 84, I mber of tubes for each o							cted. X =				ŕ		U				
	ollected at Pre-Treatme					-															
	nt visit samples may be the requisition binder			For redraws of the Pre-Tr ns.	eatment vi	sit sample	s please us	e the Pre-Ti	eatment R	eassessme	nt Visit 2										





Study Perio			Screening	Pre-Tre	eatment		Safety Follow Up											ET			
		Study Week	-8 to -7	-6	to -1			1			2	3	4	6	8	10	12	24	36	48/ES	
		Study Day (Visit Window)		Apheresis	Pre- infusion 10 to -4	. 1	2	4 or 5	7±1	11±1	14±2	21±2	28±2	42±2	56±2	70±2	84±3	168±7	252±7	336±7	
Label	Collection	Testing																			
Synovial Fluid Supernatant (d)				х	(a)								X (b) (c)				X (b) (c)				X (c)
Synovial Fluid Viable Cells (d)	4.0 mL NaHep			x	(a)								X (b) (c)				X (b) (c)				X (c)
Cryo Synovial Biopsy (d)	4.0 III. Nallep			х	(a)								X (b) (c)								X (c)
FFPE Synovial Biopsy (d)	Bard Mission Needles and 12- Well Plates			х	(a)								X (b) (c)								X (c)

Footnotes

General Note: Samples collected outside the listed scheduled visits should use the Unscheduled Visit forms provided at the back of the requisition binder.

(a) Synovial biopsy and/or synovial fluid collection during the Pre-treatment period should be performed after enrollment and at least one week prior to the planned dosing visit.

(b) The synovial biopsy/fluid collection can be performed at or up to 1 week after the scheduled assesment visit.

(c) The timing of the synovial biopsy and/or synovial fluid collection in may be changed based on evaluation of data from the first dose escalation cohot.

(d) The synovial biopsy sample/fluid collection is optional at all timepoints.





Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
		Fill tube completely with blood.			
		Immediately after collection, gently invert tubes 5 times.			
		Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical.			
ADA		Within 60 minutes of collection, centrifuge at 1,800-2,200xg for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers. If the serum is not separated from the blood after centrifugation, re-centrifuge the sample until the serum is separated	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		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.			
		Fill tube completely with blood.			
		Immediately after collection, gently invert tubes 5 times.			
		Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical.			
oploratory markers - Serum		Within 60 minutes of collection, centrifuge at 1,800-2,200xg for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers. If the serum is not separated from the blood after centrifugation, re-centrifuge the sample until the serum is separated	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		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.			
		Fill all tubes completely with blood.			
PBMC (collection)		Gently invert 8-10 times to avoid clotting.	None	Ship to MRL ambient on day of	
DMC (collection)		Do NOT Centrifuge. Do NOT open tube.	None	collection	
	10.0 mL NaHep	Ship tube to MRL ambient on day of collection			
		Fill all tubes completely.			
		Mix tubes after collection by gently inverting 8-10 times and immediately place on wet ice.			
ploratory markers -		Within 60 minutes of collection, centrifuge at 4°C at 1800g - 2200g for 10-15 minutes.		Ship to MRL frozen in weekly	
Plasma		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.	4 or 8 x 2.0 mL Sarstedt microtube	batches	
		Store at ≤-20°C until shipping			
	4.0 mL K2EDTA	Ship cryovials to MRL frozen in weekly batches.			





Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
		Fill tube completely as a partial fill results in over anticoagulated plasma, impacting results of testing.			
		Mix tube immediately after collection, gently inverting 8-10 times			
PK ddPCR		Using a pipette, divide blood equally between 2 separate aliquots	2 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
		Freeze immediately on dry ice and keep at ≤-70°C until shipping.			
	3.0 mL K2EDTA	Ship cryovials to MRL frozen in weekly batches.			
Synovial Fluid Supernatant	4.0 mL NaHep	See Biopsy Manual for instruction.	2 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
	4.0 ML Nahep				
Synovial Fluid Viable Cells	4.0 mL NaHep	See Biopsy Manual for instruction.	1 x 2.0 mL Corning Cryovials	Ship to MRL frozen in weekly batches	
				1	
Cryo Synovial Biopsy	Bard Mission Needles and 12- Well Plates	See Biopsy Manual for instruction.	2 x 2.0 mL Corning Cryovials	Ship to MRL frozen in weekly batches	
FFPE Synovial Biopsy	Bard Mission Needles and 12- Well Plates	See Biopsy Manual for instruction.	1 x 20.0 mL tube	Ship to Mosaic Refrigerated (4C) day of collection	DO NOT SEND TO MR