















		Study Period	Screening	Pre-Treatment		Safety Follow 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 Window) (Visit Window)			-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					X	X			
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 (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	X		X(x2)		X		X		X	X	X	X	X	X	X	X	X	X	X	X			
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 un scheduled PK sample should be collected within 30 minutes of a suspected infusion related 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.																									

		Study Period	Screening	Pre-Treatment		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)			-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	 4.0 mL NaHep		X (a)										X (b) (c)				X (b) (c) (d)				X (c) (d)	
Synovial Fluid Viable Cells			X (a)										X (b) (c)				X (b) (c) (d)				X (c) (d)	
Cryo Synovial Biopsy			X (a)										X (b) (c)								X (c) (d)	
FFPE Synovial Biopsy		Bard Mission Needles and 12-Well Plates		X (a)									X (b) (c)								X (c) (d)	
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 cohoh.																						
(d) The synovial biopsy sample/fluid collection at Week 12 and at the ET visit is optional.																						

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.			
		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.			
		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.			
		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.			
		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.			
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 15 minutes of collection, centrifuge at 4°C at 1800g - 2200g 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.			
	4.0 mL K2EDTA				

Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
PK ddPCR	 3.0 mL K2EDTA	Fill tube completely as a partial fill results in over anticoagulated plasma, 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			
		Using a pipette, divide blood equally between 2 separate aliquots			
		Freeze immediately on dry ice and keep at $\leq -70^{\circ}\text{C}$ until shipping.			
		Ship cryovials to MRL frozen in weekly batches.			
Synovial Fluid Supernatant	 4.0 mL NaHep	See Lab Manual for instruction.	2 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
Synovial Fluid Viable Cells	 4.0 mL NaHep	See Lab Manual for instruction.	1 x 2.0 mL Corning Cryovials	Ship to MRL frozen in weekly batches	
Cryo Synovial Biopsy	Bard Mission Needles and 12-Well Plates	See Lab 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 Lab Manual for instruction.	1 x 20.0 mL tube	Ship to Mosaic Refrigerated (4C) day of collection	DO NOT SEND TO MRL