

Table 2 Flow Chart – Schedule of Assessments

Pre-Treatment Phase		Treatment Phase ¹								Post-Treatment Phase	
Cycle Number	Screening	Cycle 1				Cycle 2, 4, 6 etc.		Cycle 3, 5, 7 etc.		EOT	1M FUP
Day within Cycle Visit Window (\pm days)	D-14 to D-1	D1	D8 (\pm 2)	D15 (\pm 2)	D22 (\pm 2)	D1	D15 (\pm 2)	D1	D15 (\pm 2)	\leq 10 d from the decision of trial treatment withdrawal	1 month after last dose of trial treatment (28+7d)
Informed Consent	X										
Baseline Characteristics/Eligibility ²	X	X									
Safety Assessments											
Medication Survey	X	X	X	X	X	X	X	X	X	X	X
(S)AE Survey and Reporting	X	X	X	X	X	X	X	X	X	X	X
DLT Evaluation (dose-escalation only) ³	X	X	X	X	C2/D1						
Vital Signs and Body Weight	X	X		X		X	X	X	X	X	X
ECOG PS	X	X				X		X		X	X
Physical Examination	X	X				X		X		X	X
Dermatological Examination	X	X		X		X	X	X	X	X	X
ECG ⁴	X									X	
Safety blood samples ⁵	X	X	X	X	X	X	X	X	X	X	X
Urinalysis ⁵	X	X		X		X		X		X	X
Pregnancy Test	X									X	
Disease Assessments											
(Archival) Tumor Biopsy Collection ^{6,7}	X										
Tumor Marker Evaluation ⁸	X						End of C			X	X
Disease Status Evaluation by CT/ MRI ^{9,10}	X						End of C			X	X
*Additional Assessments											
*PK Samples (dose-escalation only) ¹¹	X		X		X	X	X			X	X
*ADA Sample		X					X			X	X
*Biomarker Blood and Urine Sample ¹²	X						End of C2			X	
Trial Treatment											
Skin Toxicity Prophylaxis and TX ¹³	X	X	X	X	X	X	X	X	X	X	X
Infusion Reaction Prophylaxis ¹⁴	X		X								
Sym004 Infusion		X		X		X	X	X	X		
Gastrointestinal Toxicity Prophylaxis ¹⁵	X		X		X	X	X	X	X		
FOLFIRI Infusion		X		X		X	X	X	X		
Post-Infusion Monitoring		X		X		X	X	X	X		

Abbreviations (in alphabetical order): ADA, anti-drug antibody; C, Cycle; CT, computed tomography scan; D/d, day(s); DLT, dose-limiting toxicity; EOT, End of trial treatment Visit (Sym004 and FOLFIRI); ECG, electrocardiography; ECOG PS, Eastern Cooperative Oncology Group performance status; MRI, magnetic resonance imaging; 1M FUP, One Month Follow-up Visit; PK, pharmacokinetic; (S)AE, (serious) adverse event; TX, therapy

*Omitted with Amendment 3