Table 1. Treatment schedule and outcome measures.

Items		Before treatment	Administration period								At the end of the test	Post observation period	
Time point			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 10	Day 11 or at discharge before Day 10	1 week later (Day 17)	1 year later (Day 365)
Tolerance		—	—	—	—	—	—	—	—		—	(± 2 days)	(± 14 days)
Acquisition		○											
Confirmation of patient background		○											○
Administration of test drugs			→	→	→	→	→	→	→	→	→		
Confirmation of subjective symptoms		○	→	→	→	→	→	→	→	→	○	○	○
Observation of adverse events			→	→	→	→	→	→	→	→	○	○	○
Blood pressure		○		○	○	○	○	○	○		○		
Estimation of body temperature and abdominal pain		○	○	○	○	○	○	○	○		○		
Weight		○									○		
LAB data	Hematology examination	○			○		○		○		○		
	Blood biochemical examination	○			○		○		○		○		
	Urine examination	○									○		
Confirmation of concomitant medication and supportive care		○	→	→	→	→	→	→	→	→	○		
CT scan		○											