Schedule of IP-101 Study Procedures

Procedures	**Screening Period** (Day 1; includes consenting, planning EMU stay, randomization at the EMU admission, inpatient EMU time prior to the seizure qualifying for study drug administration)	**Treatment Period** (Day 1; start of study drug administration to 12h after end of study drug administration or until seizure or rescue medication)	**Safety Follow-Up** (24h after end of study drug administration)[a]
	Visit 1	**Visit 2**	**Visit 3**
	Upon Admission		
Informed consent	X		
Concomitant medications	X	X	X
Brief physical examination, including weight and height	X	X[c]	X[d]
Laboratory assessment (including urine dipstick or other confirmation)	X[e]	[c]	X
Cognitive Assessments	X	X[f]	
Vital signs (SBP, DBP, PR, RR)	X[e]	X[g]	X[g]
12-lead ECG	X	X[h]	X
Adverse Events	X	X	X
Randomization to study drug group	X		

DBP=diastolic blood pressure; ECG=electrocardiogram; EEG=electroencephalogram; EMU=Epilepsy Monitoring Unit;
IV=intravenous; PR=pulse rate; RR=respiratory rate; SBP=systolic blood pressure;
a Safety Follow-Up (SFU) assessments to be performed at least 24h after study drug administration.
b Medical history including psychiatric and substance abuse history.
c If the Screening physical examinations were performed within 7 days of Treatment Period, do not repeat.
d If any clinically significant abnormality observed after study drug administration, then perform at SFU.
e If subject has had laboratory assessments performed within the past 14 days, do not repeat.
f Assessment performed at Screening (Form 1), and at 1h (Form 2), 2h (Form 3), and 3h (Form 4) after the end of study drug administration. If study drug administration occurs for a nocturnal seizure and subject is asleep, assessment should not be performed.
g Assessments performed at the following time points: pre-dose, end of bolus, 5min, 15min, 30min, 1h, 2h, and 4h after end of bolus, unless seizure or rescue medication occurs that ends the Treatment Period. If clinically significant abnormality is observed in the final assessment of the Treatment Period, continue to monitor every 4h until resolution or end of SFU Period.
h Assessments will be performed within 60min of start of study drug administration, and a 5min continuous ECG will be performed beginning with the bolus start and stopping 2 to 5min after the end of the bolus.