

Overview of Treatment-Emergent Adverse Events
Safety Analysis Set

	Placebo (N=86)			Low Dose (N=84)			High Dose (N=84)		
	n	(%)	E	n	(%)	E	n	(%)	E
Adverse Events	65	(75.6%)	281	77	(91.7%)	412	76	(90.5%)	433
Drug-Related [1] Adverse Events	43	(50.0%)	130	72	(85.7%)	285	70	(83.3%)	275
Deaths	2	(2.3%)	2	1	(1.2%)	1		0	
Serious Adverse Events [2]		0		1	(1.2%)	1	2	(2.4%)	2
Drug-Related [1] Serious Adverse Events [2]		0		1	(1.2%)	1	1	(1.2%)	1
Adverse Events Leading to Permanent Discontinuation of Study Drug		0			0			0	
Drug-Related [1] Adverse Events Leading to Permanent Discontinuation of Study Drug		0			0			0	