

Supplementary data

Table S1. Summary of mean and mean changes from baseline of weight on month 1 and 2 in mITT population

Study Arm	Weight (g)	Actual Value						Changes from Baseline					
	Analysis Visit*	N	Mean	SD	Median	Min	Max	N	Mean	SD	Median	Min	Max
AP-32	Month 1	28	5403.6	790.9	5250.0	4100	7800	28	1034.3	445.6	1050.0	-200	1900
	Month 2	28	6246.4	835.1	6150.0	5000	8300	28	1852.1	562.8	1700.0	900	3000
CP-9	Month 1	23	5369.6	807.6	5200.0	4200	7100	23	987.0	419.2	900.0	200	1800
	Month 2	24	6275.0	969.6	6000.0	4500	8200	24	1816.7	615.5	1850.0	700	3000
	155	1	7600.0	-	-	-	-	1	3600.0	-	-	-	-
Placebo	Month 1	31	5561.3	808.6	5700.0	4200	7000	31	1132.3	385.9	1100.0	500	1800
	Month 2	28	6432.1	851.2	6500.0	5100	8200	28	1935.7	510.8	2000.0	1000	3200

Table S2. Shift table of digestive tolerance (mITT population)

		AP-32	CP-9	Placebo
		N=29[#]	N=26[#]	N=31[#]
Regurgitation				
Baseline*	Post-baseline**	n (%)	n (%)	n (%)
None	None	1 (3.4%)	3 (11.5%)	2 (6.5%)
	Mild	4 (13.8%)	0	3 (9.7%)
	Moderate	1 (3.4%)	0	0
	Severe	1 (3.4%)	0	1 (3.2%)
Mild	None	0	0	2 (6.5%)
	Mild	15 (51.7%)	14 (53.8%)	11 (35.5%)
	Moderate	2 (6.9%)	2 (7.7%)	4 (12.9%)
	Severe	2 (6.9%)	0	1 (3.2%)
Moderate	None	0	0	1 (3.2%)
	Mild	0	2 (7.7%)	2 (6.5%)
	Moderate	1 (3.4%)	0	1 (3.2%)
	Severe	1 (3.4%)	0	0
Severe	None	0	0	0
	Mild	1 (3.4%)	3 (11.5%)	1 (3.2%)
	Moderate	0	0	2 (6.5%)
	Severe	0	0	0
Flatulence				
Baseline*	Post-baseline**	n (%)	n (%)	n (%)
None	None	2 (6.9%)	3 (11.5%)	3 (9.7%)
	Seldom	4 (13.8%)	5 (19.2%)	5 (16.1%)
	Often	0	0	1 (3.2%)
Seldom	None	2 (6.9%)	2 (7.7%)	0
	Seldom	13 (44.8%)	8 (30.8%)	15 (48.4%)
	Often	2 (6.9%)	2 (7.7%)	1 (3.2%)
Often	None	0	0	1 (3.2%)
	Seldom	3 (10.3%)	1 (3.8%)	3 (9.7%)
	Often	3 (10.3%)	3 (11.5%)	2 (6.5%)

[#] Number of evaluable infants

* Baseline: the highest severity before the first dosing of study products per subject

** Post-baseline: the highest severity after baseline per subject

Two infant in the CP-9 group had baseline records but missing post-baseline data.