Supplementary Data for "Budesonide Multi-Matrix Is Efficacious for Mesalamine-Refractory, Mild to Moderate Ulcerative Colitis: A Randomized, Placebo-Controlled Trial"

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Supplementary Table 1. Biomarker concentrations [mITT population]

Assessment time	Budesonide MMX [*n* = 230]	Placebo [*n* = 228]	*P* value[a]
Serum C-reactive protein, mg/L, mean [SD]			
Baseline	8.4 [11.3]	9.2 [13.1]	
Week 8	8.6 [16.9]	6.4 [8.7][b]	0.67
Fecal calprotectin, mg/kg, mean [SD]			
Baseline	525.1 [459.6]	594.0 [869.6]	
Week 8	379.8 [362.2]	431.8 [382.7]	0.26

mITT, modified intent-to-treat; SD, standard deviation.

[a]*P* value for the difference in change from baseline between groups.

[b]Data available for 227 patients.

Supplementary Table 2. IBD-QOL scores [mITT population]

Assessment time	Budesonide MMX [n = 230]	Placebo [n = 228][a]	P value[b]
Total IBD-QOL score, mean [SD]			
Baseline	132.8 [31.4]	134.1 [32.5]	
Week 2	157.1 [31.6]	155.7 [32.6]	0.32
Week 4	164.6 [34.4]	160.2 [35.1]	0.04
Week 8	163.9 [39.4]	165.8 [36.8]	0.88
IBD-QOL bowel function subscale score, mean [SD]			
Baseline	40.5 [9.5]	40.5 [9.7]	
Week 2	49.2 [10.3][b]	48.0 [10.1]	0.2
Week 4	52.4 [11.5]	50.0 [10.9]	0.02
Week 8	52.2 [13.2]	52.2 [11.8]	1.0
IBD-QOL emotional function subscale score, mean [SD]			
Baseline	49.9 [13.5]	50.7 [14.1]	
Week 2	57.9 [13.5][c]	58.5 [13.7]	0.54
Week 4	60.3 [13.9]	59.7 [14.6]	0.13
Week 8	59.8 [15.6]	61.4 [14.8]	0.54
IBD-QOL systemic symptoms subscale score, mean [SD]			
Baseline	20.2 [5.3]	20.1 [5.7]	
Week 2	23.6 [5.1][c]	22.9 [5.6]	0.24
Week 4	24.3 [5.5]	23.7 [5.8]	0.28
Week 8	24.3 [6.1]	24.6 [5.9]	0.3
IBD-QOL social function subscale score, mean [SD]			
Baseline	22.2 [7.1]	22.8 [7.5]	
Week 2	26.3 [6.5][c]	26.2 [7.1]	0.2
Week 4	27.6 [6.6]	26.8 [7.4]	0.01
Week 8	27.6 [7.4]	27.6 [7.3]	0.16

[a]For total score and each subscale score, data available from 226 patients at baseline and week 2, and from 227 patients at weeks 4 and 8.

[b]P value for difference between groups in change from baseline.

[c]Data available for 228 patients.

IBD-QOL = inflammatory bowel disease quality of life; mITT = modified intent-to-treat population; SD = standard deviation.

Supplementary Table 3. Morning cortisol levels [safety population]

Assessment time	Budesonide MMX [$n = 255$]		Placebo [$n = 255$]	
	Mean [SD], µg/dL	Median, µg/dL	Mean [SD], µg/dL	Median, µg/dL
Baseline	12.5 [4.8]	12.0	12.0 [4.9]	11.0
Week 2	7.3 [5.2]	7.0	11.8 [4.5]	11.0
Week 4	7.3 [5.4]	7.0	12.4 [4.5]	12.0
Week 8	8.8 [6.5]	8.0	12.7 [4.6]	12.5

Supplementary Figure 1. Study design