

**SUPPLEMENTAL MATERIAL****Open-capsule budesonide for the treatment of immune-related enteritis from checkpoint inhibitors**

Patrick T. Magahis, BA<sup>1\*</sup>, Tara Corso, PA-C<sup>2\*</sup>, Pamela Livingstone, RN<sup>2</sup>, Erika Tom, RN<sup>2</sup>, Amitabh Srivastava MBBS<sup>3</sup>, Michael A. Postow, MD<sup>1,4</sup> and David M. Faleck, MD<sup>1,2</sup>

<sup>1</sup>Weill Cornell Medical College of Cornell University, New York, NY, USA

<sup>2</sup>Gastroenterology, Hepatology, and Nutrition Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA

<sup>3</sup>Department of Pathology, Memorial Sloan Kettering Cancer Center, New York, NY, USA

<sup>4</sup>Melanoma Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA

\*Co-First Authors

**Correspondence:** David Faleck, MD  
Gastroenterology, Hepatology, and Nutrition Service  
Department of Medicine  
Memorial Sloan Kettering Cancer Center  
1275 York Avenue, New York, NY, 10065  
Tel: 212-639-3904 | Fax: 212-639-2766  
Email: faleckd@mskcc.org

**Supplemental Table 1.** Characteristics of patients on open-capsule budesonide by achievement of steroid-free remission.

Characteristics	Total patients n=19	Steroid-Free Remission Achieved n=11	Steroid-Free Remission Not Achieved n=8	P-value
<b>Age, median (range)</b>	62 (29-86)	67 (32-78)	58 (29-86)	0.79
<b>Female sex, n (%)</b>	10 (53)	5 (45)	5 (63)	0.46
<b>Cancer type, n (%)</b>				0.36
Melanoma	6 (32)	2 (18)	4 (50)	
Lung	5 (26)	3 (27)	2 (25)	
Genitourinary	3 (16)	3 (27)	0 (0)	
Gynecologic	2 (11)	1 (9)	1 (12)	
Hematologic	1 (5)	1 (9)	0 (0)	
Breast	1 (5)	1 (9)	0 (0)	
Angiosarcoma	1 (5)	0 (0)	1 (12)	
<b>ICI regimen, n (%)</b>				0.31
PD-(L)1	12 (63)	8 (73)	4 (50)	
CTLA-4 + PD-(L)1	7 (37)	3 (27)	4 (50)	
<b>Degree of weight loss related to irEnteritis, n (%)</b>				0.58
I (<10% total body weight)	12 (63)	8 (73)	4 (50)	
II (10-20% total body weight)	5 (26)	2 (18)	3 (38)	
III (>20% total body weight)	2 (11)	1 (9)	1 (12)	
<b>Highest grade of diarrhea, n (%)</b>				0.44
I/II	15 (79)	8 (73)	7 (88)	
III/IV	4 (21)	3 (27)	1 (12)	
<b>Highest grade of colitis, n (%)</b>				0.20
I/II	17 (94)	11 (100)	7 (88)	
III/IV	1 (6)	0 (0)	1 (12)	
<b>GI toxicity location, n (%)</b>				0.55
Upper GI toxicity alone	11 (58)	7 (64)	4 (50)	
Combined upper and lower GI toxicity	8 (42)	4 (36)	4 (50)	
<b>Treatments for irEnteritis prior to OCB, n (%)</b>				
Systemic corticosteroids	15 (79)	8 (73)	7 (88)	0.44
Biologic agents	4 (21)	2 (18)	2 (25)	0.72
<b>Median no. of days from irEnteritis onset to OCB initiation (IQR)</b>	74 (36-144)	45 (37-199)	88 (18-124)	0.46
<b>Median no. of days of OCB treatment</b>	57 (26-89)	57 (39-83)	49 (17-106)	0.79

<b>(IQR)</b>				
<b>Clinical response, n (%)</b>	18 (95)	11 (100)	7 (88)	0.23
<b>Days from OCB initiation to clinical response, median (IQR)</b>	4 (1-7)	6 (1-12)	4 (1-5)	0.55
<b>Clinical remission, n (%)</b>	15 (79)	11 (100)	4 (50)	0.01
<b>Days from OCB initiation to clinical remission, median (IQR)</b>	27 (8-36)	12 (6-29)	33 (29-36.5)	0.01

Abbreviations: irEnteritis, immune-related enteritis. ICI, immune checkpoint inhibitor; IQR, interquartile range; EGD, esophagogastroduodenoscopy; GVHD, graft-versus-host disease.