Supplementary Online Content

Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2015.19330

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Outcomes and associated clinically-important differences		
	Range/Definition	**Reference**
Objective/Functional		
Endoscopic NPS	0-8 (both sides) 0 = no polyps; 1 = small polyps in the middle meatus not reaching below the inferior border of the middle turbinate; 2 = polyps reaching below the lower border of the middle turbinate; 3 = large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate; 4 = large polyps causing complete obstruction of the inferior nasal cavity	Gevaert P, Calus L, Van Zele T, et al. Omalizumab is effective in allergic and nonallergic patients with nasal polyps and asthma. *J Allergy Clin Immunol.* 2013;131(1):110-116.
CT scan: Lund-Mackay	0-24 (point range) Evaluates the patency using a 0-2 scale (0 = normal; 1 = partial opacification; and 2 = total opacification) of each sinus (maxillary, anterior ethmoid, posterior ethmoid, sphenoid, frontal sinus on each side) The osteomeatal complex is graded as 0 = not occluded or 2 = occluded	Lund VJ, Mackay IS. Staging in rhinosinusitus. *Rhinology.* 1993;31(4):183-184. Bhattacharyya N. Test-retest reliability of CT in the assessment of chronic rhinosinusitis. *Laryngoscope.* 1999;109(7 Pt 1):1055-1058.
PNIF (AM/PM)	PNIF can be used only as a relative measurement in the same individual over time. PNIF values of 126.7 and 158.1 L/min (or 2.1 and 2.6 L/s) have been proposed as being normal in females and males, respectively	Ottaviano G, Scadding GK, Scarpa B, Accordi D, Staffieri A, Lund VJ. Unilateral peak nasal inspiratory flow, normal values in adult population. *Rhinology*. 2012;50(4):386-392.
UPSIT (smell test)	0-40 possible correct answers 0-18 anosmia; 19-25 severe microsmia; 26-30 moderate microsmia; 31-34 mild microsmia; and 35-40 normal	Scadding G, Hellings P, Alobid I, et al. Diagnostic tools in Rhinology EAACI position paper. *Clin Transl Allergy.* 2011;1(1):2. Doty RL, Frye RE, Agrawal U. Internal consistency reliability of the fractionated and whole University of Pennsylvania Smell Identification Test. *Precept Psychophys.* 1989;45(5):381-384.
Symptoms/PROs		
SNOT-22, total and specific items scores	0-110 (higher total scores imply greater impact on quality of life) 22-items scored on a 5-category scale (0 = no problem to 5 = problem as bad as it can be)	Hopkins C, Gillett S, Slack R, Lund VJ, Browne JP. Psychometric validity of the 22-item Sinonasal Outcome Test. *Clin Otolaryngol.* 2009;34(5):447-454.

	MCID: ≥8.90	
VAS for rhinosinusitis symptoms	0-10 cm 0 = not troublesome to 10 = worst thinkable troublesome VAS 0-3 = Mild VAS >3-7 = Moderate VAS >7-10 = Severe	Fokkens W, Lund V, Mullol J; European Position Paper on Rhinosinusitis and Nasal Polyps group. European position paper on rhinosinusitis and nasal polyps 2007. *Rhinol Suppl.* 2007;(20):1-136.
AM/PM subject assessed daily symptoms (nasal congestion/ obstruction, anterior rhinorrhea, post-nasal drip, sense of smell, nocturnal awakenings)	0-3 categorical scale 0 = no symptoms; 1 = mild symptoms; 2 = moderate symptoms; and 3 = severe symptoms	Fokkens W, Lund V, Mullol J; European Position Paper on Rhinosinusitis and Nasal Polyps group. European position paper on rhinosinusitis and nasal polyps 2007. *Rhinol Suppl.* 2007;(20):1-136.
ACQ5	7-point scale 0 = no impairment to 6 = maximum impairment MCID: 0.5	Juniper EF, Svensson K, Mörk AC, Ståhl E. Measurement properties and interpretation of three shortened versions of the asthma control questionnaire. *Respir Med.* 2005;99:553-558.

Abbreviations: ACQ5, 5-question Asthma Control Questionnaire; CT, computed tomography; MCID, minimally clinically important difference; NPS, nasal polyp score; PNIF, peak nasal inspiratory flow; PROs, patient-reported outcomes; SNOT-22, 22-item SinoNasal Outcome Test; UPSIT, University of Pennsylvania Smell Identification Test; VAS, visual analog scale.

eTable 2. Change from baseline in additional secondary endpoints in patients with chronic sinusitis with nasal polyposis treated with placebo or dupilumab added to MFNS

	Placebo/MFNS (N[a]=30)			Dupilumab/MFNS (N[a]=30)			Placebo vs Dupilumab	
Endpoints[b,c]	**Baseline, Mean (SD) n[d]=30**	**Week 16, Mean (SD) n[d]=23**	**Change From Baseline, LS Mean (95% CI)**	**Baseline, Mean (SD) n[d]=30**	**Week 16, Mean (SD) n[d]=29**	**Change From Baseline, LS Mean (95% CI)**	**Difference LS Mean (95% CI)**	***P* Value**
PNIF (PM), L/min	121.3 (51.8)	144.7 (64.4)	25.8 (10.2 to 41.4)	105.2 (52.5)	168.3 (54.3)	59.2 (44.1 to 74.3)	33.4 (12.0 to 54.8)	.0028
Loss of smell (AM)	2.8 (0.5)	2.5 (0.8)	−0.1 (−0.5 to 0.2)	2.4 (0.9)	1.0 (1.0)	−1.4 (−1.7 to −1.1)	−1.3 (−1.7 to −0.8)	<.0001
Loss of smell (PM)	2.8 (0.5)	2.5 (0.8)	−0.2 (−0.5 to 0.2)	2.4 (0.9)	1.0 (1.0)	−1.4 (−1.8 to −1.1)	−1.3 (−1.7 to −0.8)	<.0001
Anterior rhinorrhea (AM)	1.1 (0.8)	1.1 (0.8)	−0.1 (−0.3 to 0.2)	1.0 (0.9)	0.4 (0.5)	−0.7 (−0.9 to −0.5)	−0.6 (−0.9 to −0.3)	<.0001
Anterior rhinorrhea (PM)	1.2 (0.7)	1.0 (0.7)	−0.2 (−0.4 to 0.1)	1.0 (0.9)	0.4 (0.4)	−0.7 (−0.9 to −0.5)	−0.5 (−0.8 to −0.2)	.0008
Posterior rhinorrhea (PM)	1.4 (0.8)	1.2 (0.8)	−0.1 (−0.3 to 0.1)	1.0 (0.9)	0.5 (0.6)	−0.5 (−0.7 to −0.3)	−0.5 (−0.8 to −0.2)	.0028
Nocturnal awakenings	1.0 (1.2)	0.8 (1.1)	−0.2 (−0.5 to −0.02)	0.9 (1.1)	0.3 (0.9)	−0.6 (−0.8 to −0.4)	−0.4 (−0.7 to −0.1)	.0076

Abbreviations: LS, least square; MFNS, mometasone furoate nasal spray; PNIF, peak nasal inspiratory flow.

[a] N, number of patients in treatment group.
[b] Symptoms were captured daily using a categorical scale: 0 = no symptoms, and 3 = severe symptoms [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].
[c] Change from baseline averaged over 4 weeks prior to each time point.
[d] n, number of patients with data for the given endpoint at the given time point.

eTable 3. Change from baseline to Week 32 in patients with chronic sinusitis with nasal polyposis treated with placebo or dupilumab added to MFNS for 16 weeks, plus 16 weeks of MFNS-only

	Placebo/MFNS (N[a]=30)					Dupilumab/MFNS (N[a]=30)					Placebo vs Dupilumab	
	Baseline		Week 32			Baseline		Week 32				
Endpoints	**Mean (SD)**	**n[b]**	**Mean (SD)**	**n[b]**	**Change From Baseline, LS Mean (95% CI)**	**Mean (SD)**	**n[b]**	**Mean (SD)**	**n[b]**	**Change From Baseline, LS Mean (95% CI)**	**Difference LS Mean (95% CI)**	***P* Value**
Bilateral endoscopic NPS[c]	5.7 (0.9)	30	5.0 (1.7)	25	−0.7 (−1.4 to −0.1)	5.9 (1.0)	30	4.2 (1.7)	28	−1.6 (−2.3 to −1.0)	−0.9 (−1.8 to −0.02)	.0447
PNIF[d] (AM), L/min	109.2 (46.8)	30	143.3 (59.1)	25	34.4 (17.9 to 51.0)	98.4 (48.5)	30	159.7 (57.4)	29	59.2 (43.4 to 75.1)	24.8 (2.2 to 47.4)	.0323
SNOT-22 total score[e]	40.6 (19.9)	30	29.7 (16.4)	26	−9.0 (−15.4 to −2.5)	41.4 (18.2)	30	21.8 (15.2)	29	−18.3 (−24.3 to −12.3)	−9.3 (−17.6 to −1.1)	.0272
Nasal congestion/ obstruction[d,f] (AM)	1.7 (0.7)	30	1.4 (0.6)	25	−0.2 (−0.5 to 0.1)	1.7 (0.7)	30	0.8 (0.8)	29	−0.8 (−1.0 to −0.5)	−0.6 (−1.0 to −0.2)	.0029
Anterior rhinorrhea[d,f] (AM)	1.1 (0.8)	30	0.9 (0.6)	25	−0.1 (−0.3 to 0.1)	1.0 (0.9)	30	0.6 (0.7)	29	−0.5 (−0.7 to −0.3)	−0.4 (−0.7 to −0.1)	.0188
Posterior rhinorrhea[d,f] (AM)	1.4 (0.8)	30	1.2 (0.7)	25	−0.1 (−0.4 to 0.2)	1.1 (0.9)	30	0.7 (0.8)	29	−0.4 (−0.7 to −0.2)	−0.3 (−0.7 to 0.1)	.0956
Loss of smell[d,f](AM)	2.8 (0.5)	30	2.5 (0.8)	25	−0.2 (−0.5 to 0.2)	2.4 (0.9)	30	1.3 (1.2)	29	−1.1 (−1.4 to −0.8)	−1.0 (−1.4 to −0.5)	.0001
Nocturnal awakenings[d,f]	1.0 (1.2)	30	0.7 (1.0)	25	−0.2 (−0.5 to 0.02)	0.9 (1.1)	30	0.2 (0.7)	29	−0.7 (−0.9 to −0.4)	−0.4 (−0.8 to −0.1)	.0164

Abbreviations: LS, least square; MFNS, mometasone furoate nasal spray; NPS, nasal polyp score; PNIF, peak nasal inspiratory flow; SNOT-22, 22-item SinoNasal Outcome Test.

[a] N, number of patients in treatment group with comorbid asthma.
[b] n, number of patients with data for the given endpoint at the given time point.
[c] NPS has a range of 0 to 8, with higher scores indicating worse outcomes [Gevaert P, et al. *J Allergy Clin Immunol.* 2013;131(1):110-116].
[d] Change from baseline averaged over 4 weeks prior to each time point.
[e] SNOT-22 has a total range of 0 to 110, with higher scores indicating poorer outcomes and with 8.9 as the minimally clinically important difference [Hopkins C, et al. *Clin Otolaryngol.*2009;34(5):447-454].
[f] Symptoms were captured using a categorical scale: 0 = no symptoms, 1 = mild symptoms, 2 = moderate symptoms, and 3 = severe symptoms. [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].

eTable 4. Change from baseline to week 16 in efficacy endpoints in patients with chronic sinusitis with nasal polyposis and comorbid asthma treated with placebo or dupilumab added to MFNS

	Placebo/MFNS (N[a]=19)					Dupilumab/MFNS (N[a]=16)					Placebo vs Dupilumab	
	Baseline		Week 16			Baseline		Week 16				
	Mean (SD)	n[b]	Mean (SD)	n[b]	Change From Baseline, LS Mean (95% CI)	Mean (SD)	n[b]	Mean (SD)	n[b]	Change From Baseline, LS Mean (95% CI)	Difference LS Mean (95% CI)	*P* Value
Bilateral endoscopic NPS[c,d]	5.5 (1.0)	19	5.8 (0.9)	15	−0.2 (−0.9 to 0.8)	5.9 (0.9)	16	3.5 (1.9)	15	−2.3 (−3.2 to −1.4)	−2.3 (−3.4 to −1.2)	.0002
NPS reduction ≥1.0,[c] No. (%)	NA	NA	2 (10.5%)	2	NA	NA	NA	12 (75.0%)	12	NA	26.05 (3.78 to 179.31)	.0009
NPS reduction ≥2.0,[c] No. (%)	NA	NA	0	0	NA	NA	NA	9 (56.3%)	9	NA	NA	NA
CT: Lund-Mackay score (total)[e]	20.0 (5.7)	19	18.8 (6.5)	17	−1.3 (−4.7 to 2.1)	19.1 (4.2)	15	10.6 (5.7)	16	−9.0 (−12.2 to −5.8)	−7.6 (−11.0 to −4.3)	<.0001
PNIF[f] (AM), L/min	115.2 (51.8)	19	134.1 (52.8)	15	24.7 (6.2 to 43.1)	107.7 (44.3)	16	168.2 (37.7)	15	56.3 (36.4 to 76.1)	31.6 (6.8 to 56.3)	.0141
SNOT-22 total score[g]	43.6 (20.7)	19	32.4 (20.8)	15	−10.7 (−18.7 to −2.7)	40.6 (16.3)	16	12.1 (7.8)	15	−29.8 (−38.3 to −21.4)	−19.1 (−29.1 to −9.2)	.0005
Sinusitis symptom severity (VAS),[h] cm	6.7 (2.4)	17	5.2 (2.7)	15	−1.6 (−3.1 to −0.1)	6.2 (2.7)	16	1.5 (1.9)	15	−4.8 (−6.2 to −3.3)	−3.1 (−4.8 to −1.5)	.0005
Smell test (UPSIT)[i]	13.8 (6.4)	19	15.3 (7.6)	16	0.4 (−4.0 to 4.8)	10.1 (5.1)	16	28.9 (9.9)	15	16.9 (12.3 to 21.5)	16.5 (11.0 to 22.1)	<.0001
Nasal congestion/obstruction (AM)[g,j]	1.7 (0.7)	19	1.6 (0.6)	15	−0.1 (−0.5 to 0.2)	1.4 (0.7)	16	0.6 (0.6)	15	−0.9 (−1.2 to −0.5)	−0.7 (−1.2 to −0.3)	.0033
Loss of smell (AM)[g,k]	2.9 (0.2)	19	2.7 (0.6)	15	−0.1 (−0.5 to 0.4)	2.5 (1.0)	16	1.1 (1.2)	15	−1.4 (−1.9 to −1.0)	−1.3 (−2.0 to −0.7)	.0001
Anterior rhinorrhea (AM)[g,j]	1.2 (0.8)	19	1.3 (0.8)	15	0.02 (−0.3 to 0.3)	0.8 (0.8)	16	0.4 (0.5)	15	−0.5 (−0.7 to −0.2)	−0.5 (−0.8 to −0.1)	.0176
Posterior rhinorrhea	1.3	19	1.3 (0.8)	15	−0.2	1.1	16	0.6 (0.6)	15	−0.7	−0.5	.0322

(AM)[g,J]	(0.8)				(−0.5 to 0.1)	(0.8)				(−1.0 to −0.3)	(−0.9 to −0.04)	
FEV_1 in patients with asthma, L[k]	2.7 (0.8)	17	2.8 (0.9)	15	0.1 (−0.1 to 0.3)	2.7 (0.7)	16	3.1 (0.6)	15	0.3 (0.1 to 0.5)	0.2 (−0.02 to 0.5)	.0739
FEV_1 (% predicted) in patients with asthma[k]	79.8 (14.6)	17	84.5 (13.7)	15	1.9 (−3.9 to 7.6)	82.2 (17.7)	16	93.1 (12.6)	15	9.0 (3.0 to 15.1)	7.2 (0.4 to 13.9)	.0397

Abbreviations: CT, computed tomography; FEV_1, forced expiratory volume in 1 second; LS, least square; MFNS, mometasone furoate nasal spray; NA, not applicable; NPS, nasal polyp score; PNIF, peak nasal inspiratory flow; SNOT-22, 22-item SinoNasal Outcome Test; UPSIT, University of Pennsylvania Smell Identification Test; VAS, visual analog scale.

[a] N, number of patients in treatment group with comorbid asthma.
[b] n, number of patients with data for the given endpoint at the given time point.
[c] NPS has a range of 0 to 8, with higher scores indicating worse outcomes [Gevaert P, et al. *J Allergy Clin Immunol.* 2013;131(1):110-116].
[d] Pre-specified secondary endpoint.
[e] The Lund-Mackay CT score has a total range of 0 to 24, with higher scores indicating more opacification [Lund VJ, Mackay IS. *Rhinology.* 1993;31(4):183-184].
[f] Change from baseline averaged over 4 weeks prior to each time point.
[f] SNOT-22 has a total range of 0 to 110, with higher scores indicating poorer outcomes and with 8.9 as the minimally clinically important difference [Hopkins C, et al. *Clin Otolaryngol.* 2009;34(5):447-454].
[g] The VAS has a range of 0 (not troublesome) to 10 (worst thinkable) [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].
[h] UPSIT has a total range of 0 to 40, with higher scores (35-40) indicating normal smell abilities [Doty RL, et al. *Precept Psychophys.* 1989;45(5):381-384].
[i] Symptoms were captured using a categorical scale: 0 = no symptoms, 1 = mild symptoms, 2 = moderate symptoms, and 3 = severe symptoms. [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].
[j] Pre-specified exploratory endpoint.

eTable 5. Change from baseline to week 16 in efficacy endpoints in patients with chronic sinusitis with nasal polyposis without comorbid asthma treated with placebo or dupilumab added to MFNS

	Placebo/MFNS, N[a]=11					Dupilumab/MFNS, N[a]=14					Placebo vs Dupilumab	
	Baseline		Week 16			Baseline		Week 16				
	Mean (SD)	n[b]	Mean (SD)	n[b]	Change From Baseline, LS Mean (95% CI)	Mean (SD)	n[b]	Week 16, Mean (SD)	n[b]	Change From Baseline, LS Mean (95% CI)	Difference LS Mean (95% CI)	*P* Value
Bilateral endoscopic NPS[c]	5.9 (0.5)	11	4.6 (2.0)	8	−1.2 (−2.3 to −0.2)	5.8 (1.2)	14	4.4 (1.8)	14	−1.4 (−2.1 to −0.6)	−0.1 (−1.4 to 1.2)	.8530
NPS reduction ≥1.0,[c] No. (%)	NA	NA	4 (36.4%)	4	NA	NA	NA	9 (64.3%)	9	NA	3.17 (0.57 to 17.56)	.1869
NPS reduction ≥2.0,[c] No. (%)	NA	NA	3 (27.3%)	3	NA	NA	NA	7 (50.0%)	7	NA	2.49 (0.44 to 14.08)	.3025
CT: Lund-Mackay score (total)[d]	16.6 (4.8)	11	16.3 (3.4)	9	0.7 (−1.5 to 2.8)	18.1 (5.8)	14	8.1 (4.1)	14	−9.4 (−11.0 to −7.8)	−10.0 (−12.7 to −7.4)	<.0001
PNIF[e] (AM), L/min	99.0 (36.5)	11	138.6 (71.2)	8	35.9 (5.2 to 66.6)	87.9 (52.4)	14	155.3 (64.3)	14	68.0 (42.4 to 93.6)	32.1 (−7.9 to 72.2)	.1103
SNOT-22 total score[f]	35.3 (18.3)	11	26.0 (17.7)	8	−11.7 (−22.6 to −0.7)	42.4 (20.8)	14	13.5 (13.9)	14	−26.1 (−34.5 to −17.7)	−14.4 (−28.1 to −0.7)	.0400
Sinusitis symptom severity (VAS),[g] cm	5.9 (3.5)	8	2.8 (3.4)	8	−2.6 (−5.4 to 0.3)	6.7 (2.9)	13	2.9 (3.3)	14	−3.5 (−5.5 to −1.6)	−1.0 (−4.4 to 2.4)	.5478
Smell test (UPSIT)[h]	18.8 (9.5)	11	18.1 (11.3)	7	−1.5 (−6.4 to 3.4)	15.8 (10.2)	14	28.5 (6.2)	13	10.6 (6.9 to 14.2)	12.1 (6.1 to 18.1)	.0005
Nasal congestion/obstruction (AM)[e,i]	1.7 (0.6)	11	1.1 (0.7)	8	−0.5 (−1.0 to −0.1)	1.9 (0.7)	14	0.8 (0.7)	14	−1.0 (−1.4 to −0.6)	−0.5 (−1.1 to 0.2)	.1326
Loss of smell (AM)[e,i]	2.6 (0.7)	11	2.1 (1.1)	8	−0.2 (−0.8 to 0.3)	2.3 (0.9)	14	1.0 (0.8)	14	−1.4 (−1.8 to −0.9)	−1.2 (−1.9 to −0.4)	.0029
Anterior rhinorrhea (AM)[e,i]	1.1 (0.8)	11	0.7 (0.7)	8	−0.3 (−0.7 to 0.1)	1.3 (1.0)	14	0.3 (0.5)	14	−0.9 (−1.2 to −0.6)	−0.6 (−1.1 to −0.1)	.0279

Posterior rhinorrhea (AM)[e,i]	1.6 (0.9)	11	1.4 (1.0)	8	−0.01 (−0.4 to 0.4)	1.0 (1.1)	14	0.5 (0.6)	14	−0.6 (−0.9 to −0.3)	−0.6 (−1.1 to −0.03)	.0378
FEV_1 in patients with asthma, L	3.6 (0.9)	10	3.6 (1.1)	7	0.1 (−0.2 to 0.4)	3.7 (0.9)	13	3.6 (0.8)	14	−0.1 (−0.3 to 0.2)	−0.2 (−0.6 to 0.2)	.3065
FEV_1 (% predicted) in patients with asthma	98.0 (19.2)	10	92.4 (21.7)	7	−3.7 (−11.8 to 4.4)	94.9 (18.7)	13	94.4 (15.7)	14	−1.7 (−7.5 to 4.2)	2.0 (−7.9 to 12.0)	.6699

Abbreviations: CT, computed tomography; FEV_1, forced expiratory volume in 1 second; LS, least square; MFNS, mometasone furoate nasal spray; NA, not applicable; NPS, nasal polyp score; PNIF, peak nasal inspiratory flow; SNOT-22, 22-item SinoNasal Outcome Test; UPSIT, University of Pennsylvania Smell Identification Test; VAS, visual analog scale.

[a] N, number of patients in treatment group with comorbid asthma.
[b] n, number of patients with data for the given endpoint at the given time point.
[c] NPS has a range of 0 to 8, with higher scores indicating worse outcomes [Gevaert P, et al. *J Allergy Clin Immunol.* 2013;131(1):110-116].
[d] The Lund-Mackay CT score has a total range of 0 to 24, with higher scores indicating more opacification [Lund VJ, Mackay IS. *Rhinology.* 1993;31(4):183-184].
[e] Change from baseline averaged over 4 weeks prior to each time point.
[f] SNOT-22 has a total range of 0 to 110, with higher scores indicating poorer outcomes and with 8.9 as the minimally clinically important difference [Hopkins C, et al. *Clin Otolaryngol.* 2009;34(5):447-454].
[g] The VAS has a range of 0 (not troublesome) to 10 (worst thinkable) [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].
[h] UPSIT has a total range of 0 to 40, with higher scores (35-40) indicating normal smell abilities [Doty RL, et al. *Precept Psychophys.* 1989;45(5):381-384].
[i] Symptoms were captured using a categorical scale: 0 = no symptoms, 1 = mild symptoms, 2 = moderate symptoms, and 3 = severe symptoms. [Fokkens W, et al. *Rhinol Suppl.* 2007;(20):1-136].

eTable 6. Number of patients with TEAEs that occurred in ≥10% of patients in either treatment group, by primary system organ class and preferred term (safety population)

Primary System Organ Class Preferred Term, n (%)	Placebo/MFNS (n = 30)	Dupilumab/MFNS (n = 30)
Any class	25 (83.3)	30 (100)
Infections and infestations	18 (60.0)	23 (76.7)
Nasopharyngitis	10 (33.3)	14 (46.7)
Bronchitis	4 (13.3)	1 (3.3)
Upper respiratory tract infection	0	4 (13.3)
Nervous system disorders	6 (20.0)	12 (40.0)
Headache	5 (16.7)	6 (20.0)
Dizziness	1 (3.3)	3 (10.0)
Respiratory, thoracic and mediastinal disorders	10 (33.3)	15 (50.0)
Asthma	3 (10.0)	2 (6.7)
Nasal polyps	3 (10.0)	1 (3.3)
Upper-airway cough syndrome	3 (10.0)	0
Epistaxis	2 (6.7)	7 (23.3)
Oropharyngeal pain	2 (6.7)	7 (23.3)
Musculoskeletal and connective tissue disorders	1 (3.3)	8 (26.7)
Back pain	0	3 (10.0)
General disorders and administration site conditions	2 (6.7)	13 (43.3)
Injection-site reaction	2 (6.7)	12 (40.0)

Abbreviations: MFNS, mometasone furoate nasal spray; TEAE, treatment-emergent adverse event.

Study Investigators

The following investigators (from centers in the European Union and USA) participated in the study.

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