

**Anhang 4-G: Ergänzende Daten zur Studie LUCENT 2****Inhaltsverzeichnis**

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**Anhang 4-G1: Subgruppenanalyse „Versagen auf eine frühere Therapie mit einem Biologikum oder mit Tofacitinib“**

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Clinical Remission Rates at Week 40  
 Non-Responder Imputation (NRI) by Subgroup (Prior UC Therapy)  
 Modified Intent-to-Treat Population - Mirikizumab Induction Responder  
 I6T-MC-AMBG - Randomized Withdrawal Maintenance Period

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Parameter: Modified Mayo Score Clinical Remission  
 Subgroup: Prior biologic or tofacitinib failure: Failed, Not failed

	Miri Responder placebo SC (N=179)	Miri Responder 200 miri SC (N=365)	Total (N=544)
Type 3 Analysis of Effects at Week 40 [1]			
Treatment (p-value)			<0.001
Prior biologic or tofacitinib failure (p-value)			0.109
Treatment*Prior biologic or tofacitinib failure (p-value)			0.173

Abbreviations: miri = mirikizumab; SC = subcutaneous; CI = confidence interval; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = nonresponder imputation; Ns = number of patients in each subgroup.

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Endoscopic Remission Rates at Week 40  
 Non-Responder Imputation (NRI) by Subgroup (Prior UC Therapy)  
 Modified Intent-to-Treat Population - Mirikizumab Induction Responder  
 I6T-MC-AMBG - Randomized Withdrawal Maintenance Period

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Parameter: Endoscopic Remission

Subgroup: Prior biologic or tofacitinib failure: Failed, Not failed

	Miri Responder placebo SC (N=179)	Miri Responder 200 miri SC (N=365)	Total (N=544)
Type 3 Analysis of Effects at Week 40 [1]			
Treatment (p-value)			<0.001
Prior biologic or tofacitinib failure (p-value)			0.043
Treatment*Prior biologic or tofacitinib failure (p-value)			0.681

Abbreviations: miri = mirikizumab; SC = subcutaneous; CI = confidence interval; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = nonresponder imputation; Ns = number of patients in each subgroup.

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Corticosteroid-free Remission Rates at Week 40  
 Non-Responder Imputation (NRI) by Subgroup (Prior UC Therapy)  
 Modified Intent-to-Treat Population - Mirikizumab Induction Responder  
 I6T-MC-AMBG - Randomized Withdrawal Maintenance Period

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Parameter: Corticosteroid Free Remission

Subgroup: Prior biologic or tofacitinib failure: Failed, Not failed

	Miri Responder placebo SC (N=179)	Miri Responder 200 miri SC (N=365)	Total (N=544)
Type 3 Analysis of Effects at Week 40 [1]			
Treatment (p-value)			<0.001
Prior biologic or tofacitinib failure (p-value)			0.199
Treatment*Prior biologic or tofacitinib failure (p-value)			0.297

Abbreviations: miri = mirikizumab; SC = subcutaneous; CI = confidence interval; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = nonresponder imputation; Ns = number of patients in each subgroup.

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Histologic-Endoscopic Mucosal Remission Rates at Week 40  
 Non-Responder Imputation (NRI) by Subgroup (Prior UC Therapy)  
 Modified Intent-to-Treat Population - Mirikizumab Induction Responder  
 I6T-MC-AMBG - Randomized Withdrawal Maintenance Period

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Parameter: Histologic-Endoscopic Mucosal Remission

Subgroup: Prior biologic or tofacitinib failure: Failed, Not failed

	Miri Responder placebo SC (N=179)	Miri Responder 200 miri SC (N=365)	Total (N=544)
Type 3 Analysis of Effects at Week 40 [1]			
Treatment (p-value)			<0.001
Prior biologic or tofacitinib failure (p-value)			0.035
Treatment*Prior biologic or tofacitinib failure (p-value)			0.563

Abbreviations: miri = mirikizumab; SC = subcutaneous; CI = confidence interval; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = nonresponder imputation; Ns = number of patients in each subgroup.

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Urgency Remission (Urgency NRS = 0 or 1) Rates at Week 40  
 Non-Responder Imputation (NRI) by Subgroup (Prior UC Therapy)  
 Modified Intent-to-Treat Population - Mirikizumab Induction Responder  
 - In patients with Urgency NRS>= 3 at AMAN baseline  
 I6T-MC-AMBG - Randomized Withdrawal Maintenance Period

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Parameter: Urgency Remission  
 Subgroup: Prior biologic or tofacitinib failure: Failed, Not failed

	Miri Responder placebo SC (N=172)	Miri Responder 200 miri SC (N=336)	Total (N=508)
Type 3 Analysis of Effects at Week 40 [1]			
Treatment (p-value)			<0.001
Prior biologic or tofacitinib failure (p-value)			0.194
Treatment*Prior biologic or tofacitinib failure (p-value)			0.976

Abbreviations: miri = mirikizumab; SC = subcutaneous; CI = confidence interval; N = number of patients in the analysis population; n = number of patients in the specified category; NRI = nonresponder imputation; Ns = number of patients in each subgroup.

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**Anhang 4-G2: Unerwünschte Ereignisse nach SOC und PT**

**Anhang 4-G2.1: Unerwünschte Ereignisse nach SOC und PT gesamt**



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**Table AMBG.8.109. Treatment-Emergent Adverse Events  
MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
Safety Population – Induction Responder  
I6T-MC-AMBG - Maintenance Period**

System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Odds ratio*d
Subjects with >= 1 TEAE	82 (60.7)	132 (68.8)	251 (64.5)	383 (65.9)	0.352	0.83
Infections and infestations	30 (22.2)	44 (22.9)	93 (23.9)	137 (23.6)	0.836	1.06
Nasopharyngitis	9 (6.7)	11 (5.7)	28 (7.2)	39 (6.7)	0.599	1.28
COVID-19	5 (3.7)	4 (2.1)	8 (2.1)	12 (2.1)	>0.999	0.99
Upper respiratory tract infection	2 (1.5)	5 (2.6)	7 (1.8)	12 (2.1)	0.543	0.69
Gastroenteritis	2 (1.5)	2 (1.0)	6 (1.5)	8 (1.4)	>0.999	1.49
Urinary tract infection	0	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Vulvovaginal mycotic infection*b	0	0	2 (1.3)	2 (0.8)	>0.999	NA
Bronchitis	0	0	4 (1.0)	4 (0.7)	0.308	NA
Herpes zoster	0	0	4 (1.0)	4 (0.7)	0.308	NA
Pharyngitis	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
Respiratory tract infection viral	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
Rhinitis	0	0	4 (1.0)	4 (0.7)	0.308	NA
Influenza	1 (0.7)	0	3 (0.8)	3 (0.5)	0.554	NA
Oral herpes	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Sinusitis	1 (0.7)	4 (2.1)	3 (0.8)	7 (1.2)	0.227	0.37
Vaginal infection*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Vulvovaginal candidiasis*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Dermatophytosis of nail	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Fungal skin infection	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Herpes simplex	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Hordeolum	0	0	2 (0.5)	2 (0.3)	>0.999	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Treatment-Emergent Adverse Events  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Infections and infestations</b>						
Otitis externa	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Pneumonia	1 (0.7)	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
Tinea versicolour	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Tooth abscess	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Acute sinusitis	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Appendicitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
COVID-19 pneumonia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Chronic tonsillitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Clostridium difficile infection	1 (0.7)	3 (1.6)	1 (0.3)	4 (0.7)	0.108	0.16
Conjunctivitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Diverticulitis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Gastroenteritis viral	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Gastrointestinal infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Impetigo	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Lower respiratory tract infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Onychomycosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Oral candidiasis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Otitis media	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Paronychia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Periodontitis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Pharyngotonsillitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Pulpitis dental	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Pyoderma	0	0	1 (0.3)	1 (0.2)	>0.999	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Treatment-Emergent Adverse Events  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Infections and infestations</b>						
Respiratory tract infection	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Tinea infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tinea pedis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tonsillitis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Tooth infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tracheitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tracheobronchitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Viral upper respiratory tract infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Aeromonas infection	1 (0.7)	0	0	0	NA	NA
Ascariasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Campylobacter infection	1 (0.7)	0	0	0	NA	NA
Clostridium difficile colitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Cystitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Cytomegalovirus colitis	1 (0.7)	0	0	0	NA	NA
Denture stomatitis	1 (0.7)	0	0	0	NA	NA
Ecthyma	1 (0.7)	0	0	0	NA	NA
Enteritis infectious	1 (0.7)	0	0	0	NA	NA
Enterobiasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Folliculitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Furuncle	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Gingival abscess	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Haemorrhoid infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Treatment-Emergent Adverse Events  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Infections and infestations</b>						
Labyrinthitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Large intestine infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Laryngitis	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Oral infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Otitis media acute	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Rhinovirus infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Staphylococcal infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Subcutaneous abscess	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Gastrointestinal disorders</b>						
Colitis ulcerative	29 (21.5)	70 (36.5)	83 (21.3)	153 (26.3)	<0.001	0.47
Abdominal pain	18 (13.3)	40 (20.8)	26 (6.7)	66 (11.4)	<0.001	0.27
Diarrhoea	3 (2.2)	4 (2.1)	11 (2.8)	15 (2.6)	0.783	1.37
Gastroesophageal reflux disease	3 (2.2)	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Dyspepsia	0	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Haemorrhoids	2 (1.5)	0	6 (1.5)	6 (1.0)	0.185	NA
Nausea	2 (1.5)	3 (1.6)	5 (1.3)	8 (1.4)	0.723	0.82
Stomatitis	2 (1.5)	5 (2.6)	4 (1.0)	9 (1.5)	0.165	0.39
Large intestine polyp	1 (0.7)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Toothache	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Abdominal distension	0	0	3 (0.8)	3 (0.5)	0.554	NA
Abdominal pain upper	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Faecaloma	0	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
	0	0	2 (0.5)	2 (0.3)	>0.999	NA

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Treatment-Emergent Adverse Events  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Gastrointestinal disorders</b>						
Food poisoning	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Frequent bowel movements	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Haematochezia	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Inguinal hernia	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Abdominal pain lower	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Abdominal tenderness	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Anal fissure	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Anal fistula	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Anal pruritus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Constipation	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Defaecation urgency	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Dental caries	2 (1.5)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Gastritis	1 (0.7)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Gingival bleeding	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Haematemesis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Haemorrhoidal haemorrhage	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Irritable bowel syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mucous stools	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Oral submucosal fibrosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Periodontal disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Proctalgia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Proctitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Rectal haemorrhage	0	3 (1.6)	1 (0.3)	4 (0.7)	0.108	0.16

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Gastrointestinal disorders</b>						
Umbilical hernia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Vomiting	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Abdominal discomfort	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Angular cheilitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Aphthous ulcer	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Duodenitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Enteritis	1 (0.7)	0	0	0	NA	NA
Flatulence	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Gastritis erosive	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Gastroesophageal sphincter insufficiency	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Lip swelling	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mouth ulceration	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Pseudopolyposis	1 (0.7)	2 (1.0)	0	2 (0.3)	0.109	0.00
Rectal polyp	0	2 (1.0)	0	2 (0.3)	0.109	0.00
<b>General disorders and administration site conditions</b>						
Injection site pain	2 (1.5)	6 (3.1)	17 (4.4)	23 (4.0)	0.652	1.42
Pyrexia	6 (4.4)	5 (2.6)	13 (3.3)	18 (3.1)	0.801	1.29
Fatigue	1 (0.7)	4 (2.1)	10 (2.6)	14 (2.4)	>0.999	1.24
Injection site reaction	1 (0.7)	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Injection site erythema	1 (0.7)	2 (1.0)	8 (2.1)	10 (1.7)	0.509	1.99

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>General disorders and administration site conditions</b>						
Influenza like illness	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Asthenia	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Injection site bruising	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Injection site pruritus	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Malaise	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Non-cardiac chest pain	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Oedema peripheral	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Peripheral swelling	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Chest discomfort	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Injection site dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site haematoma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site hypersensitivity	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site oedema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site paraesthesia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site rash	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Injection site urticaria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Administration site reaction	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Chills	1 (0.7)	0	0	0	NA	NA
Drug intolerance	1 (0.7)	0	0	0	NA	NA
Hyperpyrexia	1 (0.7)	0	0	0	NA	NA
Pain	1 (0.7)	0	0	0	NA	NA

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Musculoskeletal and connective tissue disorders	12 (8.9)	24 (12.5)	57 (14.7)	81 (13.9)	0.526	1.20
Arthralgia	4 (3.0)	8 (4.2)	26 (6.7)	34 (5.9)	0.263	1.65
Back pain	4 (3.0)	4 (2.1)	7 (1.8)	11 (1.9)	0.758	0.86
Pain in extremity	1 (0.7)	3 (1.6)	7 (1.8)	10 (1.7)	>0.999	1.15
Musculoskeletal stiffness	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Myalgia	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Neck pain	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Arthritis	1 (0.7)	4 (2.1)	2 (0.5)	6 (1.0)	0.096	0.24
Osteoarthritis	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Synovial cyst	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Chondropathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Enthesopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Exostosis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Foot deformity	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Fracture pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Intervertebral disc disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Intervertebral disc protrusion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Joint contracture	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Joint swelling	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Muscle spasms	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Osteoporosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Periarthritis	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Musculoskeletal and connective tissue disorders</b>						
Sacroiliitis	1 (0.7)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Scoliosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tendon pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tendonitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tenosynovitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Bursa disorder	1 (0.7)	0	0	0	NA	NA
Joint effusion	1 (0.7)	0	0	0	NA	NA
Muscular weakness	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Osteochondrosis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Sacral pain	1 (0.7)	0	0	0	NA	NA
Temporomandibular joint syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Skin and subcutaneous tissue disorders</b>	8 (5.9)	13 (6.8)	44 (11.3)	57 (9.8)	0.102	1.76
Rash	2 (1.5)	0	14 (3.6)	14 (2.4)	0.007	NA
Pruritus	2 (1.5)	4 (2.1)	4 (1.0)	8 (1.4)	0.450	0.49
Acne	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Dermal cyst	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Dermatitis contact	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Dry skin	2 (1.5)	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
Actinic keratosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dyshidrotic eczema	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Skin and subcutaneous tissue disorders						
Ecchymosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Eczema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Eczema asteatotic	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Erythema	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hand dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Ingrowing nail	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Ingrown hair	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Perioral dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Photosensitivity reaction	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Psoriasis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Purpura	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Rash maculo-papular	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Rash pruritic	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Skin burning sensation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Skin hyperpigmentation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Skin irritation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Skin ulcer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Urticaria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Alopecia	1 (0.7)	2 (1.0)	0	2 (0.3)	0.109	0.00
Dermatitis acneiform	1 (0.7)	0	0	0	NA	NA
Dermatitis allergic	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Lipodystrophy acquired	1 (0.7)	0	0	0	NA	NA
Nail psoriasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Skin and subcutaneous tissue disorders</b>						
Rash erythematous	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Rosacea	1 (0.7)	0	0	0	NA	NA
Sensitive skin	1 (0.7)	0	0	0	NA	NA
<b>Investigations</b>						
Blood creatine phosphokinase increased	15 (11.1)	18 (9.4)	33 (8.5)	51 (8.8)	0.756	0.90
Alanine aminotransferase increased	5 (3.7)	5 (2.6)	10 (2.6)	15 (2.6)	>0.999	0.99
Gamma-glutamyltransferase increased	1 (0.7)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
SARS-CoV-2 test positive	2 (1.5)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Aspartate aminotransferase increased	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
White blood cell count decreased	0	0	3 (0.8)	3 (0.5)	0.554	NA
Blood bilirubin increased	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Liver function test increased	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Aeromonas test positive	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Arthroscopy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Blood alkaline phosphatase increased	0	3 (1.6)	1 (0.3)	4 (0.7)	0.108	0.16
Blood cholesterol increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Blood glucose increased	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Blood pressure increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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<b>Investigations</b>						
Blood triglycerides increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Clostridium test positive	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Hepatic enzyme increased	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Lymphocyte count decreased	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mean cell volume increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Monocyte count decreased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Platelet count decreased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Renin increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Weight increased	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
White blood cell count increased	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Bacterial test positive	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Blood urea increased	1 (0.7)	0	0	0	NA	NA
Blood uric acid increased	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Body temperature increased	1 (0.7)	0	0	0	NA	NA
Crystal urine present	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Haemoglobin decreased	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Liver function test abnormal	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Red blood cell schistocytes present	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Weight decreased	2 (1.5)	0	0	0	NA	NA
<b>Nervous system disorders</b>						
Headache	9 (6.7)	9 (4.7)	31 (8.0)	40 (6.9)	0.165	1.76
	5 (3.7)	2 (1.0)	16 (4.1)	18 (3.1)	0.045	4.08

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Nervous system disorders</b>						
Hypoaesthesia	0	0	5 (1.3)	5 (0.9)	0.177	NA
Migraine	0	0	5 (1.3)	5 (0.9)	0.177	NA
Burning sensation	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Amnesia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dizziness	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Dizziness postural	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Neuropathy peripheral	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Paraesthesia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Piriformis syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Restless legs syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Sciatica	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Vascular encephalopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dysgeusia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Ischaemic stroke	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Lumbar radiculopathy	1 (0.7)	0	0	0	NA	NA
Memory impairment	1 (0.7)	0	0	0	NA	NA
Presyncope	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Tremor	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Respiratory, thoracic and mediastinal disorders</b>						
Cough	5 (3.7)	6 (3.1)	27 (6.9)	33 (5.7)	0.085	2.31
Oropharyngeal pain	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Respiratory, thoracic and mediastinal disorders						
Nasal congestion	0	0	3 (0.8)	3 (0.5)	0.554	NA
Chronic obstructive pulmonary disease	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Dyspnoea	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Rhinorrhoea	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Dyspnoea exertional	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Emphysema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Epistaxis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Haemoptysis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nasal septum deviation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nasal ulcer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Pharyngeal inflammation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Pulmonary embolism	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Sinus congestion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Sneezing	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Throat irritation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Vasomotor rhinitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Asthma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Nasal dryness	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Rhinitis allergic	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Sleep apnoea syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Wheezing	1 (0.7)	0	0	0	NA	NA

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Metabolism and nutrition disorders	9 (6.7)	11 (5.7)	19 (4.9)	30 (5.2)	0.692	0.84
Hyperglycaemia	3 (2.2)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Vitamin D deficiency	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Hypertriglyceridaemia	3 (2.2)	0	2 (0.5)	2 (0.3)	>0.999	NA
Hypokalaemia	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Acidosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Decreased appetite	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Diabetes mellitus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Food aversion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Glucose tolerance impaired	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Gout	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hypercholesterolaemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Hypoglycaemia	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Iron deficiency	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Type 2 diabetes mellitus	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Haemosiderosis	1 (0.7)	0	0	0	NA	NA
Hyperkalaemia	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Increased appetite	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Steroid diabetes	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Vitamin B12 deficiency	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Injury, poisoning and procedural complications	5 (3.7)	5 (2.6)	16 (4.1)	21 (3.6)	0.480	1.60

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Injury, poisoning and procedural complications</b>						
Spinal compression fracture	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Arthropod bite	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Arthropod sting	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Contusion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Fall	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Foot fracture	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Heat illness	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Joint dislocation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Joint injury	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Ligament sprain	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Meniscus injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Muscle injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Procedural pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Radius fracture	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Skin laceration	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tendon injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Brain contusion	1 (0.7)	0	0	0	NA	NA
Electric injury	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Patella fracture	1 (0.7)	0	0	0	NA	NA
Retinal injury	1 (0.7)	0	0	0	NA	NA
Road traffic accident	1 (0.7)	0	0	0	NA	NA
Tooth fracture	1 (0.7)	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Injury, poisoning and procedural complications</b>						
Vaccination complication	1 (0.7)	0	0	0	NA	NA
<b>Blood and lymphatic system disorders</b>						
Anaemia	11 (8.1)	12 (6.3)	15 (3.9)	27 (4.6)	0.212	0.60
Iron deficiency anaemia	8 (5.9)	9 (4.7)	8 (2.1)	17 (2.9)	0.113	0.43
Lymphopenia	0	0	3 (0.8)	3 (0.5)	0.554	NA
Lymphadenopathy	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Neutropenia	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hypersplenism	3 (2.2)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Leukopenia	1 (0.7)	0	0	0	NA	NA
Pancytopenia	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Thrombocytopenia	1 (0.7)	0	0	0	NA	NA
Thrombocytopenia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Vascular disorders</b>						
Hypertension	3 (2.2)	5 (2.6)	15 (3.9)	20 (3.4)	0.629	1.50
Aortic aneurysm	1 (0.7)	1 (0.5)	9 (2.3)	10 (1.7)	0.177	4.52
Hot flush	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Superficial vein thrombosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Thrombophlebitis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Varicose vein	0	0	1 (0.3)	1 (0.2)	>0.999	NA
White coat hypertension	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Deep vein thrombosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Hypotension	2 (1.5)	0	0	0	NA	NA
Hypotension	0	2 (1.0)	0	2 (0.3)	0.109	0.00

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Vascular disorders</b>						
Peripheral venous disease	1 (0.7)	0	0	0	NA	NA
Post thrombotic syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Psychiatric disorders</b>						
Anxiety	3 (2.2)	4 (2.1)	13 (3.3)	17 (2.9)	0.601	1.63
Depressed mood	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Depression	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Insomnia	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Insomnia	2 (1.5)	3 (1.6)	2 (0.5)	5 (0.9)	0.338	0.33
Premature ejaculation*a	0	0	1 (0.4)	1 (0.3)	>0.999	NA
Affective disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Agitation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Depression suicidal	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dysphemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Listless	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Stress	0	0	1 (0.3)	1 (0.2)	>0.999	NA
<b>Eye disorders</b>						
Dry eye	2 (1.5)	2 (1.0)	12 (3.1)	14 (2.4)	0.159	3.02
Asthenopia	0	0	3 (0.8)	3 (0.5)	0.554	NA
Elepharitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Cataract	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Conjunctivitis allergic	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Myopia	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Eye disorders</b>						
Ocular hyperaemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Pterygium	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal detachment	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal dystrophy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal haemorrhage	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Swelling of eyelid	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Chalazion	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Iridocyclitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Visual impairment	1 (0.7)	0	0	0	NA	NA
<b>Surgical and medical procedures</b>						
Hair transplant	4 (3.0)	0	8 (2.1)	8 (1.4)	0.058	NA
Knee operation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Large intestinal polypectomy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Papilloma excision	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Skin cyst excision	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Skin neoplasm excision	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Wisdom teeth removal	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Cataract operation	1 (0.7)	0	0	0	NA	NA
Inguinal hernia repair	1 (0.7)	0	0	0	NA	NA
Intraocular lens implant	1 (0.7)	0	0	0	NA	NA

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 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_ptsoc\_s\_ir\_m.rtf

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Surgical and medical procedures						
Tooth extraction	1 (0.7)	0	0	0	NA	NA
Immune system disorders	0	4 (2.1)	7 (1.8)	11 (1.9)	0.758	0.86
Seasonal allergy	0	2 (1.0)	4 (1.0)	6 (1.0)	>0.999	0.99
Hypersensitivity	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Anaphylactic reaction	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	3 (1.6)	6 (1.5)	9 (1.5)	>0.999	0.99
Skin papilloma	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Gastric cancer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Haemangioma of liver	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Lipoma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Melanocytic naevus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Basal cell carcinoma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Cholesteatoma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Reproductive system and breast disorders	1 (0.7)	0	6 (1.5)	6 (1.0)	0.185	NA
Erectile dysfunction*a	0	0	2 (0.9)	2 (0.6)	>0.999	NA
Intermenstrual bleeding*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Rectocele*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Uterine cervical metaplasia*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Reproductive system and breast disorders</b>						
Uterine polyp*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Benign prostatic hyperplasia*a	0	0	1 (0.4)	1 (0.3)	>0.999	NA
Vaginal haemorrhage*b	1 (1.6)	0	0	0	NA	NA
<b>Hepatobiliary disorders</b>						
Autoimmune hepatitis	0	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Gallbladder polyp	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Granulomatous liver disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Hepatic steatosis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Nonalcoholic fatty liver disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Non-alcoholic steatohepatitis	1 (0.7)	0	0	0	NA	NA
<b>Ear and labyrinth disorders</b>						
Vertigo	0	0	4 (1.0)	4 (0.7)	0.308	NA
Deafness	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Vertigo positional	0	0	1 (0.3)	1 (0.2)	>0.999	NA
<b>Cardiac disorders</b>						
Arteriosclerosis coronary artery	2 (1.5)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Atrioventricular block first degree	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Extrasystoles	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mitral valve incompetence	0	1 (0.5)	0	1 (0.2)	0.330	0.00

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
<b>Cardiac disorders</b>						
Mitral valve prolapse	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Sinus tachycardia	1 (0.7)	0	0	0	NA	NA
Tachycardia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Tricuspid valve incompetence	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Renal and urinary disorders</b>						
Bladder hypertrophy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Chronic kidney disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Hypercalciuria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nephrocalcinosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nephrogenic diabetes insipidus	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Renal cyst	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Renal injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Azotaemia	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Dysuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Haematuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Nephrolithiasis	2 (1.5)	0	0	0	NA	NA
Proteinuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Ureterolithiasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Congenital, familial and genetic disorders</b>						
Congenital aural fistula	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
<b>Congenital, familial and genetic disorders</b>						
Type V hyperlipidaemia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Gilbert's syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Endocrine disorders</b>						
Hyperaldosteronism	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hyperparathyroidism secondary	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Autoimmune thyroiditis	0	1 (0.5)	0	1 (0.2)	>0.999	NA
<b>Pregnancy, puerperium and perinatal conditions</b>						
Subchorionic haematoma*b	1 (0.7)	0	0	0	NA	NA
<b>Social circumstances</b>						
Denture wearer	1 (1.6)	0	0	0	NA	NA
<b>Social circumstances</b>						
Denture wearer	0	1 (0.5)	0	1 (0.2)	0.330	0.00
<b>Social circumstances</b>						
Denture wearer	0	1 (0.5)	0	1 (0.2)	0.330	0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.

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\*a - Denominator adjusted because gender-specific event for males: N=74 (Placebo Responder placebo SC), N=114 (Miri Responder placebo SC), N=229 (Miri Responder 200 miri SC).  
\*b - Denominator adjusted because gender-specific event for females: N=61 (Placebo Responder placebo SC), N=78 (Miri Responder placebo SC), N=160 (Miri Responder 200 miri SC).  
\*c - p-value was computed using Fisher's exact test.  
\*d - odds ratio based on comparator Miri Responder placebo SC as denominator.

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**Anhang 4-G2.2: Unerwünschte Ereignisse nach SOC, PT und Schweregrad**

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**Table AMBG.8.110. Treatment-Emergent Adverse Events by Maximum Severity  
MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
Safety Population - Induction Responder  
I6T-MC-AMBG - Maintenance period**

System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds_ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Subjects with >= 1 TEAE	82 (60.7)	132 (68.8)	251 (64.5)	383 (65.9)	0.352	0.83
Mild	39 (28.9)	71 (37.0)	148 (38.0)	219 (37.7)		
Moderate	32 (23.7)	49 (25.5)	87 (22.4)	136 (23.4)		
Severe	11 (8.1)	12 (6.3)	16 (4.1)	28 (4.8)	0.303	0.64
Gastrointestinal disorders	29 (21.5)	70 (36.5)	83 (21.3)	153 (26.3)	<0.001 *	0.47
Mild	13 (9.6)	30 (15.6)	53 (13.6)	83 (14.3)		
Moderate	12 (8.9)	34 (17.7)	27 (6.9)	61 (10.5)		
Severe	4 (3.0)	6 (3.1)	3 (0.8)	9 (1.5)	0.066	0.24
Colitis ulcerative	18 (13.3)	40 (20.8)	26 (6.7)	66 (11.4)	<0.001 *	0.27
Mild	4 (3.0)	10 (5.2)	6 (1.5)	16 (2.8)		
Moderate	11 (8.1)	24 (12.5)	18 (4.6)	42 (7.2)		
Severe	3 (2.2)	6 (3.1)	2 (0.5)	8 (1.4)	0.018 *	0.16
Abdominal pain	3 (2.2)	4 (2.1)	11 (2.8)	15 (2.6)	0.783	1.37
Mild	1 (0.7)	1 (0.5)	7 (1.8)	8 (1.4)		
Moderate	1 (0.7)	3 (1.6)	4 (1.0)	7 (1.2)		
Severe	1 (0.7)	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Diarrhoea	3 (2.2)	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Mild	2 (1.5)	1 (0.5)	7 (1.8)	8 (1.4)		
Moderate	0	0	3 (0.8)	3 (0.5)		
Severe	1 (0.7)	0	0	0		
Gastroesophageal reflux disease	0	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Mild	0	1 (0.5)	8 (2.1)	9 (1.5)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0		
Nausea	2 (1.5)	5 (2.6)	4 (1.0)	9 (1.5)	0.165	0.39
Mild	2 (1.5)	4 (2.1)	4 (1.0)	8 (1.4)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Haemorrhoids	2 (1.5)	3 (1.6)	5 (1.3)	8 (1.4)	0.723	0.82
Mild	2 (1.5)	1 (0.5)	5 (1.3)	6 (1.0)		
Moderate	0	2 (1.0)	0	2 (0.3)		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dyspepsia	2 (1.5)	0	6 (1.5)	6 (1.0)	0.185	NA
Mild	2 (1.5)	0	6 (1.5)	6 (1.0)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Large intestine polyp	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Mild	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Stomatitis	1 (0.7)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Mild	1 (0.7)	1 (0.5)	4 (1.0)	5 (0.9)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Abdominal pain upper	0	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
Mild	0	2 (1.0)	1 (0.3)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dental caries	2 (1.5)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Gastritis	1 (0.7)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Rectal haemorrhage	0	3 (1.6)	1 (0.3)	4 (0.7)	0.108	0.16
Mild	0	3 (1.6)	1 (0.3)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Abdominal distension	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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I6T-MC-AMBG Clinical Study Report Amendment Body

Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Constipation	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Food poisoning	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	2 (0.5)	3 (0.5)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Severe	0	0	0	0		
Frequent bowel movements	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	2 (0.5)	3 (0.5)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Severe	0	0	0	0		
Haematochezia	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	2 (0.5)	3 (0.5)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Severe	0	0	0	0		

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pseudopolyposis	1 (0.7)	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	1 (0.7)	2 (1.0)	0	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Toothache	0	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	0	0	3 (0.8)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Vomiting	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Anal fistula	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Anal pruritus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Aphthous ulcer	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	1 (0.5)	0	1 (0.2)	NA	NA
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Defaecation urgency	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	0	0	0	NA	NA
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0		
Faecaloma	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Haemorrhoidal haemorrhage	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Inguinal hernia	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Rectal polyp	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	0	0	0	NA	NA
Moderate	0	2 (1.0)	0	2 (0.3)		
Severe	0	0	0	0		
Abdominal discomfort	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Abdominal pain lower	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Abdominal tenderness	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Anal fissure	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Angular cheilitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Duodenitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Enteritis	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Flatulence	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Gastritis erosive	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Gastroesophageal sphincter insufficiency	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Gingival bleeding	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Haematemesis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Irritable bowel syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Lip swelling	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Mouth ulceration	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Mucous stools	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Oral submucosal fibrosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Periodontal disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Proctalgia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Proctitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Umbilical hernia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Infections and infestations	30 (22.2)	44 (22.9)	93 (23.9)	137 (23.6)	0.836	1.06
Mild	21 (15.6)	31 (16.1)	70 (18.0)	101 (17.4)		
Moderate	8 (5.9)	9 (4.7)	20 (5.1)	29 (5.0)		
Severe	1 (0.7)	4 (2.1)	3 (0.8)	7 (1.2)	0.227	0.37
Nasopharyngitis	9 (6.7)	11 (5.7)	28 (7.2)	39 (6.7)	0.599	1.28
Mild	8 (5.9)	7 (3.6)	24 (6.2)	31 (5.3)		
Moderate	1 (0.7)	4 (2.1)	3 (0.8)	7 (1.2)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
COVID-19	5 (3.7)	4 (2.1)	8 (2.1)	12 (2.1)	>0.999	0.99
Mild	5 (3.7)	1 (0.5)	7 (1.8)	8 (1.4)		
Moderate	0	2 (1.0)	1 (0.3)	3 (0.5)		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Upper respiratory tract infection	2 (1.5)	5 (2.6)	7 (1.8)	12 (2.1)	0.543	0.69
Mild	2 (1.5)	5 (2.6)	5 (1.3)	10 (1.7)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Gastroenteritis	2 (1.5)	2 (1.0)	6 (1.5)	8 (1.4)	>0.999	1.49
Mild	0	1 (0.5)	5 (1.3)	6 (1.0)		
Moderate	2 (1.5)	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Sinusitis	1 (0.7)	4 (2.1)	3 (0.8)	7 (1.2)	0.227	0.37
Mild	0	3 (1.6)	3 (0.8)	6 (1.0)		
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Urinary tract infection	0	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Mild	0	1 (0.5)	3 (0.8)	4 (0.7)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Clostridium difficile infection	1 (0.7)	3 (1.6)	1 (0.3)	4 (0.7)	0.108	0.16
Mild	1 (0.7)	2 (1.0)	1 (0.3)	3 (0.5)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Oral herpes	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Pharyngitis	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	1 (0.7)	0	4 (1.0)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Pneumonia	1 (0.7)	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Respiratory tract infection viral	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	1 (0.7)	0	4 (1.0)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Vulvovaginal mycotic infection*b	0	0	2 (1.3)	2 (0.8)	>0.999	NA
Mild	0	0	2 (1.3)	2 (0.8)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Bronchitis	0	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	0	0	4 (1.0)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Herpes zoster	0	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	1 (0.3)	1 (0.2)		
Influenza	1 (0.7)	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	1 (0.7)	0	2 (0.5)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Rhinitis	0	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	0	0	3 (0.8)	3 (0.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Acute sinusitis	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	0	0	0	NA	NA
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0		
Herpes simplex	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	1 (0.7)	0	2 (0.5)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Respiratory tract infection	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Vaginal infection*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	1 (0.6)	1 (0.4)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Vulvovaginal candidiasis*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	1 (0.6)	1 (0.4)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
COVID-19 pneumonia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Dermatophytosis of nail	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Diverticulitis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Fungal skin infection	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Furuncle	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Gastroenteritis viral	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hordeolum	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Laryngitis	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)	NA	NA
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0		
Otitis externa	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Periodontitis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pulpitis dental	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tinea versicolour	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Tonsillitis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Tooth abscess	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Aeromonas infection	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Appendicitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Ascariasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Campylobacter infection	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Chronic tonsillitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Clostridium difficile colitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Conjunctivitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Cystitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Cytomegalovirus colitis	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA
Denture stomatitis	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Ecthyma	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Enteritis infectious	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Enterobiasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Folliculitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Gastrointestinal infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Gingival abscess	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Haemorrhoid infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Impetigo	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Labyrinthitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Large intestine infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Lower respiratory tract infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Onychomycosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Oral candidiasis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Oral infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Otitis media	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Otitis media acute	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Paronychia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Pharyngotonsillitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pyoderma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Rhinovirus infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Staphylococcal infection	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Subcutaneous abscess	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Tinea infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tinea pedis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tooth infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tracheitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Tracheobronchitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Viral upper respiratory tract infection	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
General disorders and administration site conditions	14 (10.4)	19 (9.9)	65 (16.7)	84 (14.5)	0.033 *	1.83
Mild	11 (8.1)	13 (6.8)	46 (11.8)	59 (10.2)		
Moderate	3 (2.2)	6 (3.1)	17 (4.4)	23 (4.0)		
Severe	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Injection site pain	2 (1.5)	6 (3.1)	17 (4.4)	23 (4.0)	0.652	1.42
Mild	1 (0.7)	4 (2.1)	12 (3.1)	16 (2.8)		
Moderate	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)		
Severe	0	0	2 (0.5)	2 (0.3)	>0.999	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pyrexia	6 (4.4)	5 (2.6)	13 (3.3)	18 (3.1)	0.801	1.29
Mild	6 (4.4)	3 (1.6)	11 (2.8)	14 (2.4)		
Moderate	0	2 (1.0)	2 (0.5)	4 (0.7)		
Severe	0	0	0	0		
Fatigue	1 (0.7)	4 (2.1)	10 (2.6)	14 (2.4)	>0.999	1.24
Mild	1 (0.7)	4 (2.1)	5 (1.3)	9 (1.5)		
Moderate	0	0	5 (1.3)	5 (0.9)		
Severe	0	0	0	0		
Injection site reaction	1 (0.7)	1 (0.5)	10 (2.6)	11 (1.9)	0.111	5.04
Mild	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)		
Moderate	0	0	5 (1.3)	5 (0.9)		
Severe	0	0	0	0		
Injection site erythema	1 (0.7)	2 (1.0)	8 (2.1)	10 (1.7)	0.509	1.99
Mild	1 (0.7)	2 (1.0)	7 (1.8)	9 (1.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Influenza like illness	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Mild	0	1 (0.5)	4 (1.0)	5 (0.9)		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Asthenia	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Malaise	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Oedema peripheral	0	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Peripheral swelling	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	1 (0.7)	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Chest discomfort	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Injection site bruising	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Injection site pruritus	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Non-cardiac chest pain	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Administration site reaction	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Chills	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Drug intolerance	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hyperpyrexia	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Injection site dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Injection site haematoma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Injection site hypersensitivity	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Injection site oedema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Injection site paraesthesia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Injection site rash	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Injection site urticaria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pain	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Musculoskeletal and connective tissue disorders	12 (8.9)	24 (12.5)	57 (14.7)	81 (13.9)	0.526	1.20
Mild	7 (5.2)	14 (7.3)	39 (10.0)	53 (9.1)		
Moderate	4 (3.0)	10 (5.2)	18 (4.6)	28 (4.8)		
Severe	1 (0.7)	0	0	0	NA	NA
Arthralgia	4 (3.0)	8 (4.2)	26 (6.7)	34 (5.9)	0.263	1.65
Mild	4 (3.0)	5 (2.6)	17 (4.4)	22 (3.8)		
Moderate	0	3 (1.6)	9 (2.3)	12 (2.1)		
Severe	0	0	0	0	NA	NA
Back pain	4 (3.0)	4 (2.1)	7 (1.8)	11 (1.9)	0.758	0.86
Mild	3 (2.2)	2 (1.0)	5 (1.3)	7 (1.2)		
Moderate	1 (0.7)	2 (1.0)	2 (0.5)	4 (0.7)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pain in extremity	1 (0.7)	3 (1.6)	7 (1.8)	10 (1.7)	>0.999	1.15
Mild	1 (0.7)	3 (1.6)	6 (1.5)	9 (1.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Arthritis	1 (0.7)	4 (2.1)	2 (0.5)	6 (1.0)	0.096	0.24
Mild	1 (0.7)	3 (1.6)	1 (0.3)	4 (0.7)		
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Myalgia	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Mild	0	1 (0.5)	3 (0.8)	4 (0.7)		
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Neck pain	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Musculoskeletal stiffness	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Sacroiliitis	1 (0.7)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	0	2 (1.0)	1 (0.3)	3 (0.5)		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Synovial cyst	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Exostosis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	0	0	0		
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Osteoarthritis	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Bursa disorder	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Chondropathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Enthesopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Foot deformity	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Fracture pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Intervertebral disc disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Intervertebral disc protrusion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Joint contracture	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Joint effusion	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Joint swelling	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Muscle spasms	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Muscular weakness	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Osteochondrosis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Osteoporosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Periarthritis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Sacral pain	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA
Scoliosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Temporomandibular joint syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Tendon pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
 See complete footnote on last page of the output.

Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Tendonitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Tenosynovitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Investigations	15 (11.1)	18 (9.4)	33 (8.5)	51 (8.8)	0.756	0.90
Mild	10 (7.4)	16 (8.3)	23 (5.9)	39 (6.7)		
Moderate	4 (3.0)	1 (0.5)	10 (2.6)	11 (1.9)		
Severe	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Blood creatine phosphokinase increased	5 (3.7)	5 (2.6)	10 (2.6)	15 (2.6)	>0.999	0.99
Mild	4 (3.0)	4 (2.1)	6 (1.5)	10 (1.7)		
Moderate	0	0	4 (1.0)	4 (0.7)		
Severe	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Gamma-glutamyltransferase increased	2 (1.5)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Mild	2 (1.5)	1 (0.5)	3 (0.8)	4 (0.7)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Alanine aminotransferase increased	1 (0.7)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Mild	1 (0.7)	0	4 (1.0)	4 (0.7)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
SARS-CoV-2 test positive	1 (0.7)	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	1 (0.7)	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA
White blood cell count decreased	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
					Blood alkaline phosphatase increased	0
Mild	0	3 (1.6)	1 (0.3)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Aspartate aminotransferase increased	0	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	0	0	3 (0.8)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Blood bilirubin increased	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Blood glucose increased	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	0	2 (1.0)	0	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Blood uric acid increased	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Clostridium test positive	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hepatic enzyme increased	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Liver function test increased	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Lymphocyte count decreased	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Weight decreased	2 (1.5)	0	0	0	NA	NA
Mild	2 (1.5)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Weight increased	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
White blood cell count increased	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Aeromonas test positive	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Arthroscopy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Bacterial test positive	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Blood cholesterol increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Blood pressure increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Blood triglycerides increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Blood urea increased	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Body temperature increased	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Crystal urine present	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Haemoglobin decreased	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Liver function test abnormal	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Mean cell volume increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Monocyte count decreased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Platelet count decreased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Red blood cell schistocytes present	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Renin increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Skin and subcutaneous tissue disorders	8 (5.9)	13 (6.8)	44 (11.3)	57 (9.8)	0.102	1.76
Mild	6 (4.4)	11 (5.7)	40 (10.3)	51 (8.8)		
Moderate	2 (1.5)	2 (1.0)	4 (1.0)	6 (1.0)		
Severe	0	0	0	0	NA	NA
Rash	2 (1.5)	0	14 (3.6)	14 (2.4)	0.007 *	NA
Mild	2 (1.5)	0	13 (3.3)	13 (2.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Pruritus	2 (1.5)	4 (2.1)	4 (1.0)	8 (1.4)	0.450	0.49
Mild	2 (1.5)	4 (2.1)	3 (0.8)	7 (1.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Dry skin	2 (1.5)	2 (1.0)	2 (0.5)	4 (0.7)	0.602	0.49
Mild	2 (1.5)	1 (0.5)	2 (0.5)	3 (0.5)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Acne	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Alopecia	1 (0.7)	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	1 (0.5)	0	1 (0.2)	NA	NA
Moderate	1 (0.7)	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Erythema	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Dermal cyst	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dermatitis contact	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Rash erythematous	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Rash pruritic	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Actinic keratosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Dermatitis acneiform	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Dermatitis allergic	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Dyshidrotic eczema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Ecchymosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Eczema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Eczema asteatotic	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hand dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Ingrowing nail	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Ingrown hair	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Lipodystrophy acquired	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Nail psoriasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Perioral dermatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Photosensitivity reaction	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Psoriasis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Purpura	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Rash maculo-papular	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Rosacea	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Sensitive skin	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Skin burning sensation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Skin hyperpigmentation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Skin irritation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Skin ulcer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Urticaria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Nervous system disorders	9 (6.7)	9 (4.7)	31 (8.0)	40 (6.9)	0.165	1.76
Mild	5 (3.7)	7 (3.6)	24 (6.2)	31 (5.3)		
Moderate	4 (3.0)	0	6 (1.5)	6 (1.0)		
Severe	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Headache	5 (3.7)	2 (1.0)	16 (4.1)	18 (3.1)	0.045 *	4.08
Mild	3 (2.2)	2 (1.0)	14 (3.6)	16 (2.8)		
Moderate	2 (1.5)	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Hypoaesthesia	0	0	5 (1.3)	5 (0.9)	0.177	NA
Mild	0	0	5 (1.3)	5 (0.9)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Migraine	0	0	5 (1.3)	5 (0.9)	0.177	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Burning sensation	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Dizziness	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Dysgeusia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Neuropathy peripheral	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Paraesthesia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Presyncope	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)		
Sciatica	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0		
Amnesia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dizziness postural	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Ischaemic stroke	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Lumbar radiculopathy	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Memory impairment	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Piriformis syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Restless legs syndrome	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tremor	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Vascular encephalopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Metabolism and nutrition disorders	9 (6.7)	11 (5.7)	19 (4.9)	30 (5.2)	0.692	0.84
Mild	5 (3.7)	9 (4.7)	12 (3.1)	21 (3.6)		
Moderate	4 (3.0)	2 (1.0)	6 (1.5)	8 (1.4)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Hyperglycaemia	3 (2.2)	1 (0.5)	4 (1.0)	5 (0.9)	>0.999	1.98
Mild	3 (2.2)	1 (0.5)	4 (1.0)	5 (0.9)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Hypertriglyceridaemia	3 (2.2)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	2 (1.5)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Vitamin D deficiency	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Decreased appetite	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	0	2 (1.0)	0	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Gout	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Diabetes mellitus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Hyperkalaemia	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	2 (1.0)	0	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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Treatment-Emergent Adverse Events by Maximum Severity  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hypoglycaemia	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hypokalaemia	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Iron deficiency	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0	NA	NA
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Type 2 diabetes mellitus	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Acidosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Food aversion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Glucose tolerance impaired	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Haemosiderosis	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hypercholesterolaemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Increased appetite	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Steroid diabetes	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Vitamin B12 deficiency	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Blood and lymphatic system disorders	11 (8.1)	12 (6.3)	15 (3.9)	27 (4.6)	0.212	0.60
Mild	9 (6.7)	10 (5.2)	12 (3.1)	22 (3.8)		
Moderate	1 (0.7)	2 (1.0)	3 (0.8)	5 (0.9)		
Severe	1 (0.7)	0	0	0	NA	NA
Anaemia	8 (5.9)	9 (4.7)	8 (2.1)	17 (2.9)	0.113	0.43
Mild	6 (4.4)	7 (3.6)	5 (1.3)	12 (2.1)		
Moderate	2 (1.5)	2 (1.0)	3 (0.8)	5 (0.9)		
Severe	0	0	0	0	NA	NA
Neutropenia	3 (2.2)	2 (1.0)	1 (0.3)	3 (0.5)	0.255	0.24
Mild	3 (2.2)	2 (1.0)	1 (0.3)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Lymphopenia	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	0	1 (0.5)	2 (0.5)	3 (0.5)		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Iron deficiency anaemia	0	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	0	0	3 (0.8)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Lymphadenopathy	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Leukopenia	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	2 (1.0)	0	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Thrombocytopenia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hypersplenism	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Pancytopenia	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Respiratory, thoracic and mediastinal disorders	5 (3.7)	6 (3.1)	27 (6.9)	33 (5.7)	0.085	2.31
Mild	5 (3.7)	4 (2.1)	23 (5.9)	27 (4.6)		
Moderate	0	1 (0.5)	3 (0.8)	4 (0.7)		
Severe	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Cough	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Mild	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Oropharyngeal pain	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Mild	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Nasal congestion	0	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	0	0	3 (0.8)	3 (0.5)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Rhinorrhoea	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	1 (0.7)	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Chronic obstructive pulmonary disease	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Dyspnoea	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Epistaxis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Asthma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Dyspnoea exertional	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Emphysema	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Haemoptysis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Nasal dryness	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Nasal septum deviation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Nasal ulcer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Pharyngeal inflammation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Pulmonary embolism	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Rhinitis allergic	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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Treatment-Emergent Adverse Events by Maximum Severity  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Sinus congestion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Sleep apnoea syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0	NA	NA
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Sneezing	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Throat irritation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Vasomotor rhinitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Wheezing	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Injury, poisoning and procedural complications	5 (3.7)	5 (2.6)	16 (4.1)	21 (3.6)	0.480	1.60
Mild	4 (3.0)	5 (2.6)	12 (3.1)	17 (2.9)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	1 (0.7)	0	2 (0.5)	2 (0.3)	>0.999	NA
Ligament sprain	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Fall	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Joint injury	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Radius fracture	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Spinal compression fracture	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	1 (0.3)	1 (0.2)		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Arthropod bite	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Arthropod sting	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Brain contusion	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0		
Contusion	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Electric injury	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Foot fracture	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0	NA	NA
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Heat illness	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Joint dislocation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Meniscus injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Muscle injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Patella fracture	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0		
Procedural pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Retinal injury	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Road traffic accident	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA
Skin laceration	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Tendon injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Tooth fracture	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Vaccination complication	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Vascular disorders	3 (2.2)	5 (2.6)	15 (3.9)	20 (3.4)	0.629	1.50
Mild	0	3 (1.6)	8 (2.1)	11 (1.9)		
Moderate	2 (1.5)	1 (0.5)	6 (1.5)	7 (1.2)		
Severe	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hypertension	1 (0.7)	1 (0.5)	9 (2.3)	10 (1.7)	0.177	4.52
Mild	0	1 (0.5)	4 (1.0)	5 (0.9)		
Moderate	1 (0.7)	0	4 (1.0)	4 (0.7)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Deep vein thrombosis	2 (1.5)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA
Hypotension	0	2 (1.0)	0	2 (0.3)	0.109	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Superficial vein thrombosis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Varicose vein	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Aortic aneurysm	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hot flush	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Peripheral venous disease	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0		
Post thrombotic syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Thrombophlebitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
White coat hypertension	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Psychiatric disorders	3 (2.2)	4 (2.1)	13 (3.3)	17 (2.9)	0.601	1.63
Mild	3 (2.2)	2 (1.0)	8 (2.1)	10 (1.7)		
Moderate	0	2 (1.0)	5 (1.3)	7 (1.2)		
Severe	0	0	0	0	NA	NA
Insomnia	2 (1.5)	3 (1.6)	2 (0.5)	5 (0.9)	0.338	0.33
Mild	2 (1.5)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	2 (1.0)	1 (0.3)	3 (0.5)		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Anxiety	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Depressed mood	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Depression	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Premature ejaculation*a	0	0	1 (0.4)	1 (0.3)	>0.999	NA
Mild	0	0	1 (0.4)	1 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Affective disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Agitation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Depression suicidal	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Dysphemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Listless	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Stress	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Eye disorders	2 (1.5)	2 (1.0)	12 (3.1)	14 (2.4)	0.159	3.02
Mild	1 (0.7)	2 (1.0)	10 (2.6)	12 (2.1)		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	1 (0.3)	1 (0.2)		
Dry eye	0	0	3 (0.8)	3 (0.5)	0.554	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Blepharitis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0		
Asthenopia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Cataract	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Chalazion	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Conjunctivitis allergic	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Iridocyclitis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Myopia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Ocular hyperaemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Pterygium	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Retinal detachment	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal disorder	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Retinal dystrophy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Retinal haemorrhage	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Swelling of eyelid	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Visual impairment	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Surgical and medical procedures	4 (3.0)	0	8 (2.1)	8 (1.4)	0.058	NA
Mild	2 (1.5)	0	6 (1.5)	6 (1.0)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	2 (1.5)	0	1 (0.3)	1 (0.2)		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Large intestinal polypectomy	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Cataract operation	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (0.7)	0	0	0		
Severe	0	0	0	0	NA	NA
Hair transplant	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Inguinal hernia repair	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Intraocular lens implant	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0	NA	NA
Knee operation	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Papilloma excision	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Retinopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Skin cyst excision	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Skin neoplasm excision	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Tooth extraction	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Wisdom teeth removal	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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Treatment-Emergent Adverse Events by Maximum Severity  
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 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Immune system disorders	0	4 (2.1)	7 (1.8)	11 (1.9)	0.758	0.86
Mild	0	4 (2.1)	5 (1.3)	9 (1.5)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Seasonal allergy	0	2 (1.0)	4 (1.0)	6 (1.0)	>0.999	0.99
Mild	0	2 (1.0)	3 (0.8)	5 (0.9)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Hypersensitivity	0	1 (0.5)	3 (0.8)	4 (0.7)	>0.999	1.48
Mild	0	1 (0.5)	2 (0.5)	3 (0.5)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Anaphylactic reaction	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	3 (1.6)	6 (1.5)	9 (1.5)	>0.999	0.99
Mild	0	2 (1.0)	5 (1.3)	7 (1.2)		
Moderate	0	1 (0.5)	1 (0.3)	2 (0.3)		
Severe	0	0	0	0	NA	NA
Melanocytic naevus	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Skin papilloma	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Basal cell carcinoma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Cholesteatoma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0	NA	NA
Gastric cancer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Haemangioma of liver	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Lipoma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Renal and urinary disorders	2 (1.5)	4 (2.1)	3 (0.8)	7 (1.2)	0.227	0.37
Mild	2 (1.5)	4 (2.1)	1 (0.3)	5 (0.9)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nephrolithiasis	2 (1.5)	0	0	0	NA	NA
Mild	2 (1.5)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Azotaemia	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Bladder hypertrophy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Chronic kidney disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Dysuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Haematuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Hypercalciuria	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Nephrocalcinosis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Nephrogenic diabetes insipidus	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Proteinuria	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Renal cyst	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Renal injury	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Ureterolithiasis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Cardiac disorders	2 (1.5)	2 (1.0)	3 (0.8)	5 (0.9)	0.667	0.74
Mild	2 (1.5)	2 (1.0)	3 (0.8)	5 (0.9)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Tachycardia	1 (0.7)	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	1 (0.7)	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Arteriosclerosis coronary artery	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Atrioventricular block first degree	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Extrasystoles	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Mitral valve incompetence	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Mitral valve prolapse	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Sinus tachycardia	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Tricuspid valve incompetence	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hepatobiliary disorders	1 (0.7)	1 (0.5)	5 (1.3)	6 (1.0)	0.669	2.49
Mild	1 (0.7)	1 (0.5)	3 (0.8)	4 (0.7)		
Moderate	0	0	2 (0.5)	2 (0.3)		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hepatic steatosis	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Autoimmune hepatitis	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0	NA	NA
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0		
Gallbladder polyp	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		
Granulomatous liver disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)	NA	NA
Moderate	0	0	0	0		
Severe	0	0	0	0		

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Non-alcoholic steatohepatitis	1 (0.7)	0	0	0	NA	NA
Mild	1 (0.7)	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Nonalcoholic fatty liver disease	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Reproductive system and breast disorders	1 (0.7)	0	6 (1.5)	6 (1.0)	0.185	NA
Mild	0	0	4 (1.0)	4 (0.7)		
Moderate	1 (0.7)	0	1 (0.3)	1 (0.2)		
Severe	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Erectile dysfunction*a	0	0	2 (0.9)	2 (0.6)	>0.999	NA
Mild	0	0	2 (0.9)	2 (0.6)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Intermenstrual bleeding*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	1 (0.6)	1 (0.4)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Rectocele*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Uterine cervical metaplasia*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.6)	1 (0.4)		
Severe	0	0	0	0	NA	NA
Uterine polyp*b	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.6)	1 (0.4)		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Vaginal haemorrhage*b	1 (1.6)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	1 (1.6)	0	0	0		
Severe	0	0	0	0	NA	NA
Benign prostatic hyperplasia*a	0	0	1 (0.4)	1 (0.3)	>0.999	NA
Mild	0	0	1 (0.4)	1 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Congenital, familial and genetic disorders	1 (0.7)	1 (0.5)	2 (0.5)	3 (0.5)	>0.999	0.99
Mild	1 (0.7)	1 (0.5)	1 (0.3)	2 (0.3)		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Type V hyperlipidaemia	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	1 (0.7)	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Congenital aural fistula	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	0	0		
Moderate	0	0	1 (0.3)	1 (0.2)		
Severe	0	0	0	0	NA	NA
Gilbert's syndrome	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Ear and labyrinth disorders	0	0	4 (1.0)	4 (0.7)	0.308	NA
Mild	0	0	4 (1.0)	4 (0.7)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Vertigo	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Mild	0	0	2 (0.5)	2 (0.3)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Deafness	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Vertigo positional	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Endocrine disorders	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		
Autoimmune thyroiditis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	0	0	0		
Moderate	0	1 (0.5)	0	1 (0.2)		
Severe	0	0	0	0		

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					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Hyperaldosteronism	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Hyperparathyroidism secondary	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Mild	0	0	1 (0.3)	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0		
Pregnancy, puerperium and perinatal conditions	1 (0.7)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (0.7)	0	0	0		
Subchorionic haematoma*b	1 (1.6)	0	0	0	NA	NA
Mild	0	0	0	0		
Moderate	0	0	0	0		
Severe	1 (1.6)	0	0	0		

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
 See complete footnote on last page of the output.

Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
 Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
 Output: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/output/restricted/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.rtf

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Treatment-Emergent Adverse Events by Maximum Severity  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term Severity	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*c	Odds ratio*d
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Social circumstances	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA
Denture wearer	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Mild	0	1 (0.5)	0	1 (0.2)		
Moderate	0	0	0	0		
Severe	0	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
 See complete footnote on last page of the output.

Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
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Treatment-Emergent Adverse Events by Maximum Severity  
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Abbreviations: miri = mirikizumab; SC = subcutaneous; TEAE = treatment-emergent adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
Patients with multiple occurrences of the same event are counted under the highest severity.

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\*a - Denominator adjusted because gender-specific event for males: N=74 (Placebo Responder placebo SC), N=114 (Miri Responder placebo SC), N=229 (Miri Responder 200 miri SC).

\*b - Denominator adjusted because gender-specific event for females: N=61 (Placebo Responder placebo SC), N=78 (Miri Responder placebo SC), N=160 (Miri Responder 200 miri SC).

\*c - p-value was computed using Fisher's exact test.

\*d - odds ratio based on comparator Miri Responder placebo SC as denominator.

\* p-value <=0.05.

Dataset: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/data/analysis/restricted/adsl,adae.sas7bdat  
Program: /lillyce/prd/ly3074828/i6t\_mc\_ambg/intrml/programs/tfl/t\_a\_teae\_bymaxsev\_s\_ir\_m.sas  
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**Anhang 4-G2.3: Schwerwiegende Unerwünschte Ereignisse nach SOC und PT**

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**Table AMBG.8.125. Serious Adverse Events  
Safety Population - Induction Responder  
I6T-MC-AMBG - Maintenance Period**

System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*b		Odds ratio*c
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC	
Subjects with >= 1 SAE	7 (5.2)	15 (7.8)	13 (3.3)	28 (4.8)	0.023		0.41
Gastrointestinal disorders	1 (0.7)	8 (4.2)	1 (0.3)	9 (1.5)	<0.001		0.06
Colitis ulcerative	1 (0.7)	6 (3.1)	0	6 (1.0)	0.001		0.00
Inguinal hernia	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Rectal haemorrhage	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Rectal polyp	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Infections and infestations	3 (2.2)	3 (1.6)	3 (0.8)	6 (1.0)	0.402		0.49
Gastroenteritis	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999		NA
COVID-19	0	1 (0.5)	0	1 (0.2)	0.330		0.00
COVID-19 pneumonia	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Cytomegalovirus colitis	1 (0.7)	0	0	0	NA		NA
Diverticulitis	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Large intestine infection	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Pneumonia	1 (0.7)	0	0	0	NA		NA
Subcutaneous abscess	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Nervous system disorders	0	2 (1.0)	1 (0.3)	3 (0.5)	0.255		0.24
Ischaemic stroke	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Migraine	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Presyncope	0	1 (0.5)	0	1 (0.2)	0.330		0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; SAE = serious adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
See complete footnote on last page of the output.

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Serious Adverse Events  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*b	Odds ratio*c
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Injury, poisoning and procedural complications	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Brain contusion	1 (0.7)	0	0	0	NA	NA
Patella fracture	1 (0.7)	0	0	0	NA	NA
Road traffic accident	1 (0.7)	0	0	0	NA	NA
Spinal compression fracture	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Metabolism and nutrition disorders	0	1 (0.5)	1 (0.3)	2 (0.3)	0.552	0.49
Hypoglycaemia	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Hypokalaemia	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Musculoskeletal and connective tissue disorders	1 (0.7)	0	1 (0.3)	1 (0.2)	>0.999	NA
Back pain	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Sacral pain	1 (0.7)	0	0	0	NA	NA
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	2 (0.5)	2 (0.3)	>0.999	NA
Gastric cancer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Lipoma	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Endocrine disorders	0	1 (0.5)	0	1 (0.2)	0.330	0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; SAE = serious adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*b	Odds ratio*c
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Endocrine disorders						
Autoimmune thyroiditis	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Eye disorders	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Retinal detachment	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Immune system disorders	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Anaphylactic reaction	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Investigations	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Blood glucose increased	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Psychiatric disorders	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Depression suicidal	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Reproductive system and breast disorders	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Rectocele*a	0	0	1 (0.6)	1 (0.4)	>0.999	NA
Respiratory, thoracic and mediastinal disorders	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Asthma	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Surgical and medical procedures	0	0	1 (0.3)	1 (0.2)	>0.999	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; SAE = serious adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*b	Odds ratio*c
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ placebo SC
Surgical and medical procedures						
Retinopathy	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Vascular disorders	1 (0.7)	0	0	0	NA	NA
Deep vein thrombosis	1 (0.7)	0	0	0	NA	NA

Abbreviations: miri = mirikizumab; SC = subcutaneous; SAE = serious adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
 See complete footnote on last page of the output.

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MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
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Abbreviations: miri = mirikizumab; SC = subcutaneous; SAE = serious adverse event; N = number of subjects in the analysis population; n = number of subjects in the specified category.

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\*a - Denominator adjusted because gender-specific event for females: N=61 (Placebo Responder placebo SC), N=78 (Miri Responder placebo SC), N=160 (Miri Responder 200 miri SC).

\*b - p-value was computed using Fisher's exact test.

\*c - odds ratio based on comparator Miri Responder placebo SC as denominator.

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Approved on 18 Apr 2022 GMT

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**Anhang 4-G2.4: Unerwünschte Ereignisse nach SOC und PT, die zum Behandlungsabbruch führten**



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**Table AMBG.8.130. Adverse Events Reported as Reason for Study Treatment Discontinuation (including deaths)  
Safety Population - Induction Responder  
I6T-MC-AMBG - Maintenance Period**

System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*a		Odds ratio*b
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC	
Subjects with >= 1 AE as reason for study treatment discontinuation	1 (0.7)	16 (8.3)	6 (1.5)	22 (3.8)	<0.001		0.17
Gastrointestinal disorders	1 (0.7)	11 (5.7)	2 (0.5)	13 (2.2)	<0.001		0.09
Colitis ulcerative	1 (0.7)	11 (5.7)	2 (0.5)	13 (2.2)	<0.001		0.09
General disorders and administration site conditions	0	0	2 (0.5)	2 (0.3)	>0.999		NA
Injection site hypersensitivity	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Oedema peripheral	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Hepatobiliary disorders	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Autoimmune hepatitis	0	0	1 (0.3)	1 (0.2)	>0.999		NA
Immune system disorders	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Anaphylactic reaction	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Infections and infestations	0	1 (0.5)	0	1 (0.2)	0.330		0.00
COVID-19	0	1 (0.5)	0	1 (0.2)	0.330		0.00
Musculoskeletal and connective tissue disorders	0	1 (0.5)	0	1 (0.2)	0.330		0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Adverse Events Reported as Reason for Study Treatment Discontinuation (including deaths)  
 MedDRA Preferred Term by Decreasing Frequency within System Organ Class  
 Safety Population - Induction Responder  
 I6T-MC-AMBG - Maintenance period

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System Organ Class Preferred Term	Placebo Responder placebo SC (N=135) n (%)	Miri Responder placebo SC (N=192) n (%)	Miri Responder 200 miri SC (N=389) n (%)	Miri Responder Total (N=581) n (%)	p-values*a	Odds ratio*b
					Miri Responder 200 miri SC vs. Miri Responder placebo SC	Miri Responder 200 miri SC/ Miri Responder placebo SC
Musculoskeletal and connective tissue disorders						
Arthralgia	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Gastric cancer	0	0	1 (0.3)	1 (0.2)	>0.999	NA
Nervous system disorders	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Presyncope	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Vascular disorders	0	1 (0.5)	0	1 (0.2)	0.330	0.00
Hypotension	0	1 (0.5)	0	1 (0.2)	0.330	0.00

Abbreviations: miri = mirikizumab; SC = subcutaneous; N = number of subjects in the analysis population; n = number of subjects in the specified category.  
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Abbreviations: miri = mirikizumab; SC = subcutaneous; N = number of subjects in the analysis population; n = number of subjects in the specified category.

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\*a - p-value was computed using Fisher's exact test.  
\*b - odds ratio based on comparator Miri Responder placebo SC as denominator.

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**Anhang 4-G3: Rücklaufquoten der patientenberichteten Endpunkte**

Patientenberichteter Endpunkt	Baseline		Woche 52	
	Mirikizumab n/N (%)	Placebo n/N (%)	Mirikizumab n/N (%)	Placebo n/N (%)
Stuhlfrequenz <sup>a</sup>	365/365 (100)	179/179 (100)	317/324 (97,8)	107/109 (98,2)
Rektale Blutung <sup>a</sup>	365/365 (100)	179/179 (100)	317/324 (97,8)	107/109 (98,2)
Bowel Urgency <sup>b,c</sup>	336/336 (100)	172/172 (100)	NB	NB
Abdominelle Schmerzen <sup>d,c</sup>	303/303 (100)	159/159 (100)	NB	NB
Fatigue	361/365 (98,9)	178/179 (99,4)	185/324 (57,1)	61/109 (56,0)
WPAI:UC Aktivitätsbeeinträchtigung <sup>e,c</sup>	224/224 (100)	120/120 (100)	NB	NB
EQ-5D VAS	361/365 (98,9)	178/179 (99,4)	323/324 (99,7)	107/109 (98,2)
IBDQ	362/365 (99,2)	178/179 (99,4)	323/324 (99,7)	107/109 (98,2)
SF-36 PCS	359/365 (98,4)	178/179 (99,4)	323/324 (99,7)	107/109 (98,2)
SF-36 MCS	359/365 (98,4)	178/179 (99,4)	323/324 (99,7)	107/109 (98,2)
<p>a: Subskala des Mayo-Scores  b: Es werden Patienten betrachtet, die zu Induktionsbaseline einen Bowel Urgency Wert von <math>\geq 3</math> hatten  c: Die Größe der Patientenpopulation zum Zeitpunkt Woche 52 konnte anhand der vorliegenden Daten nicht bestimmt werden  d: Es werden Patienten betrachtet, die zu Induktionsbaseline einen Wert auf der Skala für abdominelle Schmerzen von <math>\geq 3</math> hatten  e: Es werden Patienten betrachtet, die zu Induktionsbaseline ein gültiges Beschäftigtenverhältnis hatten</p> <p>EQ-5D: EuroQol-5 Dimensionen Fragebogen; IBDQ: Inflammatory Bowel Disease Questionnaire; MCS: Mental Health Component Summary Score; n: Anzahl an Patienten mit Daten; N: Anzahl an Patienten, von denen Daten erwartet werden; NB: Nicht bestimmbar; PCS: Physical Health Component Summary Score; SF-36: 36-Item Short-Form Health Survey; VAS: Visuelle Analogskala; WPAI:UC: Work Productivity and Activity Questionnaire:Ulcerative Colitis</p>				