Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tezepelumab (Tezspire®)

AstraZeneca GmbH

Modul 4 A – Anhang 4-G-3

Add-on-Erhaltungstherapie bei Erwachsenen und Jugendlichen ab 12 Jahren mit schwerem Asthma, das trotz hochdosierter inhalativer Kortikosteroide plus eines weiteren Arzneimittels zur Erhaltungstherapie unzureichend kontrolliert ist

UE-Analysen, ohne Berücksichtigung von erkrankungsbezogenen Ereignissen

mITT-Population

RCT mit dem zu bewertenden Arzneimittel

Stand: 11.11.2022

Table MT1AA_SLMI0: Incidence of non-disease related TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	446	277 (62.1) [57.4, 66.6]	436	265 (60.8) [56.0, 65.4]	1.022 [0.920, 1.135]	1.058 [0.806, 1.387]	1.3 [-5.3, 8.0]	0.729

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 02FEB2022

Table NT1AA_SLMI0: Incidence of non-disease related TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	395	256 (64.8) [59.9, 69.5]	391	241 (61.6) [56.6, 66.5]	1.051 [0.945, 1.170]	1.146 [0.858, 1.532]	3.2 [-3.8, 10.2]	0.375

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AA_TLMI0: Incidence of non-disease related TEAEs during study period
DSAFL - adult

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	380	248 (65.3) [60.2, 70.0]	371	233 (62.8) [57.7, 67.7]	1.039 [0.933, 1.157]	1.113 [0.826, 1.499]	2.5 [-4.7, 9.6]	0.494

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AA_JLMI0: Incidence of non-disease related TEAEs during study period
DSAFL - adolescents

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	15	8 (53.3) [26.6, 78.7]	20	8 (40.0) [19.1, 63.9]	1.333 [0.652, 2.727]	1.714 [0.443, 6.629]	13.3 [-25.6, 52.3]	0.506

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table PT3AA_SLMI0: Incidence of non-disease related TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	66	29 (43.9) [31.7, 56.7]	65	32 (49.2) [36.6, 61.9]	0.893 [0.618, 1.289]	0.808 [0.406, 1.608]	-5.3 [-23.9, 13.3]	0.601

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table ST1AA_SLMI0: Incidence of non-disease related TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	73	36 (49.3) [37.4, 61.3]	76	46 (60.5) [48.6, 71.6]	0.815 [0.607, 1.094]	0.635 [0.331, 1.215]	-11.2 [-28.4, 6.0]	0.190

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table DT1AA_ULMI0: Incidence of non-disease related TEAEs during study period
DSAFNL - LTE

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	310	240 (77.4) [72.4, 82.0]	149	113 (75.8) [68.2, 82.5]	1.021 [0.916, 1.138]	1.092 [0.690, 1.730]	1.6 [-7.2, 10.4]	0.724

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table CT1AA_SLMI0: Incidence of non-disease related TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	31	22 (71.0) [52.0, 85.8]	34	28 (82.4) [65.5, 93.2]	0.862 [0.655, 1.133]	0.524 [0.162, 1.695]	-11.4 [-35.0, 12.2]	0.379

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table MT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.733
Male	154	89 (57.8) [49.6, 65.7]	156	86 (55.1) [47.0, 63.1]	1.048 [0.862, 1.275]	1.114 [0.711, 1.747]	2.7 [-9.0, 14.3]	0.649
Female	292	188 (64.4) [58.6, 69.9]	280	179 (63.9) [58.0, 69.6]	1.007 [0.891, 1.138]	1.020 [0.725, 1.436]	0.5 [-7.8, 8.7]	0.931
Age								0.170
< 65 years	361	225 (62.3) [57.1, 67.3]	373	221 (59.2) [54.1, 64.3]	1.052 [0.936, 1.182]	1.138 [0.846, 1.531]	3.1 [-4.3, 10.4]	0.406
>= 65 years	85	52 (61.2) [50.0, 71.6]	63	44 (69.8) [57.0, 80.8]	0.876 [0.693, 1.107]	0.680 [0.340, 1.360]	-8.7 [-25.4, 8.1]	0.300
Exacerbations in the year before study								0.143
<= 2	248	142 (57.3) [50.8, 63.5]	259	136 (52.5) [46.2, 58.7]	1.090 [0.931, 1.277]	1.212 [0.853, 1.720]	4.7 [-4.3, 13.8]	0.286
> 2	198	135 (68.2) [61.2, 74.6]	177	129 (72.9) [65.7, 79.3]	0.936 [0.821, 1.066]	0.797 [0.510, 1.246]	-4.7 [-14.5, 5.1]	0.365
Race								0.462
White	299	180 (60.2) [54.4, 65.8]	293	180 (61.4) [55.6, 67.0]	0.980 [0.861, 1.115]	0.950 [0.683, 1.321]	-1.2 [-9.4, 7.0]	0.801
Black or African American	23	15 (65.2) [42.7, 83.6]	21	9 (42.9) [21.8, 66.0]	1.522 [0.855, 2.710]	2.500 [0.740, 8.450]	22.4 [-10.9, 55.7]	0.225
Asian	110	71 (64.5) [54.9, 73.4]	106	65 (61.3) [51.4, 70.6]	1.053 [0.857, 1.292]	1.148 [0.661, 1.996]	3.2 [-10.6, 17.0]	0.673
Other	14	11 (78.6) [49.2, 95.3]	16	11 (68.8) [41.3, 89.0]	1.143 [0.744, 1.755]	1.667 [0.318, 8.743]	9.8 [-28.1, 47.8]	0.689

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.854
Europe	104	64 (61.5) [51.5, 70.9]	96	55 (57.3) [46.8, 67.3]	1.074 [0.853, 1.352]	1.193 [0.678, 2.099]	4.2 [-10.4, 18.9]	0.567
America	146	97 (66.4) [58.2, 74.0]	138	87 (63.0) [54.4, 71.1]	1.054 [0.887, 1.252]	1.160 [0.713, 1.889]	3.4 [-8.4, 15.2]	0.619
Asia/Pacific	107	67 (62.6) [52.7, 71.8]	107	70 (65.4) [55.6, 74.4]	0.957 [0.783, 1.170]	0.885 [0.506, 1.548]	-2.8 [-16.6, 11.0]	0.776
Rest of the world	89	49 (55.1) [44.1, 65.6]	95	53 (55.8) [45.2, 66.0]	0.987 [0.761, 1.279]	0.971 [0.543, 1.737]	-0.7 [-16.2, 14.7]	1.000
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	2 (66.7) [9.4, 99.2]	3	1 (33.3) [0.8, 90.6]				
18.5 - < 25.0 kg/m**2	124	67 (54.0) [44.9, 63.0]	129	73 (56.6) [47.6, 65.3]				
25.0 - < 30.0 kg/m**2	151	88 (58.3) [50.0, 66.2]	146	86 (58.9) [50.5, 67.0]				
>= 30.0 kg/m**2	168	120 (71.4) [64.0, 78.1]	158	105 (66.5) [58.5, 73.8]				
Baseline eosinophils - Low								0.647
< 150 cells/uL	107	70 (65.4) [55.6, 74.4]	101	62 (61.4) [51.2, 70.9]	1.066 [0.866, 1.311]	1.190 [0.676, 2.094]	4.0 [-10.0, 18.1]	0.567
>= 150 cells/uL	339	207 (61.1) [55.6, 66.3]	335	203 (60.6) [55.1, 65.9]	1.008 [0.893, 1.137]	1.020 [0.748, 1.389]	0.5 [-7.2, 8.1]	0.937
Baseline eosinophils - High								0.809
< 300 cells/uL	250	153 (61.2) [54.9, 67.3]	241	146 (60.6) [54.1, 66.8]	1.010 [0.877, 1.164]	1.026 [0.714, 1.475]	0.6 [-8.4, 9.7]	0.926
>= 300 cells/uL	196	124 (63.3) [56.1, 70.0]	195	119 (61.0) [53.8, 67.9]	1.037 [0.888, 1.210]	1.100 [0.731, 1.655]	2.2 [-7.9, 12.4]	0.677

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.385
< 25 ppb	194	119 (61.3) [54.1, 68.2]	175	111 (63.4) [55.8, 70.6]	0.967 [0.825, 1.133]	0.915 [0.600, 1.395]	-2.1 [-12.5, 8.3]	0.747
>= 25 ppb	249	156 (62.7) [56.3, 68.7]	256	151 (59.0) [52.7, 65.1]	1.062 [0.923, 1.222]	1.166 [0.816, 1.668]	3.7 [-5.2, 12.6]	0.413
Baseline specific perennial FEIA status								0.167
All negative	164	107 (65.2) [57.4, 72.5]	158	109 (69.0) [61.2, 76.1]	0.946 [0.812, 1.102]	0.844 [0.530, 1.344]	-3.7 [-14.6, 7.1]	0.480
Any positive	275	167 (60.7) [54.7, 66.5]	269	149 (55.4) [49.2, 61.4]	1.096 [0.950, 1.265]	1.245 [0.885, 1.752]	5.3 [-3.3, 14.0]	0.224
Total serum IgE								0.955
Low	138	96 (69.6) [61.2, 77.1]	135	93 (68.9) [60.4, 76.6]	1.010 [0.862, 1.183]	1.032 [0.617, 1.726]	0.7 [-11.0, 12.4]	1.000
Normal	275	162 (58.9) [52.8, 64.8]	256	148 (57.8) [51.5, 63.9]	1.019 [0.882, 1.177]	1.046 [0.741, 1.478]	1.1 [-7.7, 9.9]	0.860
High	33	19 (57.6) [39.2, 74.5]	45	24 (53.3) [37.9, 68.3]	1.080 [0.723, 1.611]	1.188 [0.480, 2.936]	4.2 [-20.7, 29.2]	0.819
OCS at baseline								0.658
Yes	55	41 (74.5) [61.0, 85.3]	55	42 (76.4) [63.0, 86.8]	0.976 [0.789, 1.208]	0.906 [0.380, 2.161]	-1.8 [-19.7, 16.1]	1.000
No	391	236 (60.4) [55.3, 65.2]	381	223 (58.5) [53.4, 63.5]	1.031 [0.918, 1.159]	1.079 [0.809, 1.438]	1.8 [-5.4, 9.0]	0.609

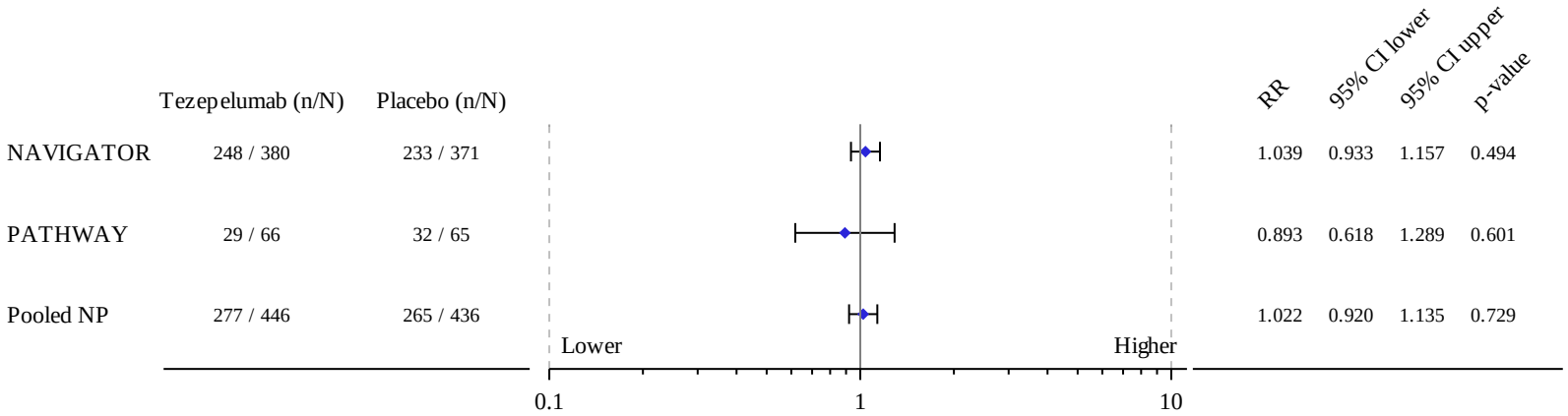
Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.295
Yes	119	84 (70.6) [61.5, 78.6]	107	68 (63.6) [53.7, 72.6]	1.111 [0.924, 1.336]	1.376 [0.788, 2.403]	7.0 [-6.1, 20.2]	0.320
No	327	193 (59.0) [53.5, 64.4]	329	197 (59.9) [54.4, 65.2]	0.986 [0.869, 1.119]	0.965 [0.707, 1.318]	-0.9 [-8.7, 7.0]	0.874
Tiotropium use at baseline								0.257
Yes	109	77 (70.6) [61.2, 79.0]	102	64 (62.7) [52.6, 72.1]	1.126 [0.929, 1.365]	1.429 [0.804, 2.540]	7.9 [-5.7, 21.5]	0.244
No	337	200 (59.3) [53.9, 64.6]	334	201 (60.2) [54.7, 65.5]	0.986 [0.871, 1.117]	0.966 [0.709, 1.315]	-0.8 [-8.6, 6.9]	0.875
Montelukast/ Cromoglicic acid use at baseline								0.948
Yes	180	115 (63.9) [56.4, 70.9]	162	101 (62.3) [54.4, 69.8]	1.025 [0.871, 1.205]	1.069 [0.688, 1.659]	1.5 [-9.3, 12.4]	0.823
No	266	162 (60.9) [54.8, 66.8]	274	164 (59.9) [53.8, 65.7]	1.018 [0.888, 1.167]	1.045 [0.740, 1.475]	1.0 [-7.6, 9.7]	0.860

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Figure MF1AA_SLMF0: Forest plot for non-disease related TEAEs during study period
DSAFL



Test for heterogeneity - p-value: 0.436, I-square: 0.0 %

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of affected patients. RR = relative risk. CI = confidence interval.
Heterogeneity was investigated with Cochran Q test. NE = not evaluable.
Source tables: NT1AA_TLMI0, PT3AA_SLMI0, MT1AA_SLMI0

Table NT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.211
Male	143	88 (61.5) [53.0, 69.5]	147	78 (53.1) [44.7, 61.3]	1.160 [0.950, 1.416]	1.415 [0.887, 2.259]	8.5 [-3.6, 20.5]	0.156
Female	252	168 (66.7) [60.5, 72.5]	244	163 (66.8) [60.5, 72.7]	0.998 [0.881, 1.130]	0.994 [0.684, 1.444]	-0.1 [-8.8, 8.6]	1.000
Age								0.127
< 65 years	319	208 (65.2) [59.7, 70.4]	338	203 (60.1) [54.6, 65.3]	1.086 [0.965, 1.222]	1.246 [0.908, 1.711]	5.1 [-2.5, 12.8]	0.197
>= 65 years	76	48 (63.2) [51.3, 73.9]	53	38 (71.7) [57.7, 83.2]	0.881 [0.692, 1.121]	0.677 [0.317, 1.444]	-8.5 [-26.4, 9.3]	0.347
Exacerbations in the year before study								0.087
<= 2	211	130 (61.6) [54.7, 68.2]	226	122 (54.0) [47.2, 60.6]	1.141 [0.972, 1.340]	1.368 [0.934, 2.003]	7.6 [-2.1, 17.3]	0.121
> 2	184	126 (68.5) [61.2, 75.1]	165	119 (72.1) [64.6, 78.8]	0.949 [0.828, 1.088]	0.840 [0.530, 1.332]	-3.6 [-13.8, 6.5]	0.483
Race								0.607
White	251	161 (64.1) [57.9, 70.1]	252	159 (63.1) [56.8, 69.1]	1.017 [0.891, 1.160]	1.046 [0.728, 1.505]	1.0 [-7.8, 9.9]	0.853
Black or African American	21	13 (61.9) [38.4, 81.9]	21	9 (42.9) [21.8, 66.0]	1.444 [0.795, 2.624]	2.167 [0.631, 7.442]	19.0 [-15.4, 53.5]	0.354
Asian	108	70 (64.8) [55.0, 73.8]	104	64 (61.5) [51.5, 70.9]	1.053 [0.857, 1.294]	1.151 [0.659, 2.013]	3.3 [-10.6, 17.2]	0.670
Other	15	12 (80.0) [51.9, 95.7]	14	9 (64.3) [35.1, 87.2]	1.244 [0.781, 1.982]	2.222 [0.417, 11.829]	15.7 [-23.4, 54.9]	0.427

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.716
Europe	65	47 (72.3) [59.8, 82.7]	61	40 (65.6) [52.3, 77.3]	1.103 [0.871, 1.396]	1.371 [0.643, 2.924]	6.7 [-11.0, 24.5]	0.446
America	151	98 (64.9) [56.7, 72.5]	152	89 (58.6) [50.3, 66.5]	1.108 [0.928, 1.324]	1.309 [0.823, 2.083]	6.3 [-5.2, 17.9]	0.288
Asia/Pacific	105	66 (62.9) [52.9, 72.1]	105	69 (65.7) [55.8, 74.7]	0.957 [0.782, 1.170]	0.883 [0.502, 1.553]	-2.9 [-16.8, 11.1]	0.773
Rest of the world	74	45 (60.8) [48.8, 72.0]	73	43 (58.9) [46.8, 70.3]	1.032 [0.792, 1.345]	1.083 [0.560, 2.094]	1.9 [-15.3, 19.1]	0.867
BMI								0.843
< 18.5 kg/m**2	5	3 (60.0) [14.7, 94.7]	7	3 (42.9) [9.9, 81.6]	1.400 [0.459, 4.271]	2.000 [0.194, 20.614]	17.1 [-56.5, 90.7]	1.000
18.5 - < 25.0 kg/m**2	117	65 (55.6) [46.1, 64.7]	119	68 (57.1) [47.7, 66.2]	0.972 [0.777, 1.217]	0.938 [0.560, 1.568]	-1.6 [-15.1, 11.9]	0.896
25.0 - < 30.0 kg/m**2	130	82 (63.1) [54.2, 71.4]	130	77 (59.2) [50.3, 67.8]	1.065 [0.877, 1.293]	1.176 [0.714, 1.937]	3.8 [-8.8, 16.5]	0.611
>= 30.0 kg/m**2	143	106 (74.1) [66.1, 81.1]	135	93 (68.9) [60.4, 76.6]	1.076 [0.927, 1.249]	1.294 [0.767, 2.181]	5.2 [-6.1, 16.6]	0.354
Baseline eosinophils - Low								0.775
< 150 cells/uL	96	63 (65.6) [55.2, 75.0]	89	54 (60.7) [49.7, 70.9]	1.082 [0.867, 1.349]	1.237 [0.680, 2.251]	5.0 [-10.0, 19.9]	0.543
>= 150 cells/uL	299	193 (64.5) [58.8, 70.0]	302	187 (61.9) [56.2, 67.4]	1.042 [0.923, 1.178]	1.120 [0.804, 1.560]	2.6 [-5.4, 10.7]	0.554
Baseline eosinophils - High								0.803
< 300 cells/uL	225	143 (63.6) [56.9, 69.8]	211	129 (61.1) [54.2, 67.8]	1.040 [0.898, 1.203]	1.109 [0.752, 1.634]	2.4 [-7.1, 12.0]	0.622
>= 300 cells/uL	170	113 (66.5) [58.8, 73.5]	180	112 (62.2) [54.7, 69.3]	1.068 [0.914, 1.249]	1.204 [0.776, 1.866]	4.2 [-6.3, 14.8]	0.436

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.173
< 25 ppb	158	96 (60.8) [52.7, 68.4]	151	96 (63.6) [55.4, 71.2]	0.956 [0.803, 1.137]	0.887 [0.560, 1.406]	-2.8 [-14.3, 8.6]	0.640
>= 25 ppb	234	158 (67.5) [61.1, 73.5]	236	143 (60.6) [54.0, 66.9]	1.114 [0.973, 1.277]	1.352 [0.926, 1.973]	6.9 [-2.2, 16.0]	0.125
Baseline specific perennial FEIA status								0.090
All negative	140	96 (68.6) [60.2, 76.1]	131	95 (72.5) [64.0, 80.0]	0.946 [0.811, 1.103]	0.827 [0.490, 1.396]	-3.9 [-15.5, 7.6]	0.507
Any positive	253	160 (63.2) [57.0, 69.2]	253	141 (55.7) [49.4, 62.0]	1.135 [0.982, 1.311]	1.367 [0.957, 1.951]	7.5 [-1.4, 16.4]	0.103
Total serum IgE								0.776
Low	116	82 (70.7) [61.5, 78.8]	125	88 (70.4) [61.6, 78.2]	1.004 [0.853, 1.182]	1.014 [0.583, 1.765]	0.3 [-12.1, 12.6]	1.000
Normal	247	155 (62.8) [56.4, 68.8]	220	129 (58.6) [51.8, 65.2]	1.070 [0.924, 1.239]	1.188 [0.819, 1.724]	4.1 [-5.2, 13.4]	0.393
High	32	19 (59.4) [40.6, 76.3]	46	24 (52.2) [36.9, 67.1]	1.138 [0.764, 1.695]	1.340 [0.538, 3.336]	7.2 [-17.8, 32.2]	0.645
OCS at baseline								0.157
Yes	47	38 (80.9) [66.7, 90.9]	42	37 (88.1) [74.4, 96.0]	0.918 [0.768, 1.097]	0.571 [0.175, 1.863]	-7.2 [-24.4, 9.9]	0.396
No	348	218 (62.6) [57.3, 67.7]	349	204 (58.5) [53.1, 63.7]	1.072 [0.950, 1.208]	1.192 [0.879, 1.616]	4.2 [-3.3, 11.7]	0.278

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.328
Yes	115	82 (71.3) [62.1, 79.4]	110	69 (62.7) [53.0, 71.8]	1.137 [0.945, 1.368]	1.477 [0.844, 2.583]	8.6 [-4.6, 21.7]	0.202
No	280	174 (62.1) [56.2, 67.8]	281	172 (61.2) [55.2, 66.9]	1.015 [0.891, 1.157]	1.040 [0.740, 1.462]	0.9 [-7.5, 9.3]	0.862
Tiotropium use at baseline								0.279
Yes	106	76 (71.7) [62.1, 80.0]	106	66 (62.3) [52.3, 71.5]	1.152 [0.952, 1.393]	1.535 [0.862, 2.734]	9.4 [-4.1, 23.0]	0.189
No	289	180 (62.3) [56.4, 67.9]	285	175 (61.4) [55.5, 67.1]	1.014 [0.892, 1.153]	1.038 [0.741, 1.454]	0.9 [-7.4, 9.2]	0.864
Montelukast/ Cromoglicic acid use at baseline								0.993
Yes	168	109 (64.9) [57.2, 72.1]	149	92 (61.7) [53.4, 69.6]	1.051 [0.888, 1.243]	1.145 [0.724, 1.809]	3.1 [-8.1, 14.4]	0.640
No	227	147 (64.8) [58.2, 71.0]	242	149 (61.6) [55.1, 67.7]	1.052 [0.916, 1.208]	1.147 [0.788, 1.670]	3.2 [-6.0, 12.3]	0.503

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_TLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.300
Male	135	84 (62.2) [53.5, 70.4]	136	75 (55.1) [46.4, 63.7]	1.128 [0.923, 1.379]	1.340 [0.825, 2.176]	7.1 [-5.4, 19.5]	0.267
Female	245	164 (66.9) [60.7, 72.8]	235	158 (67.2) [60.8, 73.2]	0.996 [0.878, 1.129]	0.987 [0.674, 1.444]	-0.3 [-9.1, 8.5]	1.000
Age								0.151
< 65 years	304	200 (65.8) [60.2, 71.1]	318	195 (61.3) [55.7, 66.7]	1.073 [0.952, 1.209]	1.213 [0.874, 1.683]	4.5 [-3.4, 12.3]	0.279
>= 65 years	76	48 (63.2) [51.3, 73.9]	53	38 (71.7) [57.7, 83.2]	0.881 [0.692, 1.121]	0.677 [0.317, 1.444]	-8.5 [-26.4, 9.3]	0.347
Exacerbations in the year before study								0.087
<= 2	204	127 (62.3) [55.2, 68.9]	214	118 (55.1) [48.2, 61.9]	1.129 [0.961, 1.327]	1.342 [0.908, 1.983]	7.1 [-2.8, 17.0]	0.164
> 2	176	121 (68.8) [61.3, 75.5]	157	115 (73.2) [65.6, 80.0]	0.939 [0.818, 1.077]	0.803 [0.499, 1.293]	-4.5 [-14.8, 5.8]	0.399
Race								0.319
White	239	155 (64.9) [58.4, 70.9]	235	154 (65.5) [59.1, 71.6]	0.990 [0.868, 1.129]	0.971 [0.665, 1.416]	-0.7 [-9.7, 8.3]	0.923
Black or African American	21	13 (61.9) [38.4, 81.9]	19	7 (36.8) [16.3, 61.6]	1.680 [0.853, 3.309]	2.786 [0.773, 10.043]	25.1 [-10.0, 60.1]	0.205
Asian	107	69 (64.5) [54.6, 73.5]	103	63 (61.2) [51.1, 70.6]	1.054 [0.856, 1.299]	1.153 [0.658, 2.019]	3.3 [-10.7, 17.3]	0.669
Other	13	11 (84.6) [54.6, 98.1]	14	9 (64.3) [35.1, 87.2]	1.316 [0.836, 2.073]	3.056 [0.475, 19.657]	20.3 [-18.9, 59.6]	0.385

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_TLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.807
Europe	64	46 (71.9) [59.2, 82.4]	60	39 (65.0) [51.6, 76.9]	1.106 [0.869, 1.407]	1.376 [0.643, 2.944]	6.9 [-11.1, 24.8]	0.444
America	140	92 (65.7) [57.2, 73.5]	134	83 (61.9) [53.2, 70.2]	1.061 [0.887, 1.269]	1.178 [0.719, 1.929]	3.8 [-8.3, 15.9]	0.532
Asia/Pacific	104	65 (62.5) [52.5, 71.8]	104	68 (65.4) [55.4, 74.4]	0.956 [0.779, 1.172]	0.882 [0.501, 1.555]	-2.9 [-16.9, 11.1]	0.773
Rest of the world	72	45 (62.5) [50.3, 73.6]	73	43 (58.9) [46.8, 70.3]	1.061 [0.816, 1.379]	1.163 [0.597, 2.266]	3.6 [-13.7, 20.9]	0.735
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	2 (66.7) [9.4, 99.2]	3	1 (33.3) [0.8, 90.6]				
18.5 - < 25.0 kg/m**2	109	60 (55.0) [45.2, 64.6]	108	64 (59.3) [49.4, 68.6]				
25.0 - < 30.0 kg/m**2	127	81 (63.8) [54.8, 72.1]	126	76 (60.3) [51.2, 68.9]				
>= 30.0 kg/m**2	141	105 (74.5) [66.4, 81.4]	134	92 (68.7) [60.1, 76.4]				
Baseline eosinophils - Low								0.761
< 150 cells/uL	95	62 (65.3) [54.8, 74.7]	87	53 (60.9) [49.9, 71.2]	1.071 [0.857, 1.339]	1.205 [0.659, 2.203]	4.3 [-10.8, 19.5]	0.645
>= 150 cells/uL	285	186 (65.3) [59.4, 70.8]	284	180 (63.4) [57.5, 69.0]	1.030 [0.911, 1.164]	1.086 [0.770, 1.530]	1.9 [-6.3, 10.1]	0.662
Baseline eosinophils - High								0.982
< 300 cells/uL	216	139 (64.4) [57.6, 70.7]	207	128 (61.8) [54.8, 68.5]	1.041 [0.899, 1.204]	1.114 [0.750, 1.654]	2.5 [-7.2, 12.2]	0.615
>= 300 cells/uL	164	109 (66.5) [58.7, 73.6]	164	105 (64.0) [56.2, 71.4]	1.038 [0.886, 1.216]	1.114 [0.707, 1.755]	2.4 [-8.5, 13.4]	0.728

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_TLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.226
< 25 ppb	155	96 (61.9) [53.8, 69.6]	145	94 (64.8) [56.5, 72.6]	0.955 [0.804, 1.135]	0.883 [0.552, 1.413]	-2.9 [-14.5, 8.7]	0.633
>= 25 ppb	222	150 (67.6) [61.0, 73.7]	222	137 (61.7) [55.0, 68.1]	1.095 [0.954, 1.257]	1.293 [0.875, 1.909]	5.9 [-3.5, 15.2]	0.234
Baseline specific perennial FEIA status								0.109
All negative	137	94 (68.6) [60.1, 76.3]	129	94 (72.9) [64.3, 80.3]	0.942 [0.807, 1.099]	0.814 [0.479, 1.383]	-4.3 [-15.9, 7.4]	0.501
Any positive	241	154 (63.9) [57.5, 70.0]	235	134 (57.0) [50.4, 63.4]	1.121 [0.968, 1.297]	1.334 [0.923, 1.929]	6.9 [-2.3, 16.1]	0.134
Total serum IgE								0.875
Low	115	82 (71.3) [62.1, 79.4]	121	85 (70.2) [61.3, 78.2]	1.015 [0.862, 1.196]	1.052 [0.600, 1.845]	1.1 [-11.4, 13.5]	0.887
Normal	235	148 (63.0) [56.5, 69.2]	212	128 (60.4) [53.5, 67.0]	1.043 [0.901, 1.208]	1.116 [0.762, 1.636]	2.6 [-6.9, 12.1]	0.626
High	30	18 (60.0) [40.6, 77.3]	38	20 (52.6) [35.8, 69.0]	1.140 [0.749, 1.735]	1.350 [0.512, 3.558]	7.4 [-19.3, 34.0]	0.626
OCS at baseline								0.178
Yes	46	37 (80.4) [66.1, 90.6]	42	37 (88.1) [74.4, 96.0]	0.913 [0.762, 1.094]	0.556 [0.170, 1.816]	-7.7 [-25.0, 9.7]	0.391
No	334	211 (63.2) [57.8, 68.4]	329	196 (59.6) [54.1, 64.9]	1.060 [0.940, 1.197]	1.164 [0.851, 1.592]	3.6 [-4.1, 11.3]	0.380

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_TLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.319
Yes	112	80 (71.4) [62.1, 79.6]	104	66 (63.5) [53.4, 72.7]	1.126 [0.934, 1.357]	1.439 [0.812, 2.551]	8.0 [-5.4, 21.4]	0.245
No	268	168 (62.7) [56.6, 68.5]	267	167 (62.5) [56.4, 68.4]	1.002 [0.879, 1.142]	1.006 [0.709, 1.428]	0.1 [-8.4, 8.7]	1.000
Tiotropium use at baseline								0.272
Yes	103	74 (71.8) [62.1, 80.3]	100	63 (63.0) [52.8, 72.4]	1.140 [0.940, 1.383]	1.499 [0.830, 2.706]	8.8 [-5.0, 22.7]	0.230
No	277	174 (62.8) [56.8, 68.5]	271	170 (62.7) [56.7, 68.5]	1.001 [0.880, 1.139]	1.004 [0.710, 1.419]	0.1 [-8.4, 8.5]	1.000
Montelukast/ Cromoglicic acid use at baseline								0.973
Yes	163	106 (65.0) [57.2, 72.3]	141	88 (62.4) [53.9, 70.4]	1.042 [0.879, 1.236]	1.120 [0.701, 1.790]	2.6 [-8.9, 14.1]	0.720
No	217	142 (65.4) [58.7, 71.7]	230	145 (63.0) [56.5, 69.3]	1.038 [0.904, 1.192]	1.110 [0.754, 1.635]	2.4 [-6.9, 11.7]	0.622

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_JLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	8	4 (50.0) [15.7, 84.3]	11	3 (27.3) [6.0, 61.0]				
Female	7	4 (57.1) [18.4, 90.1]	9	5 (55.6) [21.2, 86.3]				
Exacerbations in the year before study		n<10 all levels						NE
<= 2	7	3 (42.9) [9.9, 81.6]	12	4 (33.3) [9.9, 65.1]				
> 2	8	5 (62.5) [24.5, 91.5]	8	4 (50.0) [15.7, 84.3]				
Race		N<10 any level						NE
White	12	6 (50.0) [21.1, 78.9]	17	5 (29.4) [10.3, 56.0]				
Black or African American	0		2	2 (100.0) [15.8, 100.0]				
Asian	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Other	2	1 (50.0) [1.3, 98.7]	0					
Region		N<10 any level						NE
Europe	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
America	11	6 (54.5) [23.4, 83.3]	18	6 (33.3) [13.3, 59.0]				
Asia/Pacific	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Rest of the world	2	0 (0.0) [0.0, 84.2]	0					

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_JLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	4	2 (50.0) [6.8, 93.2]				
18.5 - < 25.0 kg/m**2	8	5 (62.5) [24.5, 91.5]	11	4 (36.4) [10.9, 69.2]				
25.0 - < 30.0 kg/m**2	3	1 (33.3) [0.8, 90.6]	4	1 (25.0) [0.6, 80.6]				
>= 30.0 kg/m**2	2	1 (50.0) [1.3, 98.7]	1	1 (100.0) [2.5, 100.0]				
Baseline eosinophils - Low		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
>= 150 cells/uL	14	7 (50.0) [23.0, 77.0]	18	7 (38.9) [17.3, 64.3]				
Baseline eosinophils - High								0.881
< 300 cells/uL	9	4 (44.4) [13.7, 78.8]	4	1 (25.0) [0.6, 80.6]	1.778 [0.280, 11.282]	2.400 [0.175, 32.879]	19.4 [-52.0, 90.9]	1.000
>= 300 cells/uL	6	4 (66.7) [22.3, 95.7]	16	7 (43.8) [19.8, 70.1]	1.524 [0.690, 3.368]	2.571 [0.361, 18.326]	22.9 [-33.4, 79.2]	0.635
Baseline FENO		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	6	2 (33.3) [4.3, 77.7]				
>= 25 ppb	12	8 (66.7) [34.9, 90.1]	14	6 (42.9) [17.7, 71.1]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_JLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status		N<10 any level						NE
All negative	3	2 (66.7) [9.4, 99.2]	2	1 (50.0) [1.3, 98.7]				
Any positive	12	6 (50.0) [21.1, 78.9]	18	7 (38.9) [17.3, 64.3]				
Total serum IgE		N<10 any level						NE
Low	1	0 (0.0) [0.0, 97.5]	4	3 (75.0) [19.4, 99.4]				
Normal	12	7 (58.3) [27.7, 84.8]	8	1 (12.5) [0.3, 52.7]				
High	2	1 (50.0) [1.3, 98.7]	8	4 (50.0) [15.7, 84.3]				
OCS at baseline		N<10 any level						NE
Yes	1	1 (100.0) [2.5, 100.0]	0					
No	14	7 (50.0) [23.0, 77.0]	20	8 (40.0) [19.1, 63.9]				
LAMA use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	6	3 (50.0) [11.8, 88.2]				
No	12	6 (50.0) [21.1, 78.9]	14	5 (35.7) [12.8, 64.9]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AA_JLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	6	3 (50.0) [11.8, 88.2]				
No	12	6 (50.0) [21.1, 78.9]	14	5 (35.7) [12.8, 64.9]				
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	5	3 (60.0) [14.7, 94.7]	8	4 (50.0) [15.7, 84.3]				
No	10	5 (50.0) [18.7, 81.3]	12	4 (33.3) [9.9, 65.1]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table PT3AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.087
Male	19	5 (26.3) [9.1, 51.2]	20	11 (55.0) [31.5, 76.9]	0.478 [0.204, 1.120]	0.292 [0.076, 1.126]	-28.7 [-63.3, 5.9]	0.105
Female	47	24 (51.1) [36.1, 65.9]	45	21 (46.7) [31.7, 62.1]	1.094 [0.719, 1.664]	1.193 [0.526, 2.704]	4.4 [-18.2, 27.0]	0.683
Age								0.651
< 65 years	57	25 (43.9) [30.7, 57.6]	55	26 (47.3) [33.7, 61.2]	0.928 [0.619, 1.391]	0.871 [0.414, 1.834]	-3.4 [-23.6, 16.8]	0.850
>= 65 years	9	4 (44.4) [13.7, 78.8]	10	6 (60.0) [26.2, 87.8]	0.741 [0.305, 1.801]	0.533 [0.086, 3.307]	-15.6 [-70.6, 39.5]	0.656
Exacerbations in the year before study								0.855
<= 2	44	15 (34.1) [20.5, 49.9]	45	18 (40.0) [25.7, 55.7]	0.852 [0.494, 1.470]	0.776 [0.327, 1.838]	-5.9 [-28.2, 16.4]	0.662
> 2	22	14 (63.6) [40.7, 82.8]	20	14 (70.0) [45.7, 88.1]	0.909 [0.593, 1.393]	0.750 [0.206, 2.730]	-6.4 [-39.6, 26.8]	0.750
Race		N<10 any level						NE
White	60	25 (41.7) [29.1, 55.1]	58	26 (44.8) [31.7, 58.5]				
Black or African American	2	2 (100.0) [15.8, 100.0]	2	2 (100.0) [15.8, 100.0]				
Asian	3	2 (66.7) [9.4, 99.2]	3	2 (66.7) [9.4, 99.2]				
Other	1	0 (0.0) [0.0, 97.5]	2	2 (100.0) [15.8, 100.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		N<10 any level						NE
Europe	40	18 (45.0) [29.3, 61.5]	36	16 (44.4) [27.9, 61.9]				
America	6	5 (83.3) [35.9, 99.6]	4	4 (100.0) [39.8, 100.0]				
Asia/Pacific	3	2 (66.7) [9.4, 99.2]	3	2 (66.7) [9.4, 99.2]				
Rest of the world	17	4 (23.5) [6.8, 49.9]	22	10 (45.5) [24.4, 67.8]				
BMI								0.415
18.5 - < 25.0 kg/m**2	15	7 (46.7) [21.3, 73.4]	21	9 (42.9) [21.8, 66.0]	1.089 [0.523, 2.265]	1.167 [0.308, 4.423]	3.8 [-34.8, 42.5]	1.000
25.0 - < 30.0 kg/m**2	24	7 (29.2) [12.6, 51.1]	20	10 (50.0) [27.2, 72.8]	0.583 [0.272, 1.250]	0.412 [0.119, 1.426]	-20.8 [-53.9, 12.2]	0.218
>= 30.0 kg/m**2	27	15 (55.6) [35.3, 74.5]	24	13 (54.2) [32.8, 74.4]	1.026 [0.623, 1.690]	1.058 [0.350, 3.193]	1.4 [-29.9, 32.7]	1.000
Baseline eosinophils - Low								0.615
< 150 cells/uL	12	8 (66.7) [34.9, 90.1]	14	9 (64.3) [35.1, 87.2]	1.037 [0.593, 1.814]	1.111 [0.219, 5.634]	2.4 [-42.0, 46.7]	1.000
>= 150 cells/uL	54	21 (38.9) [25.9, 53.1]	51	23 (45.1) [31.1, 59.7]	0.862 [0.549, 1.354]	0.775 [0.356, 1.685]	-6.2 [-27.0, 14.6]	0.557
Baseline eosinophils - High								0.445
< 300 cells/uL	34	14 (41.2) [24.6, 59.3]	34	18 (52.9) [35.1, 70.2]	0.778 [0.466, 1.297]	0.622 [0.238, 1.624]	-11.8 [-38.3, 14.7]	0.466
>= 300 cells/uL	32	15 (46.9) [29.1, 65.3]	31	14 (45.2) [27.3, 64.0]	1.038 [0.608, 1.773]	1.071 [0.398, 2.887]	1.7 [-26.1, 29.5]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.157
< 25 ppb	39	23 (59.0) [42.1, 74.4]	30	17 (56.7) [37.4, 74.5]	1.041 [0.692, 1.565]	1.099 [0.419, 2.881]	2.3 [-24.2, 28.8]	1.000
>= 25 ppb	27	6 (22.2) [8.6, 42.3]	34	14 (41.2) [24.6, 59.3]	0.540 [0.240, 1.216]	0.408 [0.131, 1.271]	-19.0 [-45.1, 7.2]	0.171
Baseline specific perennial FEIA status								0.857
All negative	27	13 (48.1) [28.7, 68.1]	29	15 (51.7) [32.5, 70.6]	0.931 [0.550, 1.575]	0.867 [0.304, 2.474]	-3.6 [-33.3, 26.2]	1.000
Any positive	34	13 (38.2) [22.2, 56.4]	34	15 (44.1) [27.2, 62.1]	0.867 [0.490, 1.533]	0.784 [0.298, 2.064]	-5.9 [-32.2, 20.4]	0.806
Total serum IgE								0.635
Low	23	14 (60.9) [38.5, 80.3]	14	8 (57.1) [28.9, 82.3]	1.065 [0.609, 1.864]	1.167 [0.303, 4.499]	3.7 [-34.7, 42.2]	1.000
Normal	40	14 (35.0) [20.6, 51.7]	44	20 (45.5) [30.4, 61.2]	0.770 [0.452, 1.311]	0.646 [0.268, 1.558]	-10.5 [-33.7, 12.8]	0.378
High	3	1 (33.3) [0.8, 90.6]	7	4 (57.1) [18.4, 90.1]	0.583 [0.104, 3.271]	0.375 [0.022, 6.348]	-23.8 [-100.0, 64.7]	1.000
OCS at baseline								0.569
Yes	9	4 (44.4) [13.7, 78.8]	13	5 (38.5) [13.9, 68.4]	1.156 [0.424, 3.151]	1.280 [0.228, 7.187]	6.0 [-45.3, 57.3]	1.000
No	57	25 (43.9) [30.7, 57.6]	52	27 (51.9) [37.6, 66.0]	0.845 [0.570, 1.252]	0.723 [0.340, 1.539]	-8.1 [-28.6, 12.5]	0.446

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.970
Yes	7	4 (57.1) [18.4, 90.1]	3	2 (66.7) [9.4, 99.2]	0.857 [0.307, 2.390]	0.667 [0.039, 11.285]	-9.5 [-98.1, 79.0]	1.000
No	59	25 (42.4) [29.6, 55.9]	62	30 (48.4) [35.5, 61.4]	0.876 [0.591, 1.298]	0.784 [0.383, 1.607]	-6.0 [-25.4, 13.4]	0.585
Tiotropium use at baseline	N<10 any level							NE
Yes	6	3 (50.0) [11.8, 88.2]	2	1 (50.0) [1.3, 98.7]				
No	60	26 (43.3) [30.6, 56.8]	63	31 (49.2) [36.4, 62.1]				
Montelukast/ Cromoglicic acid use at baseline								0.790
Yes	17	9 (52.9) [27.8, 77.0]	21	13 (61.9) [38.4, 81.9]	0.855 [0.489, 1.497]	0.692 [0.189, 2.533]	-9.0 [-45.8, 27.9]	0.743
No	49	20 (40.8) [27.0, 55.8]	44	19 (43.2) [28.3, 59.0]	0.945 [0.586, 1.525]	0.907 [0.398, 2.070]	-2.4 [-24.6, 19.9]	0.836

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.387
Male	25	11 (44.0) [24.4, 65.1]	31	20 (64.5) [45.4, 80.8]	0.682 [0.408, 1.140]	0.432 [0.147, 1.272]	-20.5 [-49.9, 8.8]	0.178
Female	48	25 (52.1) [37.2, 66.7]	45	26 (57.8) [42.2, 72.3]	0.901 [0.623, 1.303]	0.794 [0.350, 1.802]	-5.7 [-28.0, 16.7]	0.678
Age								0.998
< 65 years	58	29 (50.0) [36.6, 63.4]	62	38 (61.3) [48.1, 73.4]	0.816 [0.590, 1.129]	0.632 [0.306, 1.304]	-11.3 [-30.6, 8.1]	0.270
>= 65 years	15	7 (46.7) [21.3, 73.4]	14	8 (57.1) [28.9, 82.3]	0.817 [0.403, 1.655]	0.656 [0.151, 2.843]	-10.5 [-53.6, 32.6]	0.715
Exacerbations in the year before study								0.997
<= 2	60	30 (50.0) [36.8, 63.2]	55	34 (61.8) [47.7, 74.6]	0.809 [0.583, 1.122]	0.618 [0.294, 1.298]	-11.8 [-31.6, 7.9]	0.260
> 2	13	6 (46.2) [19.2, 74.9]	21	12 (57.1) [34.0, 78.2]	0.808 [0.403, 1.617]	0.643 [0.160, 2.585]	-11.0 [-51.6, 29.6]	0.725
Race		N<10 any level						NE
White	61	33 (54.1) [40.8, 66.9]	64	39 (60.9) [47.9, 72.9]				
Black or African American	1	0 (0.0) [0.0, 97.5]	0					
Asian	11	3 (27.3) [6.0, 61.0]	11	6 (54.5) [23.4, 83.3]				
Other	0		1	1 (100.0) [2.5, 100.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.646
Europe	27	15 (55.6) [35.3, 74.5]	32	20 (62.5) [43.7, 78.9]	0.889 [0.578, 1.368]	0.750 [0.264, 2.129]	-6.9 [-35.5, 21.6]	0.607
America	21	9 (42.9) [21.8, 66.0]	17	9 (52.9) [27.8, 77.0]	0.810 [0.416, 1.577]	0.667 [0.184, 2.412]	-10.1 [-47.2, 27.0]	0.745
Asia/Pacific	11	3 (27.3) [6.0, 61.0]	10	6 (60.0) [26.2, 87.8]	0.455 [0.153, 1.351]	0.250 [0.040, 1.564]	-32.7 [-82.5, 17.0]	0.198
Rest of the world	14	9 (64.3) [35.1, 87.2]	17	11 (64.7) [38.3, 85.8]	0.994 [0.588, 1.680]	0.982 [0.224, 4.305]	-0.4 [-40.8, 39.9]	1.000
BMI								0.140
18.5 - < 25.0 kg/m**2	20	10 (50.0) [27.2, 72.8]	23	17 (73.9) [51.6, 89.8]	0.676 [0.410, 1.116]	0.353 [0.098, 1.267]	-23.9 [-56.9, 9.1]	0.127
25.0 - < 30.0 kg/m**2	22	5 (22.7) [7.8, 45.4]	24	11 (45.8) [25.6, 67.2]	0.496 [0.205, 1.201]	0.348 [0.097, 1.250]	-23.1 [-54.0, 7.8]	0.129
>= 30.0 kg/m**2	31	21 (67.7) [48.6, 83.3]	29	18 (62.1) [42.3, 79.3]	1.091 [0.751, 1.587]	1.283 [0.443, 3.715]	5.7 [-21.8, 33.1]	0.788
Baseline eosinophils - Low								0.487
< 150 cells/uL	27	11 (40.7) [22.4, 61.2]	24	14 (58.3) [36.6, 77.9]	0.698 [0.396, 1.231]	0.491 [0.161, 1.501]	-17.6 [-48.6, 13.4]	0.267
>= 150 cells/uL	46	25 (54.3) [39.0, 69.1]	52	32 (61.5) [47.0, 74.7]	0.883 [0.628, 1.242]	0.744 [0.333, 1.665]	-7.2 [-28.8, 14.4]	0.540
Baseline eosinophils - High								0.810
< 300 cells/uL	46	20 (43.5) [28.9, 58.9]	52	29 (55.8) [41.3, 69.5]	0.780 [0.518, 1.173]	0.610 [0.274, 1.357]	-12.3 [-34.0, 9.4]	0.312
>= 300 cells/uL	27	16 (59.3) [38.8, 77.6]	24	17 (70.8) [48.9, 87.4]	0.837 [0.558, 1.254]	0.599 [0.186, 1.926]	-11.6 [-41.5, 18.3]	0.558

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.768
< 25 ppb	31	17 (54.8) [36.0, 72.7]	26	17 (65.4) [44.3, 82.8]	0.839 [0.549, 1.282]	0.643 [0.220, 1.881]	-10.5 [-39.4, 18.3]	0.588
>= 25 ppb	36	16 (44.4) [27.9, 61.9]	43	25 (58.1) [42.1, 73.0]	0.764 [0.490, 1.192]	0.576 [0.236, 1.408]	-13.7 [-38.2, 10.8]	0.263
Baseline specific perennial FEIA status								0.340
All negative	43	24 (55.8) [39.9, 70.9]	39	24 (61.5) [44.6, 76.6]	0.907 [0.630, 1.305]	0.789 [0.327, 1.908]	-5.7 [-29.5, 18.0]	0.657
Any positive	25	9 (36.0) [18.0, 57.5]	34	19 (55.9) [37.9, 72.8]	0.644 [0.353, 1.176]	0.444 [0.154, 1.283]	-19.9 [-48.5, 8.7]	0.188
Total serum IgE		N<10 any level						NE
Low	30	17 (56.7) [37.4, 74.5]	31	17 (54.8) [36.0, 72.7]				
Normal	39	17 (43.6) [27.8, 60.4]	43	28 (65.1) [49.1, 79.0]				
High	3	1 (33.3) [0.8, 90.6]	2	1 (50.0) [1.3, 98.7]				
LAMA use at baseline								0.151
Yes	34	15 (44.1) [27.2, 62.1]	40	27 (67.5) [50.9, 81.4]	0.654 [0.423, 1.010]	0.380 [0.148, 0.980]	-23.4 [-48.2, 1.5]	0.060
No	39	21 (53.8) [37.2, 69.9]	36	19 (52.8) [35.5, 69.6]	1.020 [0.668, 1.559]	1.044 [0.421, 2.588]	1.1 [-24.2, 26.3]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline								0.151
Yes	34	15 (44.1) [27.2, 62.1]	40	27 (67.5) [50.9, 81.4]	0.654 [0.423, 1.010]	0.380 [0.148, 0.980]	-23.4 [-48.2, 1.5]	0.060
No	39	21 (53.8) [37.2, 69.9]	36	19 (52.8) [35.5, 69.6]	1.020 [0.668, 1.559]	1.044 [0.421, 2.588]	1.1 [-24.2, 26.3]	1.000
Montelukast/ Cromoglicic acid use at baseline								0.849
Yes	30	15 (50.0) [31.3, 68.7]	37	22 (59.5) [42.1, 75.2]	0.841 [0.538, 1.313]	0.682 [0.258, 1.800]	-9.5 [-36.4, 17.4]	0.469
No	43	21 (48.8) [33.3, 64.5]	39	24 (61.5) [44.6, 76.6]	0.794 [0.535, 1.177]	0.597 [0.248, 1.438]	-12.7 [-36.5, 11.1]	0.274

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table DT1AA_ULSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Sex								0.024	i
Male	115	89 (77.4) [68.7, 84.7]	56	35 (62.5) [48.5, 75.1]	1.238 [0.988, 1.552]	2.054 [1.025, 4.117]	14.9 [-1.2, 31.0]	0.046	*
Female	195	151 (77.4) [70.9, 83.1]	93	78 (83.9) [74.8, 90.7]	0.923 [0.821, 1.038]	0.660 [0.346, 1.260]	-6.4 [-16.7, 3.9]	0.217	
Age								0.581	
< 65 years	250	193 (77.2) [71.5, 82.3]	127	95 (74.8) [66.3, 82.1]	1.032 [0.914, 1.165]	1.141 [0.693, 1.876]	2.4 [-7.4, 12.2]	0.610	
>= 65 years	60	47 (78.3) [65.8, 87.9]	22	18 (81.8) [59.7, 94.8]	0.957 [0.755, 1.214]	0.803 [0.231, 2.791]	-3.5 [-25.8, 18.8]	1.000	
Exacerbations in the year before study								0.668	
<= 2	173	133 (76.9) [69.9, 82.9]	88	65 (73.9) [63.4, 82.7]	1.041 [0.897, 1.208]	1.177 [0.651, 2.128]	3.0 [-9.0, 15.0]	0.647	
> 2	137	107 (78.1) [70.2, 84.7]	61	48 (78.7) [66.3, 88.1]	0.993 [0.848, 1.162]	0.966 [0.463, 2.013]	-0.6 [-14.2, 13.0]	1.000	
Race								0.400	
White	226	178 (78.8) [72.8, 83.9]	99	74 (74.7) [65.0, 82.9]	1.054 [0.922, 1.204]	1.253 [0.720, 2.181]	4.0 [-6.8, 14.8]	0.471	
Black or African American	16	11 (68.8) [41.3, 89.0]	14	11 (78.6) [49.2, 95.3]	0.875 [0.570, 1.344]	0.600 [0.114, 3.148]	-9.8 [-47.8, 28.1]	0.689	
Asian	56	41 (73.2) [59.7, 84.2]	30	22 (73.3) [54.1, 87.7]	0.998 [0.764, 1.305]	0.994 [0.365, 2.708]	-0.1 [-22.3, 22.1]	1.000	
Other	12	10 (83.3) [51.6, 97.9]	6	6 (100.0) [54.1, 100.0]	0.833 [0.647, 1.073]	0.323 + [0.013, 7.847]	-16.7 [-50.3, 16.9]	0.529	

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_ULSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.421
Europe	53	44 (83.0) [70.2, 91.9]	24	16 (66.7) [44.7, 84.4]	1.245 [0.915, 1.694]	2.444 [0.805, 7.425]	16.4 [-8.1, 40.8]	0.141
America	133	102 (76.7) [68.6, 83.6]	62	46 (74.2) [61.5, 84.5]	1.034 [0.868, 1.230]	1.144 [0.570, 2.297]	2.5 [-11.7, 16.7]	0.722
Asia/Pacific	52	38 (73.1) [59.0, 84.4]	26	20 (76.9) [56.4, 91.0]	0.950 [0.727, 1.241]	0.814 [0.271, 2.444]	-3.8 [-26.9, 19.2]	0.789
Rest of the world	72	56 (77.8) [66.4, 86.7]	37	31 (83.8) [68.0, 93.8]	0.928 [0.769, 1.120]	0.677 [0.240, 1.909]	-6.0 [-23.3, 11.3]	0.616
BMI		N<10 any level						NE
< 18.5 kg/m**2	4	2 (50.0) [6.8, 93.2]	2	1 (50.0) [1.3, 98.7]				
18.5 - < 25.0 kg/m**2	83	60 (72.3) [61.4, 81.6]	45	30 (66.7) [51.0, 80.0]				
25.0 - < 30.0 kg/m**2	104	78 (75.0) [65.6, 83.0]	48	37 (77.1) [62.7, 88.0]				
>= 30.0 kg/m**2	119	100 (84.0) [76.2, 90.1]	54	45 (83.3) [70.7, 92.1]				
Baseline eosinophils - Low								0.552
< 150 cells/uL	74	56 (75.7) [64.3, 84.9]	36	25 (69.4) [51.9, 83.7]	1.090 [0.847, 1.402]	1.369 [0.564, 3.320]	6.2 [-13.8, 26.2]	0.497
>= 150 cells/uL	236	184 (78.0) [72.1, 83.1]	113	88 (77.9) [69.1, 85.1]	1.001 [0.888, 1.128]	1.005 [0.586, 1.726]	0.1 [-9.9, 10.0]	1.000
Baseline eosinophils - High								0.117
< 300 cells/uL	180	137 (76.1) [69.2, 82.1]	83	57 (68.7) [57.6, 78.4]	1.108 [0.938, 1.309]	1.453 [0.816, 2.587]	7.4 [-5.2, 20.1]	0.228
>= 300 cells/uL	130	103 (79.2) [71.2, 85.8]	66	56 (84.8) [73.9, 92.5]	0.934 [0.816, 1.068]	0.681 [0.308, 1.509]	-5.6 [-17.9, 6.6]	0.440

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_ULSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.313
< 25 ppb	127	92 (72.4) [63.8, 80.0]	64	49 (76.6) [64.3, 86.2]	0.946 [0.796, 1.125]	0.805 [0.401, 1.616]	-4.1 [-18.3, 10.0]	0.603
>= 25 ppb	180	145 (80.6) [74.0, 86.1]	83	63 (75.9) [65.3, 84.6]	1.061 [0.922, 1.222]	1.315 [0.705, 2.454]	4.7 [-7.1, 16.4]	0.417
Baseline specific perennial FEIA status								0.974
All negative	116	96 (82.8) [74.6, 89.1]	53	43 (81.1) [68.0, 90.6]	1.020 [0.874, 1.190]	1.116 [0.482, 2.586]	1.6 [-12.3, 15.6]	0.830
Any positive	193	144 (74.6) [67.9, 80.6]	94	69 (73.4) [63.3, 82.0]	1.016 [0.878, 1.177]	1.065 [0.608, 1.865]	1.2 [-10.4, 12.8]	0.886
Total serum IgE								0.609
Low	93	74 (79.6) [69.9, 87.2]	49	41 (83.7) [70.3, 92.7]	0.951 [0.810, 1.117]	0.760 [0.306, 1.888]	-4.1 [-18.9, 10.7]	0.656
Normal	193	148 (76.7) [70.1, 82.5]	81	59 (72.8) [61.8, 82.1]	1.053 [0.902, 1.228]	1.226 [0.678, 2.218]	3.8 [-8.4, 16.1]	0.539
High	24	18 (75.0) [53.3, 90.2]	19	13 (68.4) [43.4, 87.4]	1.096 [0.747, 1.608]	1.385 [0.363, 5.276]	6.6 [-25.3, 38.4]	0.738
OCS at baseline								0.050
Yes	28	24 (85.7) [67.3, 96.0]	12	12 (100.0) [73.5, 100.0]	0.857 [0.737, 0.997]	0.218 + [0.011, 4.375]	-14.3 [-33.2, 4.6]	0.297
No	282	216 (76.6) [71.2, 81.4]	137	101 (73.7) [65.5, 80.9]	1.039 [0.922, 1.170]	1.167 [0.729, 1.866]	2.9 [-6.5, 12.3]	0.545

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_ULSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.351
Yes	83	68 (81.9) [72.0, 89.5]	42	31 (73.8) [58.0, 86.1]	1.110 [0.903, 1.365]	1.609 [0.663, 3.903]	8.1 [-9.3, 25.6]	0.352
No	227	172 (75.8) [69.7, 81.2]	107	82 (76.6) [67.5, 84.3]	0.989 [0.870, 1.124]	0.953 [0.555, 1.638]	-0.9 [-11.3, 9.6]	0.892
Tiotropium use at baseline								0.495
Yes	76	62 (81.6) [71.0, 89.5]	40	30 (75.0) [58.8, 87.3]	1.088 [0.883, 1.340]	1.476 [0.588, 3.709]	6.6 [-11.3, 24.5]	0.472
No	234	178 (76.1) [70.1, 81.4]	109	83 (76.1) [67.0, 83.8]	0.999 [0.880, 1.135]	0.996 [0.584, 1.697]	-0.1 [-10.4, 10.3]	1.000
Montelukast/ Cromoglicic acid use at baseline								0.131
Yes	123	95 (77.2) [68.8, 84.3]	55	46 (83.6) [71.2, 92.2]	0.923 [0.794, 1.074]	0.664 [0.290, 1.521]	-6.4 [-20.0, 7.2]	0.425
No	187	145 (77.5) [70.9, 83.3]	94	67 (71.3) [61.0, 80.1]	1.088 [0.937, 1.264]	1.391 [0.792, 2.444]	6.3 [-5.5, 18.0]	0.304

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table CT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.433
Male	13	8 (61.5) [31.6, 86.1]	17	14 (82.4) [56.6, 96.2]	0.747 [0.461, 1.211]	0.343 [0.064, 1.829]	-20.8 [-59.7, 18.0]	0.242
Female	18	14 (77.8) [52.4, 93.6]	17	14 (82.4) [56.6, 96.2]	0.944 [0.678, 1.315]	0.750 [0.141, 3.985]	-4.6 [-36.7, 27.5]	1.000
Age								0.908
< 65 years	25	17 (68.0) [46.5, 85.1]	29	23 (79.3) [60.3, 92.0]	0.857 [0.618, 1.189]	0.554 [0.162, 1.897]	-11.3 [-38.5, 15.9]	0.371
>= 65 years	6	5 (83.3) [35.9, 99.6]	5	5 (100.0) [47.8, 100.0]	0.833 [0.583, 1.192]	0.333 + [0.011, 10.107]	-16.7 [-64.8, 31.5]	1.000
Exacerbations in the year before study		N<10 any level						NE
<= 2	31	22 (71.0) [52.0, 85.8]	31	25 (80.6) [62.5, 92.5]				
> 2	0		3	3 (100.0) [29.2, 100.0]				
Race		N<10 any level						NE
White	28	21 (75.0) [55.1, 89.3]	32	26 (81.3) [63.6, 92.8]				
Black or African American	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Asian	1	0 (0.0) [0.0, 97.5]	1	1 (100.0) [2.5, 100.0]				
Other	1	0 (0.0) [0.0, 97.5]	0					

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Region								0.408	
Europe	22	15 (68.2) [45.1, 86.1]	21	18 (85.7) [63.7, 97.0]	0.795 [0.569, 1.112]	0.357 [0.078, 1.627]	-17.5 [-46.7, 11.7]	0.281	
America	9	7 (77.8) [40.0, 97.2]	13	10 (76.9) [46.2, 95.0]	1.011 [0.639, 1.600]	1.050 [0.137, 8.021]	0.9 [-44.1, 45.8]	1.000	
BMI								0.623	
18.5 - < 25.0 kg/m**2	6	3 (50.0) [11.8, 88.2]	10	8 (80.0) [44.4, 97.5]	0.625 [0.265, 1.474]	0.250 [0.027, 2.319]	-30.0 [-90.4, 30.4]	0.299	
25.0 - < 30.0 kg/m**2	13	10 (76.9) [46.2, 95.0]	14	11 (78.6) [49.2, 95.3]	0.979 [0.653, 1.467]	0.909 [0.148, 5.583]	-1.6 [-40.5, 37.2]	1.000	
>= 30.0 kg/m**2	12	9 (75.0) [42.8, 94.5]	10	9 (90.0) [55.5, 99.7]	0.833 [0.566, 1.227]	0.333 [0.029, 3.842]	-15.0 [-54.9, 24.9]	0.594	
Baseline eosinophils - Low								0.010	i
< 150 cells/uL	8	8 (100.0) [63.1, 100.0]	11	8 (72.7) [39.0, 94.0]	1.375 [0.958, 1.975]	7.000 + [0.312, 157.257]	27.3 [-9.8, 64.4]	0.228	
>= 150 cells/uL	23	14 (60.9) [38.5, 80.3]	23	20 (87.0) [66.4, 97.2]	0.700 [0.486, 1.007]	0.233 [0.053, 1.019]	-26.1 [-54.7, 2.5]	0.091	
Baseline eosinophils - High								0.321	
< 300 cells/uL	20	14 (70.0) [45.7, 88.1]	23	17 (73.9) [51.6, 89.8]	0.947 [0.650, 1.379]	0.824 [0.217, 3.128]	-3.9 [-35.5, 27.7]	1.000	
>= 300 cells/uL	11	8 (72.7) [39.0, 94.0]	11	11 (100.0) [71.5, 100.0]	0.727 [0.506, 1.044]	0.106 + [0.005, 2.327]	-27.3 [-62.7, 8.1]	0.214	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.173
< 25 ppb	14	11 (78.6) [49.2, 95.3]	25	20 (80.0) [59.3, 93.2]	0.982 [0.701, 1.375]	0.917 [0.183, 4.583]	-1.4 [-33.6, 30.7]	1.000
>= 25 ppb	14	8 (57.1) [28.9, 82.3]	9	8 (88.9) [51.8, 99.7]	0.643 [0.386, 1.070]	0.167 [0.016, 1.718]	-31.7 [-73.9, 10.4]	0.176
Baseline specific perennial FEIA status								0.995
All negative	16	12 (75.0) [47.6, 92.7]	10	9 (90.0) [55.5, 99.7]	0.833 [0.587, 1.183]	0.333 [0.032, 3.515]	-15.0 [-51.3, 21.3]	0.617
Any positive	14	9 (64.3) [35.1, 87.2]	22	17 (77.3) [54.6, 92.2]	0.832 [0.530, 1.307]	0.529 [0.121, 2.325]	-13.0 [-49.4, 23.5]	0.462
Total serum IgE								0.835
Low	14	11 (78.6) [49.2, 95.3]	12	11 (91.7) [61.5, 99.8]	0.857 [0.621, 1.183]	0.333 [0.030, 3.721]	-13.1 [-47.4, 21.2]	0.598
Normal	16	10 (62.5) [35.4, 84.8]	22	17 (77.3) [54.6, 92.2]	0.809 [0.520, 1.258]	0.490 [0.118, 2.030]	-14.8 [-49.7, 20.1]	0.471
OCS at baseline		N<10 any level						NE
Yes	2	1 (50.0) [1.3, 98.7]	3	3 (100.0) [29.2, 100.0]				
No	29	21 (72.4) [52.8, 87.3]	31	25 (80.6) [62.5, 92.5]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AA_SLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.145
Yes	4	4 (100.0) [39.8, 100.0]	9	8 (88.9) [51.8, 99.7]	1.125 [0.893, 1.417]	1.588 + [0.053, 47.516]	11.1 [-27.5, 49.7]	1.000
No	27	18 (66.7) [46.0, 83.5]	25	20 (80.0) [59.3, 93.2]	0.833 [0.599, 1.160]	0.500 [0.141, 1.772]	-13.3 [-40.9, 14.2]	0.355
Tiotropium use at baseline								0.127
Yes	4	4 (100.0) [39.8, 100.0]	8	7 (87.5) [47.3, 99.7]	1.143 [0.880, 1.485]	1.800 + [0.060, 54.331]	12.5 [-29.2, 54.2]	1.000
No	27	18 (66.7) [46.0, 83.5]	26	21 (80.8) [60.6, 93.4]	0.825 [0.596, 1.144]	0.476 [0.135, 1.681]	-14.1 [-41.2, 13.0]	0.352
Montelukast/ Cromoglicic acid use at baseline								0.908
Yes	6	5 (83.3) [35.9, 99.6]	5	5 (100.0) [47.8, 100.0]	0.833 [0.583, 1.192]	0.333 + [0.011, 10.107]	-16.7 [-64.8, 31.5]	1.000
No	25	17 (68.0) [46.5, 85.1]	29	23 (79.3) [60.3, 92.0]	0.857 [0.618, 1.189]	0.554 [0.162, 1.897]	-11.3 [-38.5, 15.9]	0.371

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table NT1AA_SLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.935
Western Europe	72	52 (72.2) [60.4, 82.1]	72	50 (69.4) [57.5, 79.8]	1.040 [0.843, 1.283]	1.144 [0.557, 2.349]	2.8 [-13.5, 19.0]	0.855
North America	77	51 (66.2) [54.6, 76.6]	77	49 (63.6) [51.9, 74.3]	1.041 [0.825, 1.313]	1.121 [0.578, 2.174]	2.6 [-13.8, 19.0]	0.866
South America	74	47 (63.5) [51.5, 74.4]	75	40 (53.3) [41.4, 64.9]	1.191 [0.906, 1.565]	1.523 [0.791, 2.934]	10.2 [-6.9, 27.3]	0.246
Central/Eastern Europe	20	15 (75.0) [50.9, 91.3]	18	14 (77.8) [52.4, 93.6]	0.964 [0.677, 1.373]	0.857 [0.191, 3.853]	-2.8 [-35.1, 29.5]	1.000
Asia Pacific	98	61 (62.2) [51.9, 71.8]	94	59 (62.8) [52.2, 72.5]	0.992 [0.797, 1.235]	0.978 [0.545, 1.755]	-0.5 [-15.3, 14.2]	1.000
Rest of the world	54	30 (55.6) [41.4, 69.1]	55	29 (52.7) [38.8, 66.3]	1.054 [0.746, 1.489]	1.121 [0.527, 2.382]	2.8 [-17.7, 23.4]	0.848
Baseline eosinophils (cat. N)								0.445
< 150 cells/uL	96	63 (65.6) [55.2, 75.0]	89	54 (60.7) [49.7, 70.9]	1.082 [0.867, 1.349]	1.237 [0.680, 2.251]	5.0 [-10.0, 19.9]	0.543
150 - < 300 cells/uL	129	80 (62.0) [53.1, 70.4]	122	75 (61.5) [52.2, 70.1]	1.009 [0.830, 1.226]	1.023 [0.615, 1.703]	0.5 [-12.3, 13.4]	1.000
300 - < 450 cells/uL	70	43 (61.4) [49.0, 72.8]	75	50 (66.7) [54.8, 77.1]	0.921 [0.721, 1.177]	0.796 [0.404, 1.571]	-5.2 [-22.2, 11.8]	0.604
>= 450 cells/uL	100	70 (70.0) [60.0, 78.8]	105	62 (59.0) [49.0, 68.5]	1.185 [0.966, 1.455]	1.618 [0.908, 2.885]	11.0 [-3.0, 24.9]	0.111
Baseline eosinophils (cat. Q)								0.192
Q1: < 140 cells/uL	89	57 (64.0) [53.2, 73.9]	81	47 (58.0) [46.5, 68.9]	1.104 [0.867, 1.406]	1.289 [0.694, 2.391]	6.0 [-9.8, 21.9]	0.435
Q2: 140 - < 250 cells/uL	99	65 (65.7) [55.4, 74.9]	94	57 (60.6) [50.0, 70.6]	1.083 [0.872, 1.344]	1.241 [0.691, 2.230]	5.0 [-9.6, 19.7]	0.551
Q3: 250 - < 430 cells/uL	103	61 (59.2) [49.1, 68.8]	103	70 (68.0) [58.0, 76.8]	0.871 [0.708, 1.073]	0.685 [0.387, 1.212]	-8.7 [-22.8, 5.3]	0.247
Q4: >= 430 cells/uL	104	73 (70.2) [60.4, 78.8]	113	67 (59.3) [49.6, 68.4]	1.184 [0.972, 1.442]	1.617 [0.920, 2.840]	10.9 [-2.6, 24.4]	0.118

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_SLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.236
< 25 ppb	158	96 (60.8) [52.7, 68.4]	151	96 (63.6) [55.4, 71.2]	0.956 [0.803, 1.137]	0.887 [0.560, 1.406]	-2.8 [-14.3, 8.6]	0.640
25 - < 50 ppb	114	80 (70.2) [60.9, 78.4]	116	68 (58.6) [49.1, 67.7]	1.197 [0.986, 1.454]	1.661 [0.963, 2.866]	11.6 [-1.6, 24.7]	0.075
>= 50 ppb	120	78 (65.0) [55.8, 73.5]	120	75 (62.5) [53.2, 71.2]	1.040 [0.859, 1.259]	1.114 [0.658, 1.887]	2.5 [-10.5, 15.5]	0.788

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_SLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline FENO (cat. Q)								0.059	
Q1: < 16 ppb	94	54 (57.4) [46.8, 67.6]	85	59 (69.4) [58.5, 79.0]	0.828 [0.662, 1.035]	0.595 [0.321, 1.102]	-12.0 [-27.1, 3.1]	0.121	
Q2: 16 - < 30 ppb	88	59 (67.0) [56.2, 76.7]	99	51 (51.5) [41.3, 61.7]	1.301 [1.023, 1.656]	1.915 [1.057, 3.468]	15.5 [0.6, 30.5]	0.037	*
Q3: 30 - < 56 ppb	106	75 (70.8) [61.1, 79.2]	96	66 (68.8) [58.5, 77.8]	1.029 [0.858, 1.235]	1.100 [0.603, 2.006]	2.0 [-11.7, 15.7]	0.762	
Q4: >= 56 ppb	104	66 (63.5) [53.4, 72.7]	107	63 (58.9) [49.0, 68.3]	1.078 [0.869, 1.337]	1.213 [0.697, 2.112]	4.6 [-9.5, 18.7]	0.572	
Total serum IgE (cat. N)								0.843	
Q1: < 53.1 IU/ml	94	70 (74.5) [64.4, 82.9]	99	70 (70.7) [60.7, 79.4]	1.053 [0.885, 1.253]	1.208 [0.641, 2.278]	3.8 [-9.8, 17.4]	0.629	
Q2: 53.1 - < 195.6 IU/ml	101	61 (60.4) [50.2, 70.0]	101	63 (62.4) [52.2, 71.8]	0.968 [0.778, 1.205]	0.920 [0.522, 1.621]	-2.0 [-16.4, 12.4]	0.885	
Q3: 195.6 - < 572.4 IU/ml	108	70 (64.8) [55.0, 73.8]	87	51 (58.6) [47.6, 69.1]	1.106 [0.883, 1.384]	1.300 [0.727, 2.326]	6.2 [-8.6, 21.0]	0.458	
Q4: >= 572.4 IU/ml	92	55 (59.8) [49.0, 69.9]	104	57 (54.8) [44.7, 64.6]	1.091 [0.856, 1.389]	1.226 [0.694, 2.163]	5.0 [-9.9, 19.9]	0.563	
Nasal polyps last 2 years								0.722	
Yes	33	21 (63.6) [45.1, 79.6]	31	20 (64.5) [45.4, 80.8]	0.986 [0.683, 1.424]	0.963 [0.346, 2.674]	-0.9 [-27.5, 25.8]	1.000	
No	362	235 (64.9) [59.8, 69.8]	360	221 (61.4) [56.1, 66.4]	1.057 [0.946, 1.182]	1.164 [0.860, 1.575]	3.5 [-3.8, 10.8]	0.355	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_TLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.996
Western Europe	71	51 (71.8) [59.9, 81.9]	71	49 (69.0) [56.9, 79.5]	1.041 [0.841, 1.288]	1.145 [0.557, 2.355]	2.8 [-13.6, 19.2]	0.854
North America	75	50 (66.7) [54.8, 77.1]	71	46 (64.8) [52.5, 75.8]	1.029 [0.814, 1.301]	1.087 [0.549, 2.154]	1.9 [-14.9, 18.7]	0.862
South America	65	42 (64.6) [51.8, 76.1]	63	37 (58.7) [45.6, 71.0]	1.100 [0.836, 1.447]	1.283 [0.628, 2.621]	5.9 [-12.5, 24.3]	0.586
Central/Eastern Europe	19	15 (78.9) [54.4, 93.9]	18	14 (77.8) [52.4, 93.6]	1.015 [0.723, 1.425]	1.071 [0.224, 5.128]	1.2 [-30.8, 33.1]	1.000
Asia Pacific	97	60 (61.9) [51.4, 71.5]	93	58 (62.4) [51.7, 72.2]	0.992 [0.794, 1.239]	0.979 [0.544, 1.759]	-0.5 [-15.4, 14.3]	1.000
Rest of the world	53	30 (56.6) [42.3, 70.2]	55	29 (52.7) [38.8, 66.3]	1.074 [0.761, 1.514]	1.169 [0.548, 2.497]	3.9 [-16.7, 24.5]	0.704
Baseline eosinophils (cat. N)								0.773
< 150 cells/uL	95	62 (65.3) [54.8, 74.7]	87	53 (60.9) [49.9, 71.2]	1.071 [0.857, 1.339]	1.205 [0.659, 2.203]	4.3 [-10.8, 19.5]	0.645
150 - < 300 cells/uL	121	77 (63.6) [54.4, 72.2]	120	75 (62.5) [53.2, 71.2]	1.018 [0.839, 1.235]	1.050 [0.622, 1.772]	1.1 [-11.9, 14.2]	0.894
300 - < 450 cells/uL	70	43 (61.4) [49.0, 72.8]	69	45 (65.2) [52.8, 76.3]	0.942 [0.731, 1.213]	0.849 [0.426, 1.695]	-3.8 [-21.2, 13.7]	0.726
>= 450 cells/uL	94	66 (70.2) [59.9, 79.2]	95	60 (63.2) [52.6, 72.8]	1.112 [0.908, 1.361]	1.375 [0.749, 2.525]	7.1 [-7.4, 21.5]	0.355
Baseline eosinophils (cat. Q)								0.326
Q1: < 140 cells/uL	89	57 (64.0) [53.2, 73.9]	79	46 (58.2) [46.6, 69.2]	1.100 [0.863, 1.403]	1.278 [0.686, 2.381]	5.8 [-10.1, 21.8]	0.526
Q2: 140 - < 250 cells/uL	93	63 (67.7) [57.3, 77.1]	92	57 (62.0) [51.2, 71.9]	1.093 [0.884, 1.353]	1.289 [0.704, 2.362]	5.8 [-9.0, 20.6]	0.444
Q3: 250 - < 430 cells/uL	100	59 (59.0) [48.7, 68.7]	98	66 (67.3) [57.1, 76.5]	0.876 [0.707, 1.085]	0.698 [0.390, 1.247]	-8.3 [-22.7, 6.0]	0.241
Q4: >= 430 cells/uL	98	69 (70.4) [60.3, 79.2]	102	64 (62.7) [52.6, 72.1]	1.122 [0.921, 1.367]	1.413 [0.782, 2.551]	7.7 [-6.4, 21.7]	0.295

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_TLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo					
Non-disease related TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.338
< 25 ppb	155	96 (61.9) [53.8, 69.6]	145	94 (64.8) [56.5, 72.6]	0.955 [0.804, 1.135]	0.883 [0.552, 1.413]	-2.9 [-14.5, 8.7]	0.633
25 - < 50 ppb	111	77 (69.4) [59.9, 77.8]	109	65 (59.6) [49.8, 68.9]	1.163 [0.954, 1.418]	1.533 [0.879, 2.673]	9.7 [-3.8, 23.2]	0.159
>= 50 ppb	111	73 (65.8) [56.2, 74.5]	113	72 (63.7) [54.1, 72.6]	1.032 [0.851, 1.252]	1.094 [0.632, 1.893]	2.0 [-11.4, 15.5]	0.781

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_TLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo						
Non-disease related TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline FENO (cat. Q)								0.035	i
Q1: < 16 ppb	93	54 (58.1) [47.4, 68.2]	81	58 (71.6) [60.5, 81.1]	0.811 [0.650, 1.011]	0.549 [0.291, 1.036]	-13.5 [-28.7, 1.7]	0.081	
Q2: 16 - < 30 ppb	86	59 (68.6) [57.7, 78.2]	96	50 (52.1) [41.6, 62.4]	1.317 [1.037, 1.673]	2.010 [1.096, 3.687]	16.5 [1.4, 31.6]	0.034	*
Q3: 30 - < 56 ppb	102	72 (70.6) [60.7, 79.2]	89	62 (69.7) [59.0, 79.0]	1.013 [0.842, 1.220]	1.045 [0.562, 1.945]	0.9 [-13.1, 15.0]	1.000	
Q4: >= 56 ppb	96	61 (63.5) [53.1, 73.1]	101	61 (60.4) [50.2, 70.0]	1.052 [0.845, 1.309]	1.143 [0.642, 2.033]	3.1 [-11.4, 17.7]	0.663	
Total serum IgE (cat. N)								0.862	
Q1: < 53.1 IU/ml	93	70 (75.3) [65.2, 83.6]	96	68 (70.8) [60.7, 79.7]	1.063 [0.893, 1.264]	1.253 [0.658, 2.388]	4.4 [-9.3, 18.1]	0.516	
Q2: 53.1 - < 195.6 IU/ml	100	60 (60.0) [49.7, 69.7]	99	62 (62.6) [52.3, 72.1]	0.958 [0.768, 1.195]	0.895 [0.506, 1.584]	-2.6 [-17.2, 11.9]	0.771	
Q3: 195.6 - < 572.4 IU/ml	103	67 (65.0) [55.0, 74.2]	85	51 (60.0) [48.8, 70.5]	1.084 [0.867, 1.356]	1.241 [0.685, 2.246]	5.0 [-9.9, 20.0]	0.545	
Q4: >= 572.4 IU/ml	84	51 (60.7) [49.5, 71.2]	91	52 (57.1) [46.3, 67.5]	1.063 [0.830, 1.361]	1.159 [0.634, 2.119]	3.6 [-12.1, 19.3]	0.648	
Nasal polyps last 2 years								0.837	
Yes	32	21 (65.6) [46.8, 81.4]	29	19 (65.5) [45.7, 82.1]	1.002 [0.696, 1.442]	1.005 [0.349, 2.893]	0.1 [-27.1, 27.3]	1.000	
No	348	227 (65.2) [60.0, 70.2]	342	214 (62.6) [57.2, 67.7]	1.042 [0.932, 1.166]	1.122 [0.822, 1.531]	2.7 [-4.8, 10.1]	0.477	

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_JLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)		N<10 any level						NE
Western Europe	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
North America	2	1 (50.0) [1.3, 98.7]	6	3 (50.0) [11.8, 88.2]				
South America	9	5 (55.6) [21.2, 86.3]	12	3 (25.0) [5.5, 57.2]				
Central/Eastern Europe	1	0 (0.0) [0.0, 97.5]	0					
Asia Pacific	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Rest of the world	1	0 (0.0) [0.0, 97.5]	0					
Baseline eosinophils (cat. N)		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
150 - < 300 cells/uL	8	3 (37.5) [8.5, 75.5]	2	0 (0.0) [0.0, 84.2]				
300 - < 450 cells/uL	0		6	5 (83.3) [35.9, 99.6]				
>= 450 cells/uL	6	4 (66.7) [22.3, 95.7]	10	2 (20.0) [2.5, 55.6]				
Baseline eosinophils (cat. Q)		N<10 any level						NE
Q1: < 140 cells/uL	0		2	1 (50.0) [1.3, 98.7]				
Q2: 140 - < 250 cells/uL	6	2 (33.3) [4.3, 77.7]	2	0 (0.0) [0.0, 84.2]				
Q3: 250 - < 430 cells/uL	3	2 (66.7) [9.4, 99.2]	5	4 (80.0) [28.4, 99.5]				
Q4: >= 430 cells/uL	6	4 (66.7) [22.3, 95.7]	11	3 (27.3) [6.0, 61.0]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_JLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	6	2 (33.3) [4.3, 77.7]				
25 - < 50 ppb	3	3 (100.0) [29.2, 100.0]	7	3 (42.9) [9.9, 81.6]				
>= 50 ppb	9	5 (55.6) [21.2, 86.3]	7	3 (42.9) [9.9, 81.6]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AA_JLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)		N<10 any level						NE
Q1: < 16 ppb	1	0 (0.0) [0.0, 97.5]	4	1 (25.0) [0.6, 80.6]				
Q2: 16 - < 30 ppb	2	0 (0.0) [0.0, 84.2]	3	1 (33.3) [0.8, 90.6]				
Q3: 30 - < 56 ppb	4	3 (75.0) [19.4, 99.4]	7	4 (57.1) [18.4, 90.1]				
Q4: >= 56 ppb	8	5 (62.5) [24.5, 91.5]	6	2 (33.3) [4.3, 77.7]				
Total serum IgE (cat. N)		N<10 any level						NE
Q1: < 53.1 IU/ml	1	0 (0.0) [0.0, 97.5]	3	2 (66.7) [9.4, 99.2]				
Q2: 53.1 - < 195.6 IU/ml	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
Q3: 195.6 - < 572.4 IU/ml	5	3 (60.0) [14.7, 94.7]	2	0 (0.0) [0.0, 84.2]				
Q4: >= 572.4 IU/ml	8	4 (50.0) [15.7, 84.3]	13	5 (38.5) [13.9, 68.4]				
Nasal polyps last 2 years		N<10 any level						NE
Yes	1	0 (0.0) [0.0, 97.5]	2	1 (50.0) [1.3, 98.7]				
No	14	8 (57.1) [28.9, 82.3]	18	7 (38.9) [17.3, 64.3]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table DT1AA_ULSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Age (cat. N)								0.901
< 18 years	14	7 (50.0) [23.0, 77.0]	12	6 (50.0) [21.1, 78.9]	1.000 [0.463, 2.162]	1.000 [0.214, 4.674]	0.0 [-46.3, 46.3]	1.000
18 - < 65 years	236	186 (78.8) [73.0, 83.8]	115	89 (77.4) [68.7, 84.7]	1.018 [0.904, 1.147]	1.087 [0.635, 1.859]	1.4 [-8.5, 11.3]	0.783
>= 65 years	60	47 (78.3) [65.8, 87.9]	22	18 (81.8) [59.7, 94.8]	0.957 [0.755, 1.214]	0.803 [0.231, 2.791]	-3.5 [-25.8, 18.8]	1.000
Region (cat. N)								0.602
Western Europe	58	49 (84.5) [72.6, 92.7]	25	17 (68.0) [46.5, 85.1]	1.242 [0.929, 1.661]	2.562 [0.852, 7.702]	16.5 [-6.9, 39.9]	0.136
North America	62	48 (77.4) [65.0, 87.1]	26	19 (73.1) [52.2, 88.4]	1.059 [0.809, 1.387]	1.263 [0.441, 3.615]	4.3 [-18.4, 27.0]	0.785
South America	71	54 (76.1) [64.5, 85.4]	36	27 (75.0) [57.8, 87.9]	1.014 [0.806, 1.275]	1.059 [0.417, 2.685]	1.1 [-18.3, 20.4]	1.000
Central/Eastern Europe	20	16 (80.0) [56.3, 94.3]	12	11 (91.7) [61.5, 99.8]	0.873 [0.661, 1.152]	0.364 [0.036, 3.707]	-11.7 [-41.8, 18.5]	0.626
Asia Pacific	47	33 (70.2) [55.1, 82.7]	25	19 (76.0) [54.9, 90.6]	0.924 [0.692, 1.233]	0.744 [0.245, 2.260]	-5.8 [-30.1, 18.5]	0.783
Rest of the world	52	40 (76.9) [63.2, 87.5]	25	20 (80.0) [59.3, 93.2]	0.962 [0.752, 1.230]	0.833 [0.258, 2.694]	-3.1 [-25.5, 19.3]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_ULSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. N)								0.341
< 150 cells/uL	74	56 (75.7) [64.3, 84.9]	36	25 (69.4) [51.9, 83.7]	1.090 [0.847, 1.402]	1.369 [0.564, 3.320]	6.2 [-13.8, 26.2]	0.497
150 - < 300 cells/uL	106	81 (76.4) [67.2, 84.1]	47	32 (68.1) [52.9, 80.9]	1.122 [0.898, 1.402]	1.519 [0.710, 3.247]	8.3 [-8.8, 25.5]	0.320
300 - < 450 cells/uL	58	44 (75.9) [62.8, 86.1]	31	27 (87.1) [70.2, 96.4]	0.871 [0.714, 1.062]	0.466 [0.139, 1.562]	-11.2 [-29.9, 7.4]	0.273
>= 450 cells/uL	72	59 (81.9) [71.1, 90.0]	35	29 (82.9) [66.4, 93.4]	0.989 [0.821, 1.191]	0.939 [0.324, 2.723]	-0.9 [-18.4, 16.5]	1.000
Baseline eosinophils (cat. Q)								0.871
Q1: < 140 cells/uL	67	49 (73.1) [60.9, 83.2]	33	22 (66.7) [48.2, 82.0]	1.097 [0.828, 1.454]	1.361 [0.552, 3.358]	6.5 [-15.1, 28.0]	0.640
Q2: 140 - < 250 cells/uL	85	64 (75.3) [64.7, 84.0]	40	29 (72.5) [56.1, 85.4]	1.039 [0.828, 1.302]	1.156 [0.493, 2.708]	2.8 [-15.6, 21.2]	0.827
Q3: 250 - < 430 cells/uL	83	66 (79.5) [69.2, 87.6]	37	29 (78.4) [61.8, 90.2]	1.015 [0.829, 1.241]	1.071 [0.415, 2.761]	1.1 [-16.7, 18.9]	1.000
Q4: >= 430 cells/uL	75	61 (81.3) [70.7, 89.4]	39	33 (84.6) [69.5, 94.1]	0.961 [0.809, 1.142]	0.792 [0.278, 2.255]	-3.3 [-19.6, 13.0]	0.797

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_ULSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.403
< 25 ppb	127	92 (72.4) [63.8, 80.0]	64	49 (76.6) [64.3, 86.2]	0.946 [0.796, 1.125]	0.805 [0.401, 1.616]	-4.1 [-18.3, 10.0]	0.603
25 - < 50 ppb	89	74 (83.1) [73.7, 90.2]	41	30 (73.2) [57.1, 85.8]	1.136 [0.923, 1.399]	1.809 [0.746, 4.388]	10.0 [-7.4, 27.4]	0.238
>= 50 ppb	91	71 (78.0) [68.1, 86.0]	42	33 (78.6) [63.2, 89.7]	0.993 [0.820, 1.203]	0.968 [0.398, 2.354]	-0.5 [-17.3, 16.2]	1.000
Baseline FENO (cat. Q)								0.582
Q1: < 16 ppb	72	51 (70.8) [58.9, 81.0]	38	29 (76.3) [59.8, 88.6]	0.928 [0.737, 1.169]	0.754 [0.305, 1.862]	-5.5 [-24.6, 13.6]	0.654
Q2: 16 - < 30 ppb	74	57 (77.0) [65.8, 86.0]	38	26 (68.4) [51.3, 82.5]	1.126 [0.877, 1.444]	1.548 [0.647, 3.703]	8.6 [-11.0, 28.2]	0.366
Q3: 30 - < 56 ppb	83	68 (81.9) [72.0, 89.5]	37	32 (86.5) [71.2, 95.5]	0.947 [0.805, 1.115]	0.708 [0.237, 2.119]	-4.6 [-20.3, 11.2]	0.606
Q4: >= 56 ppb	78	61 (78.2) [67.4, 86.8]	34	25 (73.5) [55.6, 87.1]	1.064 [0.842, 1.343]	1.292 [0.508, 3.282]	4.7 [-14.9, 24.2]	0.630

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_ULSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Total serum IgE (cat. N)								0.573
Q1: < 53.1 IU/ml	75	62 (82.7) [72.2, 90.4]	36	30 (83.3) [67.2, 93.6]	0.992 [0.829, 1.187]	0.954 [0.330, 2.756]	-0.7 [-17.6, 16.3]	1.000
Q2: 53.1 - < 195.6 IU/ml	73	52 (71.2) [59.4, 81.2]	42	33 (78.6) [63.2, 89.7]	0.907 [0.731, 1.124]	0.675 [0.276, 1.652]	-7.3 [-25.4, 10.7]	0.509
Q3: 195.6 - < 572.4 IU/ml	86	68 (79.1) [69.0, 87.1]	31	23 (74.2) [55.4, 88.1]	1.066 [0.843, 1.347]	1.314 [0.504, 3.424]	4.9 [-15.0, 24.7]	0.618
Q4: >= 572.4 IU/ml	76	58 (76.3) [65.2, 85.3]	40	27 (67.5) [50.9, 81.4]	1.131 [0.882, 1.450]	1.551 [0.665, 3.619]	8.8 [-10.5, 28.1]	0.378
Nasal polyps last 2 years								0.881
Yes	28	23 (82.1) [63.1, 93.9]	14	11 (78.6) [49.2, 95.3]	1.045 [0.756, 1.445]	1.255 [0.253, 6.224]	3.6 [-27.5, 34.7]	1.000
No	282	217 (77.0) [71.6, 81.7]	135	102 (75.6) [67.4, 82.5]	1.018 [0.908, 1.143]	1.080 [0.668, 1.746]	1.4 [-7.9, 10.7]	0.805

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table PT3AA_SLSIP: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race (cat. P)								0.647
White	60	25 (41.7) [29.1, 55.1]	58	26 (44.8) [31.7, 58.5]	0.929 [0.615, 1.406]	0.879 [0.424, 1.822]	-3.2 [-22.7, 16.4]	0.853
Non-white	6	4 (66.7) [22.3, 95.7]	7	6 (85.7) [42.1, 99.6]	0.778 [0.409, 1.477]	0.333 [0.022, 5.027]	-19.0 [-80.3, 42.2]	0.559
Region (cat. P)								0.873
North America/Western EU	6	5 (83.3) [35.9, 99.6]	4	4 (100.0) [39.8, 100.0]	0.833 [0.583, 1.192]	0.407 + [0.013, 12.636]	-16.7 [-67.3, 34.0]	1.000
Rest of world	60	24 (40.0) [27.6, 53.5]	61	28 (45.9) [33.1, 59.2]	0.871 [0.577, 1.317]	0.786 [0.382, 1.616]	-5.9 [-25.2, 13.4]	0.583
Baseline eosinophils (cat. P)								0.097
< 250 cells/uL	30	12 (40.0) [22.7, 59.4]	29	18 (62.1) [42.3, 79.3]	0.644 [0.382, 1.087]	0.407 [0.143, 1.161]	-22.1 [-50.3, 6.2]	0.120
>= 250 cells/uL	36	17 (47.2) [30.4, 64.5]	36	14 (38.9) [23.1, 56.5]	1.214 [0.711, 2.075]	1.406 [0.551, 3.587]	8.3 [-17.2, 33.9]	0.634
Baseline FENO (cat. P)								0.237
< 24 ppb	38	22 (57.9) [40.8, 73.7]	30	17 (56.7) [37.4, 74.5]	1.022 [0.675, 1.546]	1.051 [0.400, 2.767]	1.2 [-25.4, 27.9]	1.000
>= 24 ppb	28	7 (25.0) [10.7, 44.9]	34	14 (41.2) [24.6, 59.3]	0.607 [0.285, 1.294]	0.476 [0.159, 1.423]	-16.2 [-42.5, 10.1]	0.281

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AA_SLSIP: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. M)								0.122
< 22.0 ppb	34	21 (61.8) [43.6, 77.8]	29	16 (55.2) [35.7, 73.6]	1.119 [0.735, 1.706]	1.313 [0.479, 3.593]	6.6 [-21.0, 34.2]	0.618
>= 22.0 ppb	32	8 (25.0) [11.5, 43.4]	35	15 (42.9) [26.3, 60.6]	0.583 [0.286, 1.188]	0.444 [0.157, 1.262]	-17.9 [-43.1, 7.4]	0.197
Baseline all FEIA status								0.317
All negative	25	13 (52.0) [31.3, 72.2]	22	10 (45.5) [24.4, 67.8]	1.144 [0.632, 2.069]	1.300 [0.412, 4.101]	6.5 [-26.3, 39.4]	0.772
Any positive	35	13 (37.1) [21.5, 55.1]	41	20 (48.8) [32.9, 64.9]	0.761 [0.447, 1.298]	0.620 [0.247, 1.556]	-11.6 [-36.4, 13.2]	0.358
Th2 status								0.284
Low	41	20 (48.8) [32.9, 64.9]	30	14 (46.7) [28.3, 65.7]	1.045 [0.637, 1.714]	1.088 [0.424, 2.795]	2.1 [-24.3, 28.5]	1.000
High	25	9 (36.0) [18.0, 57.5]	34	18 (52.9) [35.1, 70.2]	0.680 [0.369, 1.253]	0.500 [0.173, 1.441]	-16.9 [-45.6, 11.7]	0.290
Baseline Periostin								0.472
Low (< 20.9 ng/ml)	27	14 (51.9) [31.9, 71.3]	32	16 (50.0) [31.9, 68.1]	1.037 [0.628, 1.713]	1.077 [0.387, 3.001]	1.9 [-27.2, 30.9]	1.000
High (>= 20.9 ng/ml)	39	15 (38.5) [23.4, 55.4]	33	16 (48.5) [30.8, 66.5]	0.793 [0.467, 1.348]	0.664 [0.260, 1.699]	-10.0 [-35.7, 15.7]	0.476

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AA_SLSIP: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Current post-BD FEV1 reversibility								0.273
Yes	57	25 (43.9) [30.7, 57.6]	60	28 (46.7) [33.7, 60.0]	0.940 [0.630, 1.401]	0.893 [0.431, 1.850]	-2.8 [-22.6, 16.9]	0.853
No	9	4 (44.4) [13.7, 78.8]	5	4 (80.0) [28.4, 99.5]	0.556 [0.237, 1.302]	0.200 [0.016, 2.575]	-35.6 [-98.9, 27.8]	0.301
Maintenance OCS use at baseline								0.722
Yes	9	4 (44.4) [13.7, 78.8]	14	6 (42.9) [17.7, 71.1]	1.037 [0.402, 2.677]	1.067 [0.197, 5.769]	1.6 [-49.1, 52.3]	1.000
No	57	25 (43.9) [30.7, 57.6]	51	26 (51.0) [36.6, 65.2]	0.860 [0.578, 1.281]	0.751 [0.352, 1.604]	-7.1 [-27.8, 13.6]	0.563
No chronic OCS use and current post-BD FEV1 reversibility								0.893
Yes	51	22 (43.1) [29.3, 57.8]	49	24 (49.0) [34.4, 63.7]	0.881 [0.576, 1.348]	0.790 [0.359, 1.738]	-5.8 [-27.4, 15.7]	0.688
No	15	7 (46.7) [21.3, 73.4]	16	8 (50.0) [24.7, 75.3]	0.933 [0.450, 1.937]	0.875 [0.214, 3.586]	-3.3 [-45.0, 38.3]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AA_SLSIS: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. S)								0.563
Western Europe/North America	22	12 (54.5) [32.2, 75.6]	24	17 (70.8) [48.9, 87.4]	0.770 [0.486, 1.220]	0.494 [0.146, 1.667]	-16.3 [-48.3, 15.7]	0.361
Central/Eastern Europe	30	17 (56.7) [37.4, 74.5]	31	18 (58.1) [39.1, 75.5]	0.976 [0.633, 1.505]	0.944 [0.342, 2.606]	-1.4 [-29.5, 26.7]	1.000
Rest of world	21	7 (33.3) [14.6, 57.0]	21	11 (52.4) [29.8, 74.3]	0.636 [0.307, 1.320]	0.455 [0.131, 1.583]	-19.0 [-53.2, 15.1]	0.350
BMI (cat. S)								0.050
< 30 kg/m**2	42	15 (35.7) [21.6, 52.0]	47	28 (59.6) [44.3, 73.6]	0.599 [0.375, 0.958]	0.377 [0.160, 0.890]	-23.9 [-46.3, -1.4]	0.034 *
>= 30.0 kg/m**2	31	21 (67.7) [48.6, 83.3]	29	18 (62.1) [42.3, 79.3]	1.091 [0.751, 1.587]	1.283 [0.443, 3.715]	5.7 [-21.8, 33.1]	0.788
OCS dose at baseline								0.651
<= 10 mg	56	28 (50.0) [36.3, 63.7]	56	33 (58.9) [45.0, 71.9]	0.848 [0.603, 1.193]	0.697 [0.330, 1.471]	-8.9 [-29.1, 11.2]	0.448
> 10 mg	17	8 (47.1) [23.0, 72.2]	20	13 (65.0) [40.8, 84.6]	0.724 [0.398, 1.317]	0.479 [0.127, 1.798]	-17.9 [-55.0, 19.1]	0.331

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table CT1AA_SLSIC: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline eosinophils (cat. C)								0.027	i
< 150 cells/uL	8	8 (100.0) [63.1, 100.0]	11	8 (72.7) [39.0, 94.0]	1.375 [0.958, 1.975]	7.000 + [0.312, 157.257]	27.3 [-9.8, 64.4]	0.228	
150 - < 300 cells/uL	12	6 (50.0) [21.1, 78.9]	12	9 (75.0) [42.8, 94.5]	0.667 [0.347, 1.281]	0.333 [0.059, 1.877]	-25.0 [-70.8, 20.8]	0.400	
>= 300 cells/uL	11	8 (72.7) [39.0, 94.0]	11	11 (100.0) [71.5, 100.0]	0.727 [0.506, 1.044]	0.106 + [0.005, 2.327]	-27.3 [-62.7, 8.1]	0.214	
Screening eosinophils (cat. C)								0.121	
< 150 cells/uL	9	8 (88.9) [51.8, 99.7]	9	6 (66.7) [29.9, 92.5]	1.333 [0.795, 2.235]	4.000 [0.329, 48.656]	22.2 [-25.9, 70.3]	0.576	
150 - < 300 cells/uL	9	6 (66.7) [29.9, 92.5]	13	11 (84.6) [54.6, 98.1]	0.788 [0.470, 1.321]	0.364 [0.047, 2.817]	-17.9 [-63.9, 28.0]	0.609	
>= 300 cells/uL	12	7 (58.3) [27.7, 84.8]	12	11 (91.7) [61.5, 99.8]	0.636 [0.383, 1.057]	0.127 [0.012, 1.330]	-33.3 [-73.6, 7.0]	0.155	
Total serum IgE (cat. C)								0.407	
Low (< 106.15 IU/ml)	15	12 (80.0) [51.9, 95.7]	13	11 (84.6) [54.6, 98.1]	0.945 [0.671, 1.333]	0.727 [0.102, 5.201]	-4.6 [-40.0, 30.7]	1.000	
High (>= 106.15 IU/ml)	15	9 (60.0) [32.3, 83.7]	21	17 (81.0) [58.1, 94.6]	0.741 [0.467, 1.177]	0.353 [0.079, 1.584]	-21.0 [-56.6, 14.7]	0.260	
Baseline IL-5								0.020	i
Low (< 0.5425 pg/ml)	15	13 (86.7) [59.5, 98.3]	19	14 (73.7) [48.8, 90.9]	1.176 [0.842, 1.643]	2.321 [0.382, 14.118]	13.0 [-19.2, 45.2]	0.426	
High (>= 0.5425 pg/ml)	16	9 (56.3) [29.9, 80.2]	15	14 (93.3) [68.1, 99.8]	0.603 [0.383, 0.948]	0.092 [0.010, 0.877]	-37.1 [-70.9, -3.2]	0.037	*

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AA_SLSIC: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFL

Non-disease related TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline IL-13								0.439
Low (< 0.034 pg/ml)	13	10 (76.9) [46.2, 95.0]	20	16 (80.0) [56.3, 94.3]	0.962 [0.664, 1.392]	0.833 [0.153, 4.528]	-3.1 [-38.3, 32.1]	1.000
High (>= 0.034 pg/ml)	18	12 (66.7) [41.0, 86.7]	14	12 (85.7) [57.2, 98.2]	0.778 [0.526, 1.149]	0.333 [0.056, 1.995]	-19.0 [-53.9, 15.8]	0.412

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table MT1AAN_SLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	446	270 (60.5) [55.8, 65.1]	436	258 (59.2) [54.4, 63.8]	1.023 [0.918, 1.140]	1.058 [0.809, 1.386]	1.4 [-5.3, 8.1]	0.681

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 02FEB2022

Table NT1AAN_SLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	395	250 (63.3) [58.3, 68.1]	391	235 (60.1) [55.1, 65.0]	1.053 [0.943, 1.176]	1.145 [0.858, 1.526]	3.2 [-3.9, 10.2]	0.379

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAN_TLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL - adult

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	380	242 (63.7) [58.6, 68.5]	371	227 (61.2) [56.0, 66.2]	1.041 [0.931, 1.163]	1.112 [0.828, 1.495]	2.5 [-4.7, 9.7]	0.498

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAN_JLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL - adolescents

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	15	8 (53.3) [26.6, 78.7]	20	8 (40.0) [19.1, 63.9]	1.333 [0.652, 2.727]	1.714 [0.443, 6.629]	13.3 [-25.6, 52.3]	0.506

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table PT3AAN_SLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	66	28 (42.4) [30.3, 55.2]	65	31 (47.7) [35.1, 60.5]	0.890 [0.609, 1.300]	0.808 [0.406, 1.610]	-5.3 [-23.8, 13.3]	0.600

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table ST1AAN_SLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	73	34 (46.6) [34.8, 58.6]	76	44 (57.9) [46.0, 69.1]	0.804 [0.589, 1.099]	0.634 [0.332, 1.211]	-11.3 [-28.6, 6.0]	0.191

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table DT1AAN_ULMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFNL - LTE

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	310	236 (76.1) [71.0, 80.8]	149	110 (73.8) [66.0, 80.7]	1.031 [0.920, 1.156]	1.131 [0.722, 1.772]	2.3 [-6.7, 11.3]	0.644

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table CT1AAN_SLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	31	22 (71.0) [52.0, 85.8]	34	27 (79.4) [62.1, 91.3]	0.894 [0.674, 1.186]	0.634 [0.203, 1.975]	-8.4 [-32.5, 15.6]	0.566

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table MT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.541
Male	154	88 (57.1) [48.9, 65.1]	156	83 (53.2) [45.1, 61.2]	1.074 [0.879, 1.313]	1.173 [0.749, 1.836]	3.9 [-7.8, 15.6]	0.496
Female	292	182 (62.3) [56.5, 67.9]	280	175 (62.5) [56.5, 68.2]	0.997 [0.878, 1.133]	0.993 [0.708, 1.393]	-0.2 [-8.5, 8.1]	1.000
Age								0.172
< 65 years	361	218 (60.4) [55.1, 65.5]	373	214 (57.4) [52.2, 62.4]	1.053 [0.933, 1.188]	1.133 [0.844, 1.520]	3.0 [-4.4, 10.4]	0.410
>= 65 years	85	52 (61.2) [50.0, 71.6]	63	44 (69.8) [57.0, 80.8]	0.876 [0.693, 1.107]	0.680 [0.340, 1.360]	-8.7 [-25.4, 8.1]	0.300
Exacerbations in the year before study								0.159
<= 2	248	139 (56.0) [49.6, 62.3]	259	133 (51.4) [45.1, 57.6]	1.091 [0.928, 1.283]	1.208 [0.852, 1.714]	4.7 [-4.4, 13.8]	0.327
> 2	198	131 (66.2) [59.1, 72.7]	177	125 (70.6) [63.3, 77.2]	0.937 [0.816, 1.075]	0.813 [0.525, 1.260]	-4.5 [-14.4, 5.5]	0.375
Race								0.494
White	299	175 (58.5) [52.7, 64.2]	293	175 (59.7) [53.9, 65.4]	0.980 [0.857, 1.120]	0.952 [0.686, 1.321]	-1.2 [-9.5, 7.1]	0.802
Black or African American	23	14 (60.9) [38.5, 80.3]	21	9 (42.9) [21.8, 66.0]	1.420 [0.785, 2.569]	2.074 [0.623, 6.910]	18.0 [-15.6, 51.6]	0.365
Asian	110	70 (63.6) [53.9, 72.6]	106	64 (60.4) [50.4, 69.7]	1.054 [0.855, 1.299]	1.148 [0.663, 1.990]	3.3 [-10.6, 17.1]	0.675
Other	14	11 (78.6) [49.2, 95.3]	16	10 (62.5) [35.4, 84.8]	1.257 [0.787, 2.007]	2.200 [0.431, 11.219]	16.1 [-22.6, 54.8]	0.440

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.728
Europe	104	61 (58.7) [48.6, 68.2]	96	52 (54.2) [43.7, 64.4]	1.083 [0.848, 1.383]	1.200 [0.686, 2.101]	4.5 [-10.3, 19.2]	0.569
America	146	97 (66.4) [58.2, 74.0]	138	85 (61.6) [52.9, 69.7]	1.079 [0.905, 1.285]	1.234 [0.760, 2.006]	4.8 [-7.0, 16.7]	0.458
Asia/Pacific	107	66 (61.7) [51.8, 70.9]	107	69 (64.5) [54.6, 73.5]	0.957 [0.779, 1.174]	0.887 [0.509, 1.545]	-2.8 [-16.7, 11.1]	0.777
Rest of the world	89	46 (51.7) [40.8, 62.4]	95	52 (54.7) [44.2, 65.0]	0.944 [0.720, 1.239]	0.885 [0.495, 1.579]	-3.1 [-18.6, 12.5]	0.768
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	2 (66.7) [9.4, 99.2]	3	1 (33.3) [0.8, 90.6]				
18.5 - < 25.0 kg/m**2	124	66 (53.2) [44.1, 62.2]	129	70 (54.3) [45.3, 63.1]				
25.0 - < 30.0 kg/m**2	151	86 (57.0) [48.7, 65.0]	146	84 (57.5) [49.1, 65.7]				
>= 30.0 kg/m**2	168	116 (69.0) [61.5, 75.9]	158	103 (65.2) [57.2, 72.6]				
Baseline eosinophils - Low								0.757
< 150 cells/uL	107	67 (62.6) [52.7, 71.8]	101	60 (59.4) [49.2, 69.1]	1.054 [0.848, 1.311]	1.145 [0.655, 1.999]	3.2 [-11.0, 17.4]	0.671
>= 150 cells/uL	339	203 (59.9) [54.4, 65.1]	335	198 (59.1) [53.6, 64.4]	1.013 [0.894, 1.148]	1.033 [0.759, 1.405]	0.8 [-6.9, 8.5]	0.875
Baseline eosinophils - High								0.433
< 300 cells/uL	250	147 (58.8) [52.4, 65.0]	241	144 (59.8) [53.3, 66.0]	0.984 [0.850, 1.140]	0.961 [0.671, 1.378]	-1.0 [-10.1, 8.1]	0.855
>= 300 cells/uL	196	123 (62.8) [55.6, 69.5]	195	114 (58.5) [51.2, 65.5]	1.073 [0.915, 1.260]	1.197 [0.798, 1.797]	4.3 [-5.9, 14.5]	0.409

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.334
< 25 ppb	194	115 (59.3) [52.0, 66.3]	175	108 (61.7) [54.1, 68.9]	0.961 [0.814, 1.133]	0.903 [0.594, 1.372]	-2.4 [-13.0, 8.1]	0.670
>= 25 ppb	249	153 (61.4) [55.1, 67.5]	256	147 (57.4) [51.1, 63.6]	1.070 [0.926, 1.236]	1.182 [0.828, 1.687]	4.0 [-4.9, 13.0]	0.366
Baseline specific perennial FEIA status								0.176
All negative	164	103 (62.8) [54.9, 70.2]	158	105 (66.5) [58.5, 73.8]	0.945 [0.804, 1.111]	0.852 [0.539, 1.347]	-3.7 [-14.7, 7.4]	0.560
Any positive	275	164 (59.6) [53.6, 65.5]	269	146 (54.3) [48.1, 60.3]	1.099 [0.949, 1.272]	1.245 [0.886, 1.749]	5.4 [-3.3, 14.0]	0.226
Total serum IgE								0.829
Low	138	93 (67.4) [58.9, 75.1]	135	92 (68.1) [59.6, 75.9]	0.989 [0.840, 1.165]	0.966 [0.581, 1.605]	-0.8 [-12.6, 11.1]	0.898
Normal	275	158 (57.5) [51.4, 63.4]	256	143 (55.9) [49.5, 62.0]	1.029 [0.886, 1.194]	1.067 [0.757, 1.505]	1.6 [-7.2, 10.4]	0.727
High	33	19 (57.6) [39.2, 74.5]	45	23 (51.1) [35.8, 66.3]	1.126 [0.748, 1.696]	1.298 [0.525, 3.207]	6.5 [-18.5, 31.4]	0.649
OCS at baseline								0.512
Yes	55	39 (70.9) [57.1, 82.4]	55	41 (74.5) [61.0, 85.3]	0.951 [0.756, 1.196]	0.832 [0.359, 1.929]	-3.6 [-22.1, 14.8]	0.831
No	391	231 (59.1) [54.0, 64.0]	381	217 (57.0) [51.8, 62.0]	1.037 [0.920, 1.170]	1.091 [0.820, 1.452]	2.1 [-5.1, 9.3]	0.560

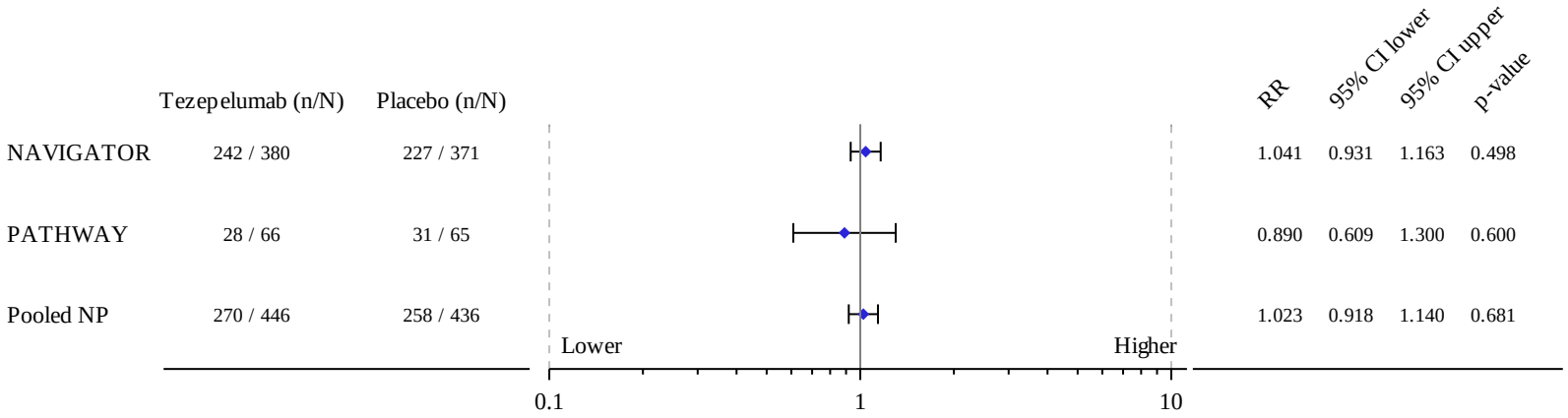
Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.363
Yes	119	81 (68.1) [58.9, 76.3]	107	66 (61.7) [51.8, 70.9]	1.104 [0.909, 1.339]	1.324 [0.765, 2.291]	6.4 [-7.0, 19.7]	0.331
No	327	189 (57.8) [52.2, 63.2]	329	192 (58.4) [52.8, 63.7]	0.990 [0.870, 1.128]	0.977 [0.717, 1.333]	-0.6 [-8.4, 7.3]	0.937
Tiotropium use at baseline								0.328
Yes	109	74 (67.9) [58.3, 76.5]	102	62 (60.8) [50.6, 70.3]	1.117 [0.912, 1.367]	1.364 [0.775, 2.401]	7.1 [-6.8, 21.0]	0.315
No	337	196 (58.2) [52.7, 63.5]	334	196 (58.7) [53.2, 64.0]	0.991 [0.872, 1.126]	0.979 [0.720, 1.330]	-0.5 [-8.3, 7.2]	0.938
Montelukast/ Cromoglicic acid use at baseline								0.962
Yes	180	112 (62.2) [54.7, 69.3]	162	99 (61.1) [53.1, 68.7]	1.018 [0.861, 1.204]	1.048 [0.677, 1.622]	1.1 [-9.8, 12.0]	0.911
No	266	158 (59.4) [53.2, 65.4]	274	159 (58.0) [51.9, 63.9]	1.024 [0.889, 1.179]	1.058 [0.751, 1.491]	1.4 [-7.3, 10.0]	0.793

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Figure MF1AAN_SLMF0: Forest plot for non-disease related non-severe TEAEs during study period
DSAFL



Test for heterogeneity - p-value: 0.436, I-square: 0.0 %

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of affected patients. RR = relative risk. CI = confidence interval.
Heterogeneity was investigated with Cochran Q test. NE = not evaluable.
Source tables: NT1AAN_TLMI0, PT3AAN_SLMI0, MT1AAN_SLMI0

Table NT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.168
Male	143	87 (60.8) [52.3, 68.9]	147	76 (51.7) [43.3, 60.0]	1.177 [0.959, 1.443]	1.451 [0.910, 2.314]	9.1 [-2.9, 21.2]	0.125
Female	252	163 (64.7) [58.4, 70.6]	244	159 (65.2) [58.8, 71.1]	0.993 [0.872, 1.130]	0.979 [0.677, 1.416]	-0.5 [-9.3, 8.3]	0.925
Age								0.129
< 65 years	319	202 (63.3) [57.8, 68.6]	338	197 (58.3) [52.8, 63.6]	1.086 [0.961, 1.229]	1.236 [0.903, 1.692]	5.0 [-2.7, 12.8]	0.201
>= 65 years	76	48 (63.2) [51.3, 73.9]	53	38 (71.7) [57.7, 83.2]	0.881 [0.692, 1.121]	0.677 [0.317, 1.444]	-8.5 [-26.4, 9.3]	0.347
Exacerbations in the year before study								0.098
<= 2	211	127 (60.2) [53.2, 66.8]	226	119 (52.7) [45.9, 59.3]	1.143 [0.969, 1.349]	1.359 [0.930, 1.987]	7.5 [-2.2, 17.3]	0.123
> 2	184	123 (66.8) [59.5, 73.6]	165	116 (70.3) [62.7, 77.2]	0.951 [0.825, 1.096]	0.852 [0.541, 1.341]	-3.5 [-13.8, 6.9]	0.564
Race								0.580
White	251	157 (62.5) [56.2, 68.6]	252	155 (61.5) [55.2, 67.5]	1.017 [0.887, 1.166]	1.045 [0.729, 1.498]	1.0 [-7.8, 9.9]	0.854
Black or African American	21	12 (57.1) [34.0, 78.2]	21	9 (42.9) [21.8, 66.0]	1.333 [0.719, 2.472]	1.778 [0.524, 6.035]	14.3 [-20.4, 49.0]	0.538
Asian	108	69 (63.9) [54.1, 72.9]	104	63 (60.6) [50.5, 70.0]	1.055 [0.855, 1.301]	1.151 [0.661, 2.007]	3.3 [-10.7, 17.3]	0.672
Other	15	12 (80.0) [51.9, 95.7]	14	8 (57.1) [28.9, 82.3]	1.400 [0.833, 2.354]	3.000 [0.576, 15.614]	22.9 [-16.9, 62.7]	0.245

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.599
Europe	65	45 (69.2) [56.6, 80.1]	61	38 (62.3) [49.0, 74.4]	1.111 [0.862, 1.432]	1.362 [0.651, 2.850]	6.9 [-11.2, 25.1]	0.455
America	151	98 (64.9) [56.7, 72.5]	152	87 (57.2) [49.0, 65.2]	1.134 [0.946, 1.358]	1.381 [0.869, 2.196]	7.7 [-3.9, 19.3]	0.195
Asia/Pacific	105	65 (61.9) [51.9, 71.2]	105	68 (64.8) [54.8, 73.8]	0.956 [0.778, 1.175]	0.884 [0.504, 1.550]	-2.9 [-16.8, 11.1]	0.775
Rest of the world	74	42 (56.8) [44.7, 68.2]	73	42 (57.5) [45.4, 69.0]	0.986 [0.746, 1.305]	0.969 [0.504, 1.862]	-0.8 [-18.1, 16.6]	1.000
BMI								0.927
< 18.5 kg/m**2	5	3 (60.0) [14.7, 94.7]	7	3 (42.9) [9.9, 81.6]	1.400 [0.459, 4.271]	2.000 [0.194, 20.614]	17.1 [-56.5, 90.7]	1.000
18.5 - < 25.0 kg/m**2	117	64 (54.7) [45.2, 63.9]	119	65 (54.6) [45.2, 63.8]	1.001 [0.794, 1.263]	1.003 [0.601, 1.675]	0.1 [-13.5, 13.6]	1.000
25.0 - < 30.0 kg/m**2	130	80 (61.5) [52.6, 69.9]	130	76 (58.5) [49.5, 67.0]	1.053 [0.863, 1.284]	1.137 [0.692, 1.868]	3.1 [-9.6, 15.7]	0.704
>= 30.0 kg/m**2	143	103 (72.0) [63.9, 79.2]	135	91 (67.4) [58.8, 75.2]	1.069 [0.915, 1.248]	1.245 [0.746, 2.079]	4.6 [-6.9, 16.1]	0.434
Baseline eosinophils - Low								0.757
< 150 cells/uL	96	61 (63.5) [53.1, 73.1]	89	52 (58.4) [47.5, 68.8]	1.088 [0.863, 1.371]	1.240 [0.686, 2.242]	5.1 [-10.0, 20.3]	0.547
>= 150 cells/uL	299	189 (63.2) [57.5, 68.7]	302	183 (60.6) [54.8, 66.1]	1.043 [0.920, 1.183]	1.117 [0.804, 1.553]	2.6 [-5.5, 10.7]	0.557
Baseline eosinophils - High								0.507
< 300 cells/uL	225	138 (61.3) [54.6, 67.7]	211	127 (60.2) [53.2, 66.8]	1.019 [0.876, 1.185]	1.049 [0.714, 1.541]	1.1 [-8.5, 10.8]	0.845
>= 300 cells/uL	170	112 (65.9) [58.2, 73.0]	180	108 (60.0) [52.4, 67.2]	1.098 [0.935, 1.290]	1.287 [0.833, 1.989]	5.9 [-4.8, 16.6]	0.270

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.183
< 25 ppb	158	93 (58.9) [50.8, 66.6]	151	93 (61.6) [53.3, 69.4]	0.956 [0.797, 1.146]	0.892 [0.566, 1.408]	-2.7 [-14.3, 8.8]	0.643
>= 25 ppb	234	155 (66.2) [59.8, 72.3]	236	140 (59.3) [52.8, 65.6]	1.117 [0.971, 1.284]	1.345 [0.924, 1.958]	6.9 [-2.2, 16.1]	0.128
Baseline specific perennial FEIA status								0.099
All negative	140	93 (66.4) [58.0, 74.2]	131	92 (70.2) [61.6, 77.9]	0.946 [0.804, 1.112]	0.839 [0.502, 1.401]	-3.8 [-15.6, 8.0]	0.517
Any positive	253	157 (62.1) [55.8, 68.1]	253	138 (54.5) [48.2, 60.8]	1.138 [0.981, 1.319]	1.363 [0.956, 1.943]	7.5 [-1.5, 16.5]	0.105
Total serum IgE								0.637
Low	116	80 (69.0) [59.7, 77.2]	125	87 (69.6) [60.7, 77.5]	0.991 [0.837, 1.173]	0.971 [0.561, 1.678]	-0.6 [-13.1, 11.9]	1.000
Normal	247	151 (61.1) [54.7, 67.2]	220	125 (56.8) [50.0, 63.5]	1.076 [0.924, 1.253]	1.195 [0.826, 1.730]	4.3 [-5.0, 13.7]	0.348
High	32	19 (59.4) [40.6, 76.3]	46	23 (50.0) [34.9, 65.1]	1.188 [0.790, 1.784]	1.462 [0.587, 3.638]	9.4 [-15.6, 34.3]	0.491
OCS at baseline								0.118
Yes	47	36 (76.6) [62.0, 87.7]	42	36 (85.7) [71.5, 94.6]	0.894 [0.731, 1.092]	0.545 [0.182, 1.633]	-9.1 [-27.5, 9.2]	0.296
No	348	214 (61.5) [56.2, 66.6]	349	199 (57.0) [51.6, 62.3]	1.078 [0.953, 1.220]	1.204 [0.890, 1.629]	4.5 [-3.1, 12.0]	0.248

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.410
Yes	115	79 (68.7) [59.4, 77.0]	110	67 (60.9) [51.1, 70.1]	1.128 [0.929, 1.369]	1.408 [0.813, 2.440]	7.8 [-5.6, 21.1]	0.264
No	280	171 (61.1) [55.1, 66.8]	281	168 (59.8) [53.8, 65.6]	1.021 [0.893, 1.168]	1.055 [0.752, 1.480]	1.3 [-7.2, 9.7]	0.796
Tiotropium use at baseline								0.364
Yes	106	73 (68.9) [59.1, 77.5]	106	64 (60.4) [50.4, 69.7]	1.141 [0.933, 1.394]	1.452 [0.824, 2.557]	8.5 [-5.3, 22.3]	0.250
No	289	177 (61.2) [55.4, 66.9]	285	171 (60.0) [54.1, 65.7]	1.021 [0.895, 1.165]	1.054 [0.754, 1.473]	1.2 [-7.1, 9.6]	0.798
Montelukast/ Cromoglicic acid use at baseline								0.784
Yes	168	106 (63.1) [55.3, 70.4]	149	91 (61.1) [52.8, 68.9]	1.033 [0.869, 1.228]	1.090 [0.692, 1.717]	2.0 [-9.3, 13.4]	0.729
No	227	144 (63.4) [56.8, 69.7]	242	144 (59.5) [53.0, 65.7]	1.066 [0.924, 1.230]	1.181 [0.813, 1.714]	3.9 [-5.3, 13.2]	0.394

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_TLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.242
Male	135	83 (61.5) [52.7, 69.7]	136	73 (53.7) [44.9, 62.3]	1.145 [0.933, 1.407]	1.378 [0.849, 2.234]	7.8 [-4.7, 20.3]	0.220
Female	245	159 (64.9) [58.6, 70.9]	235	154 (65.5) [59.1, 71.6]	0.990 [0.869, 1.129]	0.972 [0.668, 1.416]	-0.6 [-9.6, 8.3]	0.924
Age								0.152
< 65 years	304	194 (63.8) [58.1, 69.2]	318	189 (59.4) [53.8, 64.9]	1.074 [0.948, 1.216]	1.204 [0.871, 1.664]	4.4 [-3.6, 12.3]	0.284
>= 65 years	76	48 (63.2) [51.3, 73.9]	53	38 (71.7) [57.7, 83.2]	0.881 [0.692, 1.121]	0.677 [0.317, 1.444]	-8.5 [-26.4, 9.3]	0.347
Exacerbations in the year before study								0.098
<= 2	204	124 (60.8) [53.7, 67.5]	214	115 (53.7) [46.8, 60.6]	1.131 [0.958, 1.336]	1.334 [0.904, 1.969]	7.0 [-2.9, 17.0]	0.166
> 2	176	118 (67.0) [59.6, 73.9]	157	112 (71.3) [63.6, 78.3]	0.940 [0.814, 1.085]	0.817 [0.512, 1.304]	-4.3 [-14.8, 6.2]	0.409
Race								0.303
White	239	151 (63.2) [56.7, 69.3]	235	150 (63.8) [57.3, 70.0]	0.990 [0.864, 1.135]	0.972 [0.669, 1.413]	-0.6 [-9.7, 8.4]	0.924
Black or African American	21	12 (57.1) [34.0, 78.2]	19	7 (36.8) [16.3, 61.6]	1.551 [0.774, 3.110]	2.286 [0.641, 8.149]	20.3 [-15.0, 55.6]	0.225
Asian	107	68 (63.6) [53.7, 72.6]	103	62 (60.2) [50.1, 69.7]	1.056 [0.853, 1.306]	1.153 [0.660, 2.013]	3.4 [-10.7, 17.4]	0.671
Other	13	11 (84.6) [54.6, 98.1]	14	8 (57.1) [28.9, 82.3]	1.481 [0.890, 2.465]	4.125 [0.654, 26.007]	27.5 [-12.5, 67.4]	0.209

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_TLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.759
Europe	64	44 (68.8) [55.9, 79.8]	60	37 (61.7) [48.2, 73.9]	1.115 [0.860, 1.444]	1.368 [0.651, 2.871]	7.1 [-11.3, 25.4]	0.453
America	140	92 (65.7) [57.2, 73.5]	134	81 (60.4) [51.6, 68.8]	1.087 [0.906, 1.304]	1.254 [0.767, 2.050]	5.3 [-6.9, 17.4]	0.383
Asia/Pacific	104	64 (61.5) [51.5, 70.9]	104	67 (64.4) [54.4, 73.6]	0.955 [0.775, 1.177]	0.884 [0.503, 1.552]	-2.9 [-17.0, 11.2]	0.774
Rest of the world	72	42 (58.3) [46.1, 69.8]	73	42 (57.5) [45.4, 69.0]	1.014 [0.768, 1.338]	1.033 [0.534, 1.998]	0.8 [-16.7, 18.2]	1.000
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	2 (66.7) [9.4, 99.2]	3	1 (33.3) [0.8, 90.6]				
18.5 - < 25.0 kg/m**2	109	59 (54.1) [44.3, 63.7]	108	61 (56.5) [46.6, 66.0]				
25.0 - < 30.0 kg/m**2	127	79 (62.2) [53.2, 70.7]	126	75 (59.5) [50.4, 68.2]				
>= 30.0 kg/m**2	141	102 (72.3) [64.2, 79.5]	134	90 (67.2) [58.5, 75.0]				
Baseline eosinophils - Low								0.743
< 150 cells/uL	95	60 (63.2) [52.6, 72.8]	87	51 (58.6) [47.6, 69.1]	1.077 [0.853, 1.361]	1.210 [0.666, 2.197]	4.5 [-10.7, 19.8]	0.547
>= 150 cells/uL	285	182 (63.9) [58.0, 69.4]	284	176 (62.0) [56.0, 67.6]	1.030 [0.908, 1.169]	1.084 [0.772, 1.524]	1.9 [-6.4, 10.2]	0.665
Baseline eosinophils - High								0.673
< 300 cells/uL	216	134 (62.0) [55.2, 68.5]	207	126 (60.9) [53.9, 67.6]	1.019 [0.876, 1.185]	1.051 [0.710, 1.554]	1.2 [-8.6, 10.9]	0.842
>= 300 cells/uL	164	108 (65.9) [58.1, 73.1]	164	101 (61.6) [53.7, 69.1]	1.069 [0.908, 1.259]	1.203 [0.766, 1.888]	4.3 [-6.7, 15.3]	0.491

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_TLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.239
< 25 ppb	155	93 (60.0) [51.8, 67.8]	145	91 (62.8) [54.3, 70.6]	0.956 [0.799, 1.144]	0.890 [0.559, 1.418]	-2.8 [-14.4, 8.9]	0.637
>= 25 ppb	222	147 (66.2) [59.6, 72.4]	222	134 (60.4) [53.6, 66.8]	1.097 [0.952, 1.265]	1.287 [0.874, 1.895]	5.9 [-3.5, 15.3]	0.237
Baseline specific perennial FEIA status								0.117
All negative	137	91 (66.4) [57.9, 74.3]	129	91 (70.5) [61.9, 78.2]	0.942 [0.800, 1.108]	0.826 [0.492, 1.388]	-4.1 [-16.0, 7.8]	0.511
Any positive	241	151 (62.7) [56.2, 68.8]	235	131 (55.7) [49.1, 62.2]	1.124 [0.967, 1.306]	1.332 [0.923, 1.922]	6.9 [-2.3, 16.1]	0.136
Total serum IgE								0.736
Low	115	80 (69.6) [60.3, 77.8]	121	84 (69.4) [60.4, 77.5]	1.002 [0.846, 1.187]	1.007 [0.578, 1.753]	0.1 [-12.5, 12.7]	1.000
Normal	235	144 (61.3) [54.7, 67.5]	212	124 (58.5) [51.5, 65.2]	1.048 [0.900, 1.220]	1.123 [0.769, 1.640]	2.8 [-6.8, 12.3]	0.563
High	30	18 (60.0) [40.6, 77.3]	38	19 (50.0) [33.4, 66.6]	1.200 [0.779, 1.848]	1.500 [0.570, 3.951]	10.0 [-16.6, 36.6]	0.468
OCS at baseline								0.130
Yes	46	35 (76.1) [61.2, 87.4]	42	36 (85.7) [71.5, 94.6]	0.888 [0.724, 1.088]	0.530 [0.177, 1.590]	-9.6 [-28.2, 8.9]	0.290
No	334	207 (62.0) [56.5, 67.2]	329	191 (58.1) [52.5, 63.4]	1.068 [0.943, 1.209]	1.178 [0.863, 1.607]	3.9 [-3.8, 11.7]	0.341

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_TLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.400
Yes	112	77 (68.8) [59.3, 77.2]	104	64 (61.5) [51.5, 70.9]	1.117 [0.918, 1.360]	1.375 [0.784, 2.412]	7.2 [-6.4, 20.8]	0.317
No	268	165 (61.6) [55.5, 67.4]	267	163 (61.0) [54.9, 66.9]	1.008 [0.881, 1.154]	1.022 [0.722, 1.447]	0.5 [-8.1, 9.1]	0.929
Tiotropium use at baseline								0.355
Yes	103	71 (68.9) [59.1, 77.7]	100	61 (61.0) [50.7, 70.6]	1.130 [0.922, 1.385]	1.419 [0.795, 2.532]	7.9 [-6.1, 22.0]	0.243
No	277	171 (61.7) [55.7, 67.5]	271	166 (61.3) [55.2, 67.1]	1.008 [0.883, 1.151]	1.020 [0.723, 1.440]	0.5 [-8.0, 9.0]	0.930
Montelukast/ Cromoglicic acid use at baseline								0.814
Yes	163	103 (63.2) [55.3, 70.6]	141	87 (61.7) [53.1, 69.8]	1.024 [0.860, 1.220]	1.066 [0.669, 1.697]	1.5 [-10.1, 13.1]	0.813
No	217	139 (64.1) [57.3, 70.4]	230	140 (60.9) [54.2, 67.2]	1.052 [0.911, 1.215]	1.146 [0.781, 1.681]	3.2 [-6.2, 12.6]	0.496

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_JLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	8	4 (50.0) [15.7, 84.3]	11	3 (27.3) [6.0, 61.0]				
Female	7	4 (57.1) [18.4, 90.1]	9	5 (55.6) [21.2, 86.3]				
Exacerbations in the year before study		n<10 all levels						NE
<= 2	7	3 (42.9) [9.9, 81.6]	12	4 (33.3) [9.9, 65.1]				
> 2	8	5 (62.5) [24.5, 91.5]	8	4 (50.0) [15.7, 84.3]				
Race		N<10 any level						NE
White	12	6 (50.0) [21.1, 78.9]	17	5 (29.4) [10.3, 56.0]				
Black or African American	0		2	2 (100.0) [15.8, 100.0]				
Asian	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Other	2	1 (50.0) [1.3, 98.7]	0					
Region		N<10 any level						NE
Europe	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
America	11	6 (54.5) [23.4, 83.3]	18	6 (33.3) [13.3, 59.0]				
Asia/Pacific	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Rest of the world	2	0 (0.0) [0.0, 84.2]	0					

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_JLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	4	2 (50.0) [6.8, 93.2]				
18.5 - < 25.0 kg/m**2	8	5 (62.5) [24.5, 91.5]	11	4 (36.4) [10.9, 69.2]				
25.0 - < 30.0 kg/m**2	3	1 (33.3) [0.8, 90.6]	4	1 (25.0) [0.6, 80.6]				
>= 30.0 kg/m**2	2	1 (50.0) [1.3, 98.7]	1	1 (100.0) [2.5, 100.0]				
Baseline eosinophils - Low		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
>= 150 cells/uL	14	7 (50.0) [23.0, 77.0]	18	7 (38.9) [17.3, 64.3]				
Baseline eosinophils - High								0.881
< 300 cells/uL	9	4 (44.4) [13.7, 78.8]	4	1 (25.0) [0.6, 80.6]	1.778 [0.280, 11.282]	2.400 [0.175, 32.879]	19.4 [-52.0, 90.9]	1.000
>= 300 cells/uL	6	4 (66.7) [22.3, 95.7]	16	7 (43.8) [19.8, 70.1]	1.524 [0.690, 3.368]	2.571 [0.361, 18.326]	22.9 [-33.4, 79.2]	0.635
Baseline FENO		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	6	2 (33.3) [4.3, 77.7]				
>= 25 ppb	12	8 (66.7) [34.9, 90.1]	14	6 (42.9) [17.7, 71.1]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_JLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status		N<10 any level						NE
All negative	3	2 (66.7) [9.4, 99.2]	2	1 (50.0) [1.3, 98.7]				
Any positive	12	6 (50.0) [21.1, 78.9]	18	7 (38.9) [17.3, 64.3]				
Total serum IgE		N<10 any level						NE
Low	1	0 (0.0) [0.0, 97.5]	4	3 (75.0) [19.4, 99.4]				
Normal	12	7 (58.3) [27.7, 84.8]	8	1 (12.5) [0.3, 52.7]				
High	2	1 (50.0) [1.3, 98.7]	8	4 (50.0) [15.7, 84.3]				
OCS at baseline		N<10 any level						NE
Yes	1	1 (100.0) [2.5, 100.0]	0					
No	14	7 (50.0) [23.0, 77.0]	20	8 (40.0) [19.1, 63.9]				
LAMA use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	6	3 (50.0) [11.8, 88.2]				
No	12	6 (50.0) [21.1, 78.9]	14	5 (35.7) [12.8, 64.9]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAN_JLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	6	3 (50.0) [11.8, 88.2]				
No	12	6 (50.0) [21.1, 78.9]	14	5 (35.7) [12.8, 64.9]				
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	5	3 (60.0) [14.7, 94.7]	8	4 (50.0) [15.7, 84.3]				
No	10	5 (50.0) [18.7, 81.3]	12	4 (33.3) [9.9, 65.1]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table PT3AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.164
Male	19	5 (26.3) [9.1, 51.2]	20	10 (50.0) [27.2, 72.8]	0.526 [0.220, 1.257]	0.357 [0.093, 1.372]	-23.7 [-58.3, 11.0]	0.191
Female	47	23 (48.9) [34.1, 63.9]	45	21 (46.7) [31.7, 62.1]	1.049 [0.684, 1.608]	1.095 [0.483, 2.483]	2.3 [-20.3, 24.9]	0.838
Age								0.656
< 65 years	57	24 (42.1) [29.1, 55.9]	55	25 (45.5) [32.0, 59.4]	0.926 [0.609, 1.410]	0.873 [0.413, 1.842]	-3.3 [-23.5, 16.8]	0.849
>= 65 years	9	4 (44.4) [13.7, 78.8]	10	6 (60.0) [26.2, 87.8]	0.741 [0.305, 1.801]	0.533 [0.086, 3.307]	-15.6 [-70.6, 39.5]	0.656
Exacerbations in the year before study								0.861
<= 2	44	15 (34.1) [20.5, 49.9]	45	18 (40.0) [25.7, 55.7]	0.852 [0.494, 1.470]	0.776 [0.327, 1.838]	-5.9 [-28.2, 16.4]	0.662
> 2	22	13 (59.1) [36.4, 79.3]	20	13 (65.0) [40.8, 84.6]	0.909 [0.566, 1.460]	0.778 [0.222, 2.719]	-5.9 [-40.0, 28.2]	0.758
Race		N<10 any level						NE
White	60	24 (40.0) [27.6, 53.5]	58	25 (43.1) [30.2, 56.8]				
Black or African American	2	2 (100.0) [15.8, 100.0]	2	2 (100.0) [15.8, 100.0]				
Asian	3	2 (66.7) [9.4, 99.2]	3	2 (66.7) [9.4, 99.2]				
Other	1	0 (0.0) [0.0, 97.5]	2	2 (100.0) [15.8, 100.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		N<10 any level						NE
Europe	40	17 (42.5) [27.0, 59.1]	36	15 (41.7) [25.5, 59.2]				
America	6	5 (83.3) [35.9, 99.6]	4	4 (100.0) [39.8, 100.0]				
Asia/Pacific	3	2 (66.7) [9.4, 99.2]	3	2 (66.7) [9.4, 99.2]				
Rest of the world	17	4 (23.5) [6.8, 49.9]	22	10 (45.5) [24.4, 67.8]				
BMI								0.614
18.5 - < 25.0 kg/m**2	15	7 (46.7) [21.3, 73.4]	21	9 (42.9) [21.8, 66.0]	1.089 [0.523, 2.265]	1.167 [0.308, 4.423]	3.8 [-34.8, 42.5]	1.000
25.0 - < 30.0 kg/m**2	24	7 (29.2) [12.6, 51.1]	20	9 (45.0) [23.1, 68.5]	0.648 [0.294, 1.428]	0.503 [0.145, 1.748]	-15.8 [-48.8, 17.1]	0.352
>= 30.0 kg/m**2	27	14 (51.9) [31.9, 71.3]	24	13 (54.2) [32.8, 74.4]	0.957 [0.571, 1.606]	0.911 [0.303, 2.743]	-2.3 [-33.7, 29.1]	1.000
Baseline eosinophils - Low								0.987
< 150 cells/uL	12	7 (58.3) [27.7, 84.8]	14	9 (64.3) [35.1, 87.2]	0.907 [0.489, 1.682]	0.778 [0.159, 3.795]	-6.0 [-51.2, 39.3]	1.000
>= 150 cells/uL	54	21 (38.9) [25.9, 53.1]	51	22 (43.1) [29.3, 57.8]	0.902 [0.569, 1.427]	0.839 [0.385, 1.828]	-4.2 [-25.0, 16.5]	0.695
Baseline eosinophils - High								0.265
< 300 cells/uL	34	13 (38.2) [22.2, 56.4]	34	18 (52.9) [35.1, 70.2]	0.722 [0.424, 1.229]	0.550 [0.210, 1.445]	-14.7 [-41.1, 11.7]	0.330
>= 300 cells/uL	32	15 (46.9) [29.1, 65.3]	31	13 (41.9) [24.5, 60.9]	1.118 [0.642, 1.946]	1.222 [0.451, 3.306]	4.9 [-22.7, 32.6]	0.801

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.254
< 25 ppb	39	22 (56.4) [39.6, 72.2]	30	17 (56.7) [37.4, 74.5]	0.995 [0.656, 1.511]	0.990 [0.379, 2.585]	-0.3 [-26.8, 26.3]	1.000
>= 25 ppb	27	6 (22.2) [8.6, 42.3]	34	13 (38.2) [22.2, 56.4]	0.581 [0.255, 1.326]	0.462 [0.147, 1.444]	-16.0 [-42.0, 10.0]	0.266
Baseline specific perennial FEIA status								0.883
All negative	27	12 (44.4) [25.5, 64.7]	29	14 (48.3) [29.4, 67.5]	0.921 [0.523, 1.621]	0.857 [0.299, 2.454]	-3.8 [-33.5, 25.9]	0.795
Any positive	34	13 (38.2) [22.2, 56.4]	34	15 (44.1) [27.2, 62.1]	0.867 [0.490, 1.533]	0.784 [0.298, 2.064]	-5.9 [-32.2, 20.4]	0.806
Total serum IgE								0.794
Low	23	13 (56.5) [34.5, 76.8]	14	8 (57.1) [28.9, 82.3]	0.989 [0.555, 1.763]	0.975 [0.255, 3.730]	-0.6 [-39.3, 38.0]	1.000
Normal	40	14 (35.0) [20.6, 51.7]	44	19 (43.2) [28.3, 59.0]	0.811 [0.472, 1.393]	0.709 [0.293, 1.712]	-8.2 [-31.4, 15.0]	0.506
High	3	1 (33.3) [0.8, 90.6]	7	4 (57.1) [18.4, 90.1]	0.583 [0.104, 3.271]	0.375 [0.022, 6.348]	-23.8 [-100.0, 64.7]	1.000
OCS at baseline								0.567
Yes	9	4 (44.4) [13.7, 78.8]	13	5 (38.5) [13.9, 68.4]	1.156 [0.424, 3.151]	1.280 [0.228, 7.187]	6.0 [-45.3, 57.3]	1.000
No	57	24 (42.1) [29.1, 55.9]	52	26 (50.0) [35.8, 64.2]	0.842 [0.560, 1.266]	0.727 [0.341, 1.549]	-7.9 [-28.4, 12.6]	0.446

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.979
Yes	7	4 (57.1) [18.4, 90.1]	3	2 (66.7) [9.4, 99.2]	0.857 [0.307, 2.390]	0.667 [0.039, 11.285]	-9.5 [-98.1, 79.0]	1.000
No	59	24 (40.7) [28.1, 54.3]	62	29 (46.8) [34.0, 59.9]	0.870 [0.579, 1.306]	0.780 [0.380, 1.603]	-6.1 [-25.4, 13.2]	0.583
Tiotropium use at baseline	N<10 any level							NE
Yes	6	3 (50.0) [11.8, 88.2]	2	1 (50.0) [1.3, 98.7]				
No	60	25 (41.7) [29.1, 55.1]	63	30 (47.6) [34.9, 60.6]				
Montelukast/ Cromoglicic acid use at baseline								0.936
Yes	17	9 (52.9) [27.8, 77.0]	21	12 (57.1) [34.0, 78.2]	0.926 [0.518, 1.657]	0.844 [0.233, 3.053]	-4.2 [-41.3, 32.9]	1.000
No	49	19 (38.8) [25.2, 53.8]	44	19 (43.2) [28.3, 59.0]	0.898 [0.551, 1.464]	0.833 [0.364, 1.908]	-4.4 [-26.6, 17.8]	0.679

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.229
Male	25	10 (40.0) [21.1, 61.3]	31	20 (64.5) [45.4, 80.8]	0.620 [0.359, 1.071]	0.367 [0.124, 1.087]	-24.5 [-53.7, 4.6]	0.106
Female	48	24 (50.0) [35.2, 64.8]	45	24 (53.3) [37.9, 68.3]	0.938 [0.633, 1.389]	0.875 [0.388, 1.975]	-3.3 [-25.8, 19.1]	0.836
Age								0.671
< 65 years	58	27 (46.6) [33.3, 60.1]	62	37 (59.7) [46.4, 71.9]	0.780 [0.553, 1.100]	0.588 [0.285, 1.213]	-13.1 [-32.5, 6.3]	0.200
>= 65 years	15	7 (46.7) [21.3, 73.4]	14	7 (50.0) [23.0, 77.0]	0.933 [0.440, 1.982]	0.875 [0.204, 3.761]	-3.3 [-46.6, 39.9]	1.000
Exacerbations in the year before study								0.629
<= 2	60	29 (48.3) [35.2, 61.6]	55	32 (58.2) [44.1, 71.3]	0.831 [0.589, 1.172]	0.672 [0.322, 1.405]	-9.8 [-29.8, 10.1]	0.351
> 2	13	5 (38.5) [13.9, 68.4]	21	12 (57.1) [34.0, 78.2]	0.673 [0.308, 1.470]	0.469 [0.114, 1.925]	-18.7 [-58.8, 21.4]	0.481
Race		N<10 any level						NE
White	61	31 (50.8) [37.7, 63.9]	64	37 (57.8) [44.8, 70.1]				
Black or African American	1	0 (0.0) [0.0, 97.5]	0					
Asian	11	3 (27.3) [6.0, 61.0]	11	6 (54.5) [23.4, 83.3]				
Other	0		1	1 (100.0) [2.5, 100.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.646
Europe	27	14 (51.9) [31.9, 71.3]	32	20 (62.5) [43.7, 78.9]	0.830 [0.528, 1.303]	0.646 [0.228, 1.829]	-10.6 [-39.3, 18.0]	0.440
America	21	8 (38.1) [18.1, 61.6]	17	7 (41.2) [18.4, 67.1]	0.925 [0.421, 2.033]	0.879 [0.238, 3.249]	-3.1 [-39.7, 33.5]	1.000
Asia/Pacific	11	3 (27.3) [6.0, 61.0]	10	6 (60.0) [26.2, 87.8]	0.455 [0.153, 1.351]	0.250 [0.040, 1.564]	-32.7 [-82.5, 17.0]	0.198
Rest of the world	14	9 (64.3) [35.1, 87.2]	17	11 (64.7) [38.3, 85.8]	0.994 [0.588, 1.680]	0.982 [0.224, 4.305]	-0.4 [-40.8, 39.9]	1.000
BMI								0.130
18.5 - < 25.0 kg/m**2	20	10 (50.0) [27.2, 72.8]	23	17 (73.9) [51.6, 89.8]	0.676 [0.410, 1.116]	0.353 [0.098, 1.267]	-23.9 [-56.9, 9.1]	0.127
25.0 - < 30.0 kg/m**2	22	4 (18.2) [5.2, 40.3]	24	10 (41.7) [22.1, 63.4]	0.436 [0.160, 1.192]	0.311 [0.080, 1.204]	-23.5 [-53.3, 6.3]	0.114
>= 30.0 kg/m**2	31	20 (64.5) [45.4, 80.8]	29	17 (58.6) [38.9, 76.5]	1.101 [0.736, 1.645]	1.283 [0.452, 3.641]	5.9 [-22.0, 33.8]	0.791
Baseline eosinophils - Low								0.320
< 150 cells/uL	27	10 (37.0) [19.4, 57.6]	24	14 (58.3) [36.6, 77.9]	0.635 [0.350, 1.153]	0.420 [0.136, 1.296]	-21.3 [-52.1, 9.5]	0.165
>= 150 cells/uL	46	24 (52.2) [36.9, 67.1]	52	30 (57.7) [43.2, 71.3]	0.904 [0.630, 1.298]	0.800 [0.360, 1.777]	-5.5 [-27.3, 16.2]	0.685
Baseline eosinophils - High								0.565
< 300 cells/uL	46	19 (41.3) [27.0, 56.8]	52	29 (55.8) [41.3, 69.5]	0.741 [0.486, 1.128]	0.558 [0.250, 1.245]	-14.5 [-36.1, 7.2]	0.164
>= 300 cells/uL	27	15 (55.6) [35.3, 74.5]	24	15 (62.5) [40.6, 81.2]	0.889 [0.562, 1.405]	0.750 [0.244, 2.304]	-6.9 [-37.8, 23.9]	0.777

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.865
< 25 ppb	31	16 (51.6) [33.1, 69.8]	26	17 (65.4) [44.3, 82.8]	0.789 [0.508, 1.227]	0.565 [0.193, 1.649]	-13.8 [-42.7, 15.1]	0.420
>= 25 ppb	36	15 (41.7) [25.5, 59.2]	43	24 (55.8) [39.9, 70.9]	0.747 [0.467, 1.193]	0.565 [0.231, 1.384]	-14.1 [-38.6, 10.3]	0.261
Baseline specific perennial FEIA status								0.190
All negative	43	23 (53.5) [37.7, 68.8]	39	22 (56.4) [39.6, 72.2]	0.948 [0.641, 1.404]	0.889 [0.372, 2.124]	-2.9 [-26.9, 21.1]	0.827
Any positive	25	8 (32.0) [14.9, 53.5]	34	19 (55.9) [37.9, 72.8]	0.573 [0.301, 1.091]	0.372 [0.126, 1.093]	-23.9 [-52.1, 4.3]	0.112
Total serum IgE		N<10 any level						NE
Low	30	17 (56.7) [37.4, 74.5]	31	15 (48.4) [30.2, 66.9]				
Normal	39	15 (38.5) [23.4, 55.4]	43	28 (65.1) [49.1, 79.0]				
High	3	1 (33.3) [0.8, 90.6]	2	1 (50.0) [1.3, 98.7]				
LAMA use at baseline								0.233
Yes	34	14 (41.2) [24.6, 59.3]	40	25 (62.5) [45.8, 77.3]	0.659 [0.413, 1.052]	0.420 [0.165, 1.071]	-21.3 [-46.4, 3.7]	0.102
No	39	20 (51.3) [34.8, 67.6]	36	19 (52.8) [35.5, 69.6]	0.972 [0.629, 1.501]	0.942 [0.380, 2.332]	-1.5 [-26.8, 23.8]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline								0.233
Yes	34	14 (41.2) [24.6, 59.3]	40	25 (62.5) [45.8, 77.3]	0.659 [0.413, 1.052]	0.420 [0.165, 1.071]	-21.3 [-46.4, 3.7]	0.102
No	39	20 (51.3) [34.8, 67.6]	36	19 (52.8) [35.5, 69.6]	0.972 [0.629, 1.501]	0.942 [0.380, 2.332]	-1.5 [-26.8, 23.8]	1.000
Montelukast/ Cromoglicic acid use at baseline								0.611
Yes	30	15 (50.0) [31.3, 68.7]	37	21 (56.8) [39.5, 72.9]	0.881 [0.559, 1.389]	0.762 [0.290, 2.004]	-6.8 [-33.8, 20.2]	0.628
No	43	19 (44.2) [29.1, 60.1]	39	23 (59.0) [42.1, 74.4]	0.749 [0.489, 1.147]	0.551 [0.229, 1.324]	-14.8 [-38.6, 9.1]	0.194

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table DT1AAN_ULSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Sex								0.011	i
Male	115	88 (76.5) [67.7, 83.9]	56	33 (58.9) [45.0, 71.9]	1.299 [1.021, 1.652]	2.272 [1.145, 4.507]	17.6 [1.2, 34.0]	0.021	*
Female	195	148 (75.9) [69.3, 81.7]	93	77 (82.8) [73.6, 89.8]	0.917 [0.812, 1.035]	0.654 [0.348, 1.229]	-6.9 [-17.4, 3.6]	0.223	
Age								0.320	
< 65 years	250	191 (76.4) [70.6, 81.5]	127	92 (72.4) [63.8, 80.0]	1.055 [0.928, 1.198]	1.232 [0.757, 2.003]	4.0 [-6.0, 13.9]	0.450	
>= 65 years	60	45 (75.0) [62.1, 85.3]	22	18 (81.8) [59.7, 94.8]	0.917 [0.717, 1.171]	0.667 [0.195, 2.283]	-6.8 [-29.4, 15.8]	0.768	
Exacerbations in the year before study								0.577	
<= 2	173	129 (74.6) [67.4, 80.9]	88	62 (70.5) [59.8, 79.7]	1.058 [0.901, 1.243]	1.229 [0.694, 2.178]	4.1 [-8.3, 16.5]	0.555	
> 2	137	107 (78.1) [70.2, 84.7]	61	48 (78.7) [66.3, 88.1]	0.993 [0.848, 1.162]	0.966 [0.463, 2.013]	-0.6 [-14.2, 13.0]	1.000	
Race								0.611	
White	226	176 (77.9) [71.9, 83.1]	99	72 (72.7) [62.9, 81.2]	1.071 [0.932, 1.231]	1.320 [0.767, 2.271]	5.1 [-5.9, 16.2]	0.324	
Black or African American	16	10 (62.5) [35.4, 84.8]	14	11 (78.6) [49.2, 95.3]	0.795 [0.498, 1.270]	0.455 [0.089, 2.318]	-16.1 [-54.8, 22.6]	0.440	
Asian	56	41 (73.2) [59.7, 84.2]	30	22 (73.3) [54.1, 87.7]	0.998 [0.764, 1.305]	0.994 [0.365, 2.708]	-0.1 [-22.3, 22.1]	1.000	
Other	12	9 (75.0) [42.8, 94.5]	6	5 (83.3) [35.9, 99.6]	0.900 [0.554, 1.461]	0.600 [0.049, 7.408]	-8.3 [-59.4, 42.8]	1.000	

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_ULSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.531
Europe	53	43 (81.1) [68.0, 90.6]	24	16 (66.7) [44.7, 84.4]	1.217 [0.891, 1.661]	2.150 [0.721, 6.411]	14.5 [-10.2, 39.1]	0.244
America	133	102 (76.7) [68.6, 83.6]	62	45 (72.6) [59.8, 83.1]	1.057 [0.883, 1.264]	1.243 [0.625, 2.472]	4.1 [-10.3, 18.5]	0.593
Asia/Pacific	52	38 (73.1) [59.0, 84.4]	26	20 (76.9) [56.4, 91.0]	0.950 [0.727, 1.241]	0.814 [0.271, 2.444]	-3.8 [-26.9, 19.2]	0.789
Rest of the world	72	53 (73.6) [61.9, 83.3]	37	29 (78.4) [61.8, 90.2]	0.939 [0.755, 1.169]	0.770 [0.300, 1.974]	-4.8 [-23.5, 14.0]	0.646
BMI		N<10 any level						NE
< 18.5 kg/m**2	4	2 (50.0) [6.8, 93.2]	2	1 (50.0) [1.3, 98.7]				
18.5 - < 25.0 kg/m**2	83	60 (72.3) [61.4, 81.6]	45	30 (66.7) [51.0, 80.0]				
25.0 - < 30.0 kg/m**2	104	75 (72.1) [62.5, 80.5]	48	36 (75.0) [60.4, 86.4]				
>= 30.0 kg/m**2	119	99 (83.2) [75.2, 89.4]	54	43 (79.6) [66.5, 89.4]				
Baseline eosinophils - Low								0.738
< 150 cells/uL	74	55 (74.3) [62.8, 83.8]	36	25 (69.4) [51.9, 83.7]	1.070 [0.830, 1.381]	1.274 [0.528, 3.072]	4.9 [-15.2, 25.0]	0.651
>= 150 cells/uL	236	181 (76.7) [70.8, 81.9]	113	85 (75.2) [66.2, 82.9]	1.020 [0.898, 1.158]	1.084 [0.643, 1.829]	1.5 [-8.8, 11.7]	0.789
Baseline eosinophils - High								0.293
< 300 cells/uL	180	135 (75.0) [68.0, 81.1]	83	57 (68.7) [57.6, 78.4]	1.092 [0.923, 1.292]	1.368 [0.771, 2.428]	6.3 [-6.4, 19.0]	0.298
>= 300 cells/uL	130	101 (77.7) [69.6, 84.5]	66	53 (80.3) [68.7, 89.1]	0.967 [0.832, 1.125]	0.854 [0.410, 1.779]	-2.6 [-15.7, 10.5]	0.717

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_ULSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline FENO								0.418	
< 25 ppb	127	90 (70.9) [62.1, 78.6]	64	47 (73.4) [60.9, 83.7]	0.965 [0.802, 1.161]	0.880 [0.448, 1.726]	-2.6 [-17.1, 12.0]	0.737	
>= 25 ppb	180	143 (79.4) [72.8, 85.1]	83	62 (74.7) [64.0, 83.6]	1.064 [0.919, 1.230]	1.309 [0.709, 2.416]	4.7 [-7.2, 16.7]	0.425	
Baseline specific perennial FEIA status								0.821	
All negative	116	96 (82.8) [74.6, 89.1]	53	42 (79.2) [65.9, 89.2]	1.044 [0.889, 1.227]	1.257 [0.554, 2.855]	3.5 [-10.8, 17.8]	0.669	
Any positive	193	140 (72.5) [65.7, 78.7]	94	67 (71.3) [61.0, 80.1]	1.018 [0.872, 1.188]	1.064 [0.616, 1.840]	1.3 [-10.6, 13.2]	0.889	
Total serum IgE								0.731	
Low	93	74 (79.6) [69.9, 87.2]	49	40 (81.6) [68.0, 91.2]	0.975 [0.824, 1.153]	0.876 [0.363, 2.116]	-2.1 [-17.2, 13.1]	0.828	
Normal	193	144 (74.6) [67.9, 80.6]	81	57 (70.4) [59.2, 80.0]	1.060 [0.900, 1.249]	1.237 [0.695, 2.203]	4.2 [-8.3, 16.8]	0.549	
High	24	18 (75.0) [53.3, 90.2]	19	13 (68.4) [43.4, 87.4]	1.096 [0.747, 1.608]	1.385 [0.363, 5.276]	6.6 [-25.3, 38.4]	0.738	
OCS at baseline								0.042	i
Yes	28	24 (85.7) [67.3, 96.0]	12	12 (100.0) [73.5, 100.0]	0.857 [0.737, 0.997]	0.218 + [0.011, 4.375]	-14.3 [-33.2, 4.6]	0.297	
No	282	212 (75.2) [69.7, 80.1]	137	98 (71.5) [63.2, 78.9]	1.051 [0.927, 1.191]	1.205 [0.762, 1.907]	3.6 [-6.0, 13.3]	0.477	

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_ULSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE

	Teze+Teze		Pbo+Pbo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.523
Yes	83	67 (80.7) [70.6, 88.6]	42	31 (73.8) [58.0, 86.1]	1.094 [0.888, 1.347]	1.486 [0.618, 3.575]	6.9 [-10.7, 24.5]	0.490
No	227	169 (74.4) [68.3, 80.0]	107	79 (73.8) [64.4, 81.9]	1.008 [0.880, 1.155]	1.033 [0.611, 1.744]	0.6 [-10.1, 11.4]	0.894
Tiotropium use at baseline								0.701
Yes	76	61 (80.3) [69.5, 88.5]	40	30 (75.0) [58.8, 87.3]	1.070 [0.867, 1.321]	1.356 [0.545, 3.373]	5.3 [-12.8, 23.3]	0.635
No	234	175 (74.8) [68.7, 80.2]	109	80 (73.4) [64.1, 81.4]	1.019 [0.890, 1.167]	1.075 [0.641, 1.804]	1.4 [-9.3, 12.1]	0.792
Montelukast/ Cromoglicic acid use at baseline								0.156
Yes	123	94 (76.4) [67.9, 83.6]	55	45 (81.8) [69.1, 90.9]	0.934 [0.797, 1.095]	0.720 [0.323, 1.606]	-5.4 [-19.4, 8.6]	0.557
No	187	142 (75.9) [69.2, 81.9]	94	65 (69.1) [58.8, 78.3]	1.098 [0.938, 1.285]	1.408 [0.811, 2.443]	6.8 [-5.2, 18.8]	0.252

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table CT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.316
Male	13	8 (61.5) [31.6, 86.1]	17	14 (82.4) [56.6, 96.2]	0.747 [0.461, 1.211]	0.343 [0.064, 1.829]	-20.8 [-59.7, 18.0]	0.242
Female	18	14 (77.8) [52.4, 93.6]	17	13 (76.5) [50.1, 93.2]	1.017 [0.709, 1.460]	1.077 [0.222, 5.219]	1.3 [-32.3, 34.9]	1.000
Age								0.772
< 65 years	25	17 (68.0) [46.5, 85.1]	29	22 (75.9) [56.5, 89.7]	0.896 [0.639, 1.257]	0.676 [0.205, 2.235]	-7.9 [-35.6, 19.9]	0.557
>= 65 years	6	5 (83.3) [35.9, 99.6]	5	5 (100.0) [47.8, 100.0]	0.833 [0.583, 1.192]	0.333 + [0.011, 10.107]	-16.7 [-64.8, 31.5]	1.000
Exacerbations in the year before study		N<10 any level						NE
<= 2	31	22 (71.0) [52.0, 85.8]	31	24 (77.4) [58.9, 90.4]				
> 2	0		3	3 (100.0) [29.2, 100.0]				
Race		N<10 any level						NE
White	28	21 (75.0) [55.1, 89.3]	32	25 (78.1) [60.0, 90.7]				
Black or African American	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Asian	1	0 (0.0) [0.0, 97.5]	1	1 (100.0) [2.5, 100.0]				
Other	1	0 (0.0) [0.0, 97.5]	0					

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Region								0.263	
Europe	22	15 (68.2) [45.1, 86.1]	21	18 (85.7) [63.7, 97.0]	0.795 [0.569, 1.112]	0.357 [0.078, 1.627]	-17.5 [-46.7, 11.7]	0.281	
America	9	7 (77.8) [40.0, 97.2]	13	9 (69.2) [38.6, 90.9]	1.123 [0.679, 1.858]	1.556 [0.218, 11.086]	8.5 [-37.8, 54.9]	1.000	
BMI								0.645	
18.5 - < 25.0 kg/m**2	6	3 (50.0) [11.8, 88.2]	10	8 (80.0) [44.4, 97.5]	0.625 [0.265, 1.474]	0.250 [0.027, 2.319]	-30.0 [-90.4, 30.4]	0.299	
25.0 - < 30.0 kg/m**2	13	10 (76.9) [46.2, 95.0]	14	11 (78.6) [49.2, 95.3]	0.979 [0.653, 1.467]	0.909 [0.148, 5.583]	-1.6 [-40.5, 37.2]	1.000	
>= 30.0 kg/m**2	12	9 (75.0) [42.8, 94.5]	10	8 (80.0) [44.4, 97.5]	0.938 [0.598, 1.471]	0.750 [0.099, 5.693]	-5.0 [-49.0, 39.0]	1.000	
Baseline eosinophils - Low								0.019	i
< 150 cells/uL	8	8 (100.0) [63.1, 100.0]	11	8 (72.7) [39.0, 94.0]	1.375 [0.958, 1.975]	7.000 + [0.312, 157.257]	27.3 [-9.8, 64.4]	0.228	
>= 150 cells/uL	23	14 (60.9) [38.5, 80.3]	23	19 (82.6) [61.2, 95.0]	0.737 [0.505, 1.075]	0.327 [0.084, 1.283]	-21.7 [-51.3, 7.9]	0.189	
Baseline eosinophils - High								0.551	
< 300 cells/uL	20	14 (70.0) [45.7, 88.1]	23	17 (73.9) [51.6, 89.8]	0.947 [0.650, 1.379]	0.824 [0.217, 3.128]	-3.9 [-35.5, 27.7]	1.000	
>= 300 cells/uL	11	8 (72.7) [39.0, 94.0]	11	10 (90.9) [58.7, 99.8]	0.800 [0.532, 1.202]	0.267 [0.023, 3.080]	-18.2 [-58.6, 22.2]	0.586	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.132
< 25 ppb	14	11 (78.6) [49.2, 95.3]	25	19 (76.0) [54.9, 90.6]	1.034 [0.728, 1.469]	1.158 [0.240, 5.578]	2.6 [-30.2, 35.4]	1.000
>= 25 ppb	14	8 (57.1) [28.9, 82.3]	9	8 (88.9) [51.8, 99.7]	0.643 [0.386, 1.070]	0.167 [0.016, 1.718]	-31.7 [-73.9, 10.4]	0.176
Baseline specific perennial FEIA status								0.843
All negative	16	12 (75.0) [47.6, 92.7]	10	9 (90.0) [55.5, 99.7]	0.833 [0.587, 1.183]	0.333 [0.032, 3.515]	-15.0 [-51.3, 21.3]	0.617
Any positive	14	9 (64.3) [35.1, 87.2]	22	16 (72.7) [49.8, 89.3]	0.884 [0.554, 1.410]	0.675 [0.160, 2.851]	-8.4 [-45.5, 28.6]	0.716
Total serum IgE								0.993
Low	14	11 (78.6) [49.2, 95.3]	12	11 (91.7) [61.5, 99.8]	0.857 [0.621, 1.183]	0.333 [0.030, 3.721]	-13.1 [-47.4, 21.2]	0.598
Normal	16	10 (62.5) [35.4, 84.8]	22	16 (72.7) [49.8, 89.3]	0.859 [0.544, 1.358]	0.625 [0.157, 2.485]	-10.2 [-45.8, 25.3]	0.725
OCS at baseline		N<10 any level						NE
Yes	2	1 (50.0) [1.3, 98.7]	3	3 (100.0) [29.2, 100.0]				
No	29	21 (72.4) [52.8, 87.3]	31	24 (77.4) [58.9, 90.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AAN_SLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.241
Yes	4	4 (100.0) [39.8, 100.0]	9	8 (88.9) [51.8, 99.7]	1.125 [0.893, 1.417]	1.588 + [0.053, 47.516]	11.1 [-27.5, 49.7]	1.000
No	27	18 (66.7) [46.0, 83.5]	25	19 (76.0) [54.9, 90.6]	0.877 [0.621, 1.240]	0.632 [0.187, 2.134]	-9.3 [-37.6, 18.9]	0.548
Tiotropium use at baseline								0.206
Yes	4	4 (100.0) [39.8, 100.0]	8	7 (87.5) [47.3, 99.7]	1.143 [0.880, 1.485]	1.800 + [0.060, 54.331]	12.5 [-29.2, 54.2]	1.000
No	27	18 (66.7) [46.0, 83.5]	26	20 (76.9) [56.4, 91.0]	0.867 [0.617, 1.217]	0.600 [0.178, 2.019]	-10.3 [-38.1, 17.6]	0.544
Montelukast/ Cromoglicic acid use at baseline								0.772
Yes	6	5 (83.3) [35.9, 99.6]	5	5 (100.0) [47.8, 100.0]	0.833 [0.583, 1.192]	0.333 + [0.011, 10.107]	-16.7 [-64.8, 31.5]	1.000
No	25	17 (68.0) [46.5, 85.1]	29	22 (75.9) [56.5, 89.7]	0.896 [0.639, 1.257]	0.676 [0.205, 2.235]	-7.9 [-35.6, 19.9]	0.557

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table NT1AAN_SLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.915
Western Europe	72	50 (69.4) [57.5, 79.8]	72	48 (66.7) [54.6, 77.3]	1.042 [0.833, 1.303]	1.136 [0.564, 2.291]	2.8 [-13.8, 19.4]	0.858
North America	77	51 (66.2) [54.6, 76.6]	77	47 (61.0) [49.2, 72.0]	1.085 [0.854, 1.379]	1.252 [0.648, 2.417]	5.2 [-11.3, 21.7]	0.615
South America	74	47 (63.5) [51.5, 74.4]	75	40 (53.3) [41.4, 64.9]	1.191 [0.906, 1.565]	1.523 [0.791, 2.934]	10.2 [-6.9, 27.3]	0.246
Central/Eastern Europe	20	15 (75.0) [50.9, 91.3]	18	14 (77.8) [52.4, 93.6]	0.964 [0.677, 1.373]	0.857 [0.191, 3.853]	-2.8 [-35.1, 29.5]	1.000
Asia Pacific	98	60 (61.2) [50.8, 70.9]	94	58 (61.7) [51.1, 71.5]	0.992 [0.793, 1.241]	0.980 [0.548, 1.753]	-0.5 [-15.3, 14.3]	1.000
Rest of the world	54	27 (50.0) [36.1, 63.9]	55	28 (50.9) [37.1, 64.6]	0.982 [0.677, 1.425]	0.964 [0.455, 2.043]	-0.9 [-21.5, 19.7]	1.000
Baseline eosinophils (cat. N)								0.165
< 150 cells/uL	96	61 (63.5) [53.1, 73.1]	89	52 (58.4) [47.5, 68.8]	1.088 [0.863, 1.371]	1.240 [0.686, 2.242]	5.1 [-10.0, 20.3]	0.547
150 - < 300 cells/uL	129	77 (59.7) [50.7, 68.2]	122	75 (61.5) [52.2, 70.1]	0.971 [0.795, 1.185]	0.928 [0.559, 1.540]	-1.8 [-14.7, 11.1]	0.797
300 - < 450 cells/uL	70	42 (60.0) [47.6, 71.5]	75	50 (66.7) [54.8, 77.1]	0.900 [0.701, 1.155]	0.750 [0.381, 1.477]	-6.7 [-23.7, 10.4]	0.490
>= 450 cells/uL	100	70 (70.0) [60.0, 78.8]	105	58 (55.2) [45.2, 65.0]	1.267 [1.022, 1.571]	1.891 [1.064, 3.361]	14.8 [0.7, 28.8]	0.031 *
Baseline eosinophils (cat. Q)								0.050
Q1: < 140 cells/uL	89	55 (61.8) [50.9, 71.9]	81	45 (55.6) [44.1, 66.6]	1.112 [0.863, 1.434]	1.294 [0.702, 2.387]	6.2 [-9.7, 22.2]	0.438
Q2: 140 - < 250 cells/uL	99	64 (64.6) [54.4, 74.0]	94	57 (60.6) [50.0, 70.6]	1.066 [0.857, 1.326]	1.187 [0.662, 2.128]	4.0 [-10.7, 18.7]	0.655
Q3: 250 - < 430 cells/uL	103	58 (56.3) [46.2, 66.1]	103	70 (68.0) [58.0, 76.8]	0.829 [0.668, 1.028]	0.608 [0.344, 1.073]	-11.7 [-25.8, 2.5]	0.114
Q4: >= 430 cells/uL	104	73 (70.2) [60.4, 78.8]	113	63 (55.8) [46.1, 65.1]	1.259 [1.024, 1.548]	1.869 [1.067, 3.274]	14.4 [0.8, 28.1]	0.035 *

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_SLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.249
< 25 ppb	158	93 (58.9) [50.8, 66.6]	151	93 (61.6) [53.3, 69.4]	0.956 [0.797, 1.146]	0.892 [0.566, 1.408]	-2.7 [-14.3, 8.8]	0.643
25 - < 50 ppb	114	79 (69.3) [60.0, 77.6]	116	67 (57.8) [48.2, 66.9]	1.200 [0.984, 1.462]	1.651 [0.960, 2.839]	11.5 [-1.7, 24.8]	0.076
>= 50 ppb	120	76 (63.3) [54.1, 71.9]	120	73 (60.8) [51.5, 69.6]	1.041 [0.854, 1.269]	1.112 [0.660, 1.874]	2.5 [-10.6, 15.6]	0.790

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_SLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.167
Q1: < 16 ppb	94	53 (56.4) [45.8, 66.6]	85	56 (65.9) [54.8, 75.8]	0.856 [0.677, 1.082]	0.669 [0.365, 1.227]	-9.5 [-24.8, 5.8]	0.221
Q2: 16 - < 30 ppb	88	57 (64.8) [53.9, 74.7]	99	51 (51.5) [41.3, 61.7]	1.257 [0.984, 1.607]	1.731 [0.960, 3.118]	13.3 [-1.8, 28.3]	0.076
Q3: 30 - < 56 ppb	106	74 (69.8) [60.1, 78.3]	96	65 (67.7) [57.4, 76.9]	1.031 [0.856, 1.242]	1.103 [0.608, 2.001]	2.1 [-11.7, 15.9]	0.763
Q4: >= 56 ppb	104	64 (61.5) [51.5, 70.9]	107	61 (57.0) [47.1, 66.5]	1.079 [0.863, 1.350]	1.207 [0.696, 2.091]	4.5 [-9.7, 18.7]	0.575
Total serum IgE (cat. N)								0.757
Q1: < 53.1 IU/ml	94	69 (73.4) [63.3, 82.0]	99	69 (69.7) [59.6, 78.5]	1.053 [0.881, 1.258]	1.200 [0.641, 2.246]	3.7 [-10.0, 17.5]	0.633
Q2: 53.1 - < 195.6 IU/ml	101	58 (57.4) [47.2, 67.2]	101	61 (60.4) [50.2, 70.0]	0.951 [0.755, 1.197]	0.884 [0.505, 1.550]	-3.0 [-17.5, 11.6]	0.775
Q3: 195.6 - < 572.4 IU/ml	108	68 (63.0) [53.1, 72.1]	87	49 (56.3) [45.3, 66.9]	1.118 [0.884, 1.414]	1.318 [0.741, 2.346]	6.6 [-8.2, 21.5]	0.379
Q4: >= 572.4 IU/ml	92	55 (59.8) [49.0, 69.9]	104	56 (53.8) [43.8, 63.7]	1.110 [0.869, 1.418]	1.274 [0.722, 2.248]	5.9 [-9.0, 20.8]	0.471
Nasal polyps last 2 years								0.940
Yes	33	21 (63.6) [45.1, 79.6]	31	19 (61.3) [42.2, 78.2]	1.038 [0.710, 1.519]	1.105 [0.402, 3.043]	2.3 [-24.5, 29.2]	1.000
No	362	229 (63.3) [58.1, 68.2]	360	216 (60.0) [54.7, 65.1]	1.054 [0.940, 1.183]	1.148 [0.850, 1.550]	3.3 [-4.1, 10.6]	0.400

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_TLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.993
Western Europe	71	49 (69.0) [56.9, 79.5]	71	47 (66.2) [54.0, 77.0]	1.043 [0.830, 1.309]	1.137 [0.563, 2.298]	2.8 [-14.0, 19.6]	0.858
North America	75	50 (66.7) [54.8, 77.1]	71	44 (62.0) [49.7, 73.2]	1.076 [0.844, 1.371]	1.227 [0.623, 2.418]	4.7 [-12.2, 21.6]	0.606
South America	65	42 (64.6) [51.8, 76.1]	63	37 (58.7) [45.6, 71.0]	1.100 [0.836, 1.447]	1.283 [0.628, 2.621]	5.9 [-12.5, 24.3]	0.586
Central/Eastern Europe	19	15 (78.9) [54.4, 93.9]	18	14 (77.8) [52.4, 93.6]	1.015 [0.723, 1.425]	1.071 [0.224, 5.128]	1.2 [-30.8, 33.1]	1.000
Asia Pacific	97	59 (60.8) [50.4, 70.6]	93	57 (61.3) [50.6, 71.2]	0.992 [0.791, 1.245]	0.981 [0.547, 1.757]	-0.5 [-15.4, 14.5]	1.000
Rest of the world	53	27 (50.9) [36.8, 64.9]	55	28 (50.9) [37.1, 64.6]	1.001 [0.691, 1.449]	1.001 [0.471, 2.130]	0.0 [-20.7, 20.7]	1.000
Baseline eosinophils (cat. N)								0.412
< 150 cells/uL	95	60 (63.2) [52.6, 72.8]	87	51 (58.6) [47.6, 69.1]	1.077 [0.853, 1.361]	1.210 [0.666, 2.197]	4.5 [-10.7, 19.8]	0.547
150 - < 300 cells/uL	121	74 (61.2) [51.9, 69.9]	120	75 (62.5) [53.2, 71.2]	0.979 [0.802, 1.193]	0.945 [0.562, 1.589]	-1.3 [-14.4, 11.8]	0.895
300 - < 450 cells/uL	70	42 (60.0) [47.6, 71.5]	69	45 (65.2) [52.8, 76.3]	0.920 [0.711, 1.190]	0.800 [0.402, 1.593]	-5.2 [-22.7, 12.3]	0.600
>= 450 cells/uL	94	66 (70.2) [59.9, 79.2]	95	56 (58.9) [48.4, 68.9]	1.191 [0.962, 1.474]	1.642 [0.899, 2.997]	11.3 [-3.3, 25.9]	0.129
Baseline eosinophils (cat. Q)								0.111
Q1: < 140 cells/uL	89	55 (61.8) [50.9, 71.9]	79	44 (55.7) [44.1, 66.9]	1.110 [0.859, 1.433]	1.287 [0.695, 2.383]	6.1 [-10.0, 22.2]	0.437
Q2: 140 - < 250 cells/uL	93	62 (66.7) [56.1, 76.1]	92	57 (62.0) [51.2, 71.9]	1.076 [0.868, 1.334]	1.228 [0.672, 2.243]	4.7 [-10.2, 19.6]	0.541
Q3: 250 - < 430 cells/uL	100	56 (56.0) [45.7, 65.9]	98	66 (67.3) [57.1, 76.5]	0.832 [0.666, 1.038]	0.617 [0.346, 1.100]	-11.3 [-25.8, 3.1]	0.110
Q4: >= 430 cells/uL	98	69 (70.4) [60.3, 79.2]	102	60 (58.8) [48.6, 68.5]	1.197 [0.973, 1.472]	1.666 [0.927, 2.993]	11.6 [-2.6, 25.7]	0.104

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_TLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.353
< 25 ppb	155	93 (60.0) [51.8, 67.8]	145	91 (62.8) [54.3, 70.6]	0.956 [0.799, 1.144]	0.890 [0.559, 1.418]	-2.8 [-14.4, 8.9]	0.637
25 - < 50 ppb	111	76 (68.5) [59.0, 77.0]	109	64 (58.7) [48.9, 68.1]	1.166 [0.953, 1.427]	1.527 [0.878, 2.654]	9.8 [-3.8, 23.3]	0.161
>= 50 ppb	111	71 (64.0) [54.3, 72.9]	113	70 (61.9) [52.3, 70.9]	1.033 [0.845, 1.262]	1.090 [0.634, 1.876]	2.0 [-11.5, 15.6]	0.783

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_TLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.114
Q1: < 16 ppb	93	53 (57.0) [46.3, 67.2]	81	55 (67.9) [56.6, 77.8]	0.839 [0.666, 1.058]	0.626 [0.336, 1.166]	-10.9 [-26.4, 4.5]	0.160
Q2: 16 - < 30 ppb	86	57 (66.3) [55.3, 76.1]	96	50 (52.1) [41.6, 62.4]	1.273 [0.997, 1.624]	1.808 [0.992, 3.295]	14.2 [-1.0, 29.4]	0.070
Q3: 30 - < 56 ppb	102	71 (69.6) [59.7, 78.3]	89	61 (68.5) [57.8, 78.0]	1.016 [0.840, 1.229]	1.051 [0.568, 1.944]	1.1 [-13.1, 15.3]	0.877
Q4: >= 56 ppb	96	59 (61.5) [51.0, 71.2]	101	59 (58.4) [48.2, 68.1]	1.052 [0.837, 1.322]	1.135 [0.642, 2.008]	3.0 [-11.7, 17.7]	0.771
Total serum IgE (cat. N)								0.788
Q1: < 53.1 IU/ml	93	69 (74.2) [64.1, 82.7]	96	67 (69.8) [59.6, 78.7]	1.063 [0.890, 1.270]	1.244 [0.658, 2.352]	4.4 [-9.4, 18.2]	0.521
Q2: 53.1 - < 195.6 IU/ml	100	57 (57.0) [46.7, 66.9]	99	60 (60.6) [50.3, 70.3]	0.941 [0.745, 1.187]	0.862 [0.490, 1.516]	-3.6 [-18.3, 11.1]	0.666
Q3: 195.6 - < 572.4 IU/ml	103	65 (63.1) [53.0, 72.4]	85	49 (57.6) [46.4, 68.3]	1.095 [0.866, 1.384]	1.257 [0.698, 2.262]	5.5 [-9.7, 20.6]	0.458
Q4: >= 572.4 IU/ml	84	51 (60.7) [49.5, 71.2]	91	51 (56.0) [45.2, 66.4]	1.083 [0.843, 1.392]	1.212 [0.664, 2.214]	4.7 [-11.1, 20.4]	0.544
Nasal polyps last 2 years								0.932
Yes	32	21 (65.6) [46.8, 81.4]	29	18 (62.1) [42.3, 79.3]	1.057 [0.724, 1.545]	1.167 [0.410, 3.322]	3.6 [-23.9, 31.0]	0.796
No	348	221 (63.5) [58.2, 68.6]	342	209 (61.1) [55.7, 66.3]	1.039 [0.925, 1.167]	1.107 [0.814, 1.507]	2.4 [-5.1, 9.9]	0.530

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_JLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)		N<10 any level						NE
Western Europe	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
North America	2	1 (50.0) [1.3, 98.7]	6	3 (50.0) [11.8, 88.2]				
South America	9	5 (55.6) [21.2, 86.3]	12	3 (25.0) [5.5, 57.2]				
Central/Eastern Europe	1	0 (0.0) [0.0, 97.5]	0					
Asia Pacific	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Rest of the world	1	0 (0.0) [0.0, 97.5]	0					
Baseline eosinophils (cat. N)		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
150 - < 300 cells/uL	8	3 (37.5) [8.5, 75.5]	2	0 (0.0) [0.0, 84.2]				
300 - < 450 cells/uL	0		6	5 (83.3) [35.9, 99.6]				
>= 450 cells/uL	6	4 (66.7) [22.3, 95.7]	10	2 (20.0) [2.5, 55.6]				
Baseline eosinophils (cat. Q)		N<10 any level						NE
Q1: < 140 cells/uL	0		2	1 (50.0) [1.3, 98.7]				
Q2: 140 - < 250 cells/uL	6	2 (33.3) [4.3, 77.7]	2	0 (0.0) [0.0, 84.2]				
Q3: 250 - < 430 cells/uL	3	2 (66.7) [9.4, 99.2]	5	4 (80.0) [28.4, 99.5]				
Q4: >= 430 cells/uL	6	4 (66.7) [22.3, 95.7]	11	3 (27.3) [6.0, 61.0]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_JLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	6	2 (33.3) [4.3, 77.7]				
25 - < 50 ppb	3	3 (100.0) [29.2, 100.0]	7	3 (42.9) [9.9, 81.6]				
>= 50 ppb	9	5 (55.6) [21.2, 86.3]	7	3 (42.9) [9.9, 81.6]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAN_JLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL - adolescents

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)		N<10 any level						NE
Q1: < 16 ppb	1	0 (0.0) [0.0, 97.5]	4	1 (25.0) [0.6, 80.6]				
Q2: 16 - < 30 ppb	2	0 (0.0) [0.0, 84.2]	3	1 (33.3) [0.8, 90.6]				
Q3: 30 - < 56 ppb	4	3 (75.0) [19.4, 99.4]	7	4 (57.1) [18.4, 90.1]				
Q4: >= 56 ppb	8	5 (62.5) [24.5, 91.5]	6	2 (33.3) [4.3, 77.7]				
Total serum IgE (cat. N)		N<10 any level						NE
Q1: < 53.1 IU/ml	1	0 (0.0) [0.0, 97.5]	3	2 (66.7) [9.4, 99.2]				
Q2: 53.1 - < 195.6 IU/ml	1	1 (100.0) [2.5, 100.0]	2	1 (50.0) [1.3, 98.7]				
Q3: 195.6 - < 572.4 IU/ml	5	3 (60.0) [14.7, 94.7]	2	0 (0.0) [0.0, 84.2]				
Q4: >= 572.4 IU/ml	8	4 (50.0) [15.7, 84.3]	13	5 (38.5) [13.9, 68.4]				
Nasal polyps last 2 years		N<10 any level						NE
Yes	1	0 (0.0) [0.0, 97.5]	2	1 (50.0) [1.3, 98.7]				
No	14	8 (57.1) [28.9, 82.3]	18	7 (38.9) [17.3, 64.3]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table DT1AAN_ULSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Age (cat. N)								0.658
< 18 years	14	7 (50.0) [23.0, 77.0]	12	6 (50.0) [21.1, 78.9]	1.000 [0.463, 2.162]	1.000 [0.214, 4.674]	0.0 [-46.3, 46.3]	1.000
18 - < 65 years	236	184 (78.0) [72.1, 83.1]	115	86 (74.8) [65.8, 82.4]	1.043 [0.919, 1.183]	1.193 [0.708, 2.010]	3.2 [-7.0, 13.4]	0.503
>= 65 years	60	45 (75.0) [62.1, 85.3]	22	18 (81.8) [59.7, 94.8]	0.917 [0.717, 1.171]	0.667 [0.195, 2.283]	-6.8 [-29.4, 15.8]	0.768
Region (cat. N)								0.664
Western Europe	58	48 (82.8) [70.6, 91.4]	25	17 (68.0) [46.5, 85.1]	1.217 [0.908, 1.632]	2.259 [0.766, 6.664]	14.8 [-8.8, 38.3]	0.154
North America	62	48 (77.4) [65.0, 87.1]	26	19 (73.1) [52.2, 88.4]	1.059 [0.809, 1.387]	1.263 [0.441, 3.615]	4.3 [-18.4, 27.0]	0.785
South America	71	54 (76.1) [64.5, 85.4]	36	26 (72.2) [54.8, 85.8]	1.053 [0.828, 1.340]	1.222 [0.492, 3.037]	3.8 [-15.9, 23.6]	0.814
Central/Eastern Europe	20	16 (80.0) [56.3, 94.3]	12	11 (91.7) [61.5, 99.8]	0.873 [0.661, 1.152]	0.364 [0.036, 3.707]	-11.7 [-41.8, 18.5]	0.626
Asia Pacific	47	33 (70.2) [55.1, 82.7]	25	19 (76.0) [54.9, 90.6]	0.924 [0.692, 1.233]	0.744 [0.245, 2.260]	-5.8 [-30.1, 18.5]	0.783
Rest of the world	52	37 (71.2) [56.9, 82.9]	25	18 (72.0) [50.6, 87.9]	0.988 [0.732, 1.333]	0.959 [0.333, 2.767]	-0.8 [-25.3, 23.6]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_ULSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. N)								0.495
< 150 cells/uL	74	55 (74.3) [62.8, 83.8]	36	25 (69.4) [51.9, 83.7]	1.070 [0.830, 1.381]	1.274 [0.528, 3.072]	4.9 [-15.2, 25.0]	0.651
150 - < 300 cells/uL	106	80 (75.5) [66.2, 83.3]	47	32 (68.1) [52.9, 80.9]	1.108 [0.886, 1.387]	1.442 [0.677, 3.072]	7.4 [-9.8, 24.6]	0.429
300 - < 450 cells/uL	58	43 (74.1) [61.0, 84.7]	31	26 (83.9) [66.3, 94.5]	0.884 [0.712, 1.098]	0.551 [0.179, 1.695]	-9.7 [-29.4, 9.9]	0.425
>= 450 cells/uL	72	58 (80.6) [69.5, 88.9]	35	27 (77.1) [59.9, 89.6]	1.044 [0.844, 1.292]	1.228 [0.460, 3.275]	3.4 [-15.4, 22.2]	0.799
Baseline eosinophils (cat. Q)								0.985
Q1: < 140 cells/uL	67	48 (71.6) [59.3, 82.0]	33	22 (66.7) [48.2, 82.0]	1.075 [0.809, 1.428]	1.263 [0.515, 3.100]	5.0 [-16.7, 26.6]	0.647
Q2: 140 - < 250 cells/uL	85	64 (75.3) [64.7, 84.0]	40	29 (72.5) [56.1, 85.4]	1.039 [0.828, 1.302]	1.156 [0.493, 2.708]	2.8 [-15.6, 21.2]	0.827
Q3: 250 - < 430 cells/uL	83	64 (77.1) [66.6, 85.6]	37	28 (75.7) [58.8, 88.2]	1.019 [0.820, 1.266]	1.083 [0.436, 2.687]	1.4 [-17.0, 19.9]	1.000
Q4: >= 430 cells/uL	75	60 (80.0) [69.2, 88.4]	39	31 (79.5) [63.5, 90.7]	1.006 [0.828, 1.224]	1.032 [0.395, 2.700]	0.5 [-17.0, 18.0]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_ULSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.568
< 25 ppb	127	90 (70.9) [62.1, 78.6]	64	47 (73.4) [60.9, 83.7]	0.965 [0.802, 1.161]	0.880 [0.448, 1.726]	-2.6 [-17.1, 12.0]	0.737
25 - < 50 ppb	89	73 (82.0) [72.5, 89.4]	41	30 (73.2) [57.1, 85.8]	1.121 [0.909, 1.382]	1.673 [0.696, 4.023]	8.9 [-8.7, 26.4]	0.254
>= 50 ppb	91	70 (76.9) [66.9, 85.1]	42	32 (76.2) [60.5, 87.9]	1.010 [0.824, 1.237]	1.042 [0.440, 2.465]	0.7 [-16.5, 18.0]	1.000
Baseline FENO (cat. Q)								0.357
Q1: < 16 ppb	72	49 (68.1) [56.0, 78.6]	38	29 (76.3) [59.8, 88.6]	0.892 [0.703, 1.131]	0.661 [0.270, 1.621]	-8.3 [-27.6, 11.0]	0.389
Q2: 16 - < 30 ppb	74	57 (77.0) [65.8, 86.0]	38	24 (63.2) [46.0, 78.2]	1.220 [0.928, 1.602]	1.956 [0.833, 4.590]	13.9 [-6.2, 33.9]	0.180
Q3: 30 - < 56 ppb	83	67 (80.7) [70.6, 88.6]	37	31 (83.8) [68.0, 93.8]	0.963 [0.808, 1.149]	0.810 [0.289, 2.271]	-3.1 [-19.6, 13.5]	0.802
Q4: >= 56 ppb	78	60 (76.9) [66.0, 85.7]	34	25 (73.5) [55.6, 87.1]	1.046 [0.827, 1.324]	1.200 [0.475, 3.030]	3.4 [-16.2, 23.0]	0.811

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_ULSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Total serum IgE (cat. N)								0.734
Q1: < 53.1 IU/ml	75	62 (82.7) [72.2, 90.4]	36	29 (80.6) [64.0, 91.8]	1.026 [0.848, 1.242]	1.151 [0.415, 3.190]	2.1 [-15.5, 19.7]	0.796
Q2: 53.1 - < 195.6 IU/ml	73	52 (71.2) [59.4, 81.2]	42	32 (76.2) [60.5, 87.9]	0.935 [0.748, 1.169]	0.774 [0.323, 1.851]	-5.0 [-23.4, 13.5]	0.665
Q3: 195.6 - < 572.4 IU/ml	86	64 (74.4) [63.9, 83.2]	31	22 (71.0) [52.0, 85.8]	1.049 [0.811, 1.356]	1.190 [0.477, 2.970]	3.5 [-17.2, 24.1]	0.813
Q4: >= 572.4 IU/ml	76	58 (76.3) [65.2, 85.3]	40	27 (67.5) [50.9, 81.4]	1.131 [0.882, 1.450]	1.551 [0.665, 3.619]	8.8 [-10.5, 28.1]	0.378
Nasal polyps last 2 years								0.548
Yes	28	23 (82.1) [63.1, 93.9]	14	10 (71.4) [41.9, 91.6]	1.150 [0.791, 1.671]	1.840 [0.407, 8.328]	10.7 [-22.2, 43.7]	0.451
No	282	213 (75.5) [70.1, 80.4]	135	100 (74.1) [65.8, 81.2]	1.020 [0.904, 1.150]	1.080 [0.675, 1.730]	1.5 [-8.0, 10.9]	0.809

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table PT3AAN_SLSIP: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race (cat. P)								0.654
White	60	24 (40.0) [27.6, 53.5]	58	25 (43.1) [30.2, 56.8]	0.928 [0.605, 1.424]	0.880 [0.423, 1.831]	-3.1 [-22.6, 16.4]	0.852
Non-white	6	4 (66.7) [22.3, 95.7]	7	6 (85.7) [42.1, 99.6]	0.778 [0.409, 1.477]	0.333 [0.022, 5.027]	-19.0 [-80.3, 42.2]	0.559
Region (cat. P)								0.892
North America/Western EU	6	5 (83.3) [35.9, 99.6]	4	4 (100.0) [39.8, 100.0]	0.833 [0.583, 1.192]	0.407 + [0.013, 12.636]	-16.7 [-67.3, 34.0]	1.000
Rest of world	60	23 (38.3) [26.1, 51.8]	61	27 (44.3) [31.5, 57.6]	0.866 [0.565, 1.327]	0.783 [0.379, 1.617]	-5.9 [-25.1, 13.2]	0.581
Baseline eosinophils (cat. P)								0.100
< 250 cells/uL	30	12 (40.0) [22.7, 59.4]	29	18 (62.1) [42.3, 79.3]	0.644 [0.382, 1.087]	0.407 [0.143, 1.161]	-22.1 [-50.3, 6.2]	0.120
>= 250 cells/uL	36	16 (44.4) [27.9, 61.9]	36	13 (36.1) [20.8, 53.8]	1.231 [0.698, 2.171]	1.415 [0.550, 3.645]	8.3 [-17.0, 33.7]	0.631
Baseline FENO (cat. P)								0.373
< 24 ppb	38	21 (55.3) [38.3, 71.4]	30	17 (56.7) [37.4, 74.5]	0.975 [0.638, 1.490]	0.945 [0.360, 2.478]	-1.4 [-28.1, 25.3]	1.000
>= 24 ppb	28	7 (25.0) [10.7, 44.9]	34	13 (38.2) [22.2, 56.4]	0.654 [0.303, 1.413]	0.538 [0.179, 1.618]	-13.2 [-39.4, 12.9]	0.291

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAN_SLSIP: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. M)								0.215
< 22.0 ppb	34	20 (58.8) [40.7, 75.4]	29	16 (55.2) [35.7, 73.6]	1.066 [0.692, 1.642]	1.161 [0.427, 3.158]	3.7 [-24.1, 31.4]	0.803
>= 22.0 ppb	32	8 (25.0) [11.5, 43.4]	35	14 (40.0) [23.9, 57.9]	0.625 [0.303, 1.290]	0.500 [0.175, 1.425]	-15.0 [-40.1, 10.1]	0.207
Baseline all FEIA status								0.509
All negative	25	12 (48.0) [27.8, 68.7]	22	10 (45.5) [24.4, 67.8]	1.056 [0.572, 1.950]	1.108 [0.351, 3.494]	2.5 [-30.3, 35.4]	1.000
Any positive	35	13 (37.1) [21.5, 55.1]	41	19 (46.3) [30.7, 62.6]	0.802 [0.466, 1.379]	0.684 [0.273, 1.717]	-9.2 [-34.0, 15.6]	0.488
Th2 status								0.431
Low	41	19 (46.3) [30.7, 62.6]	30	14 (46.7) [28.3, 65.7]	0.993 [0.599, 1.645]	0.987 [0.384, 2.537]	-0.3 [-26.7, 26.0]	1.000
High	25	9 (36.0) [18.0, 57.5]	34	17 (50.0) [32.4, 67.6]	0.720 [0.387, 1.340]	0.563 [0.195, 1.620]	-14.0 [-42.7, 14.7]	0.305
Baseline Periostin								0.737
Low (< 20.9 ng/ml)	27	13 (48.1) [28.7, 68.1]	32	16 (50.0) [31.9, 68.1]	0.963 [0.571, 1.624]	0.929 [0.333, 2.587]	-1.9 [-30.9, 27.2]	1.000
High (>= 20.9 ng/ml)	39	15 (38.5) [23.4, 55.4]	33	15 (45.5) [28.1, 63.6]	0.846 [0.491, 1.460]	0.750 [0.293, 1.922]	-7.0 [-32.6, 18.6]	0.634

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAN_SLSIP: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Current post-BD FEV1 reversibility								0.281
Yes	57	24 (42.1) [29.1, 55.9]	60	27 (45.0) [32.1, 58.4]	0.936 [0.619, 1.415]	0.889 [0.428, 1.847]	-2.9 [-22.6, 16.8]	0.852
No	9	4 (44.4) [13.7, 78.8]	5	4 (80.0) [28.4, 99.5]	0.556 [0.237, 1.302]	0.200 [0.016, 2.575]	-35.6 [-98.9, 27.8]	0.301
Maintenance OCS use at baseline								0.721
Yes	9	4 (44.4) [13.7, 78.8]	14	6 (42.9) [17.7, 71.1]	1.037 [0.402, 2.677]	1.067 [0.197, 5.769]	1.6 [-49.1, 52.3]	1.000
No	57	24 (42.1) [29.1, 55.9]	51	25 (49.0) [34.8, 63.4]	0.859 [0.568, 1.299]	0.756 [0.354, 1.618]	-6.9 [-27.5, 13.7]	0.562
No chronic OCS use and current post-BD FEV1 reversibility								0.887
Yes	51	21 (41.2) [27.6, 55.8]	49	23 (46.9) [32.5, 61.7]	0.877 [0.563, 1.366]	0.791 [0.359, 1.745]	-5.8 [-27.2, 15.7]	0.687
No	15	7 (46.7) [21.3, 73.4]	16	8 (50.0) [24.7, 75.3]	0.933 [0.450, 1.937]	0.875 [0.214, 3.586]	-3.3 [-45.0, 38.3]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAN_SLSIS: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Region (cat. S)								0.440	
Western Europe/North America	22	11 (50.0) [28.2, 71.8]	24	15 (62.5) [40.6, 81.2]	0.800 [0.476, 1.346]	0.600 [0.185, 1.944]	-12.5 [-45.3, 20.3]	0.552	
Central/Eastern Europe	30	17 (56.7) [37.4, 74.5]	31	18 (58.1) [39.1, 75.5]	0.976 [0.633, 1.505]	0.944 [0.342, 2.606]	-1.4 [-29.5, 26.7]	1.000	
Rest of world	21	6 (28.6) [11.3, 52.2]	21	11 (52.4) [29.8, 74.3]	0.545 [0.248, 1.201]	0.364 [0.101, 1.303]	-23.8 [-57.4, 9.8]	0.208	
BMI (cat. S)								0.049	i
< 30 kg/m**2	42	14 (33.3) [19.6, 49.5]	47	27 (57.4) [42.2, 71.7]	0.580 [0.354, 0.950]	0.370 [0.156, 0.878]	-24.1 [-46.4, -1.8]	0.033	*
>= 30.0 kg/m**2	31	20 (64.5) [45.4, 80.8]	29	17 (58.6) [38.9, 76.5]	1.101 [0.736, 1.645]	1.283 [0.452, 3.641]	5.9 [-22.0, 33.8]	0.791	
OCS dose at baseline								0.402	
<= 10 mg	56	27 (48.2) [34.7, 62.0]	56	31 (55.4) [41.5, 68.7]	0.871 [0.608, 1.247]	0.751 [0.357, 1.579]	-7.1 [-27.4, 13.1]	0.571	
> 10 mg	17	7 (41.2) [18.4, 67.1]	20	13 (65.0) [40.8, 84.6]	0.633 [0.330, 1.217]	0.377 [0.099, 1.430]	-23.8 [-60.6, 13.0]	0.194	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table CT1AAN_SLSIC: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline eosinophils (cat. C)								0.061	
< 150 cells/uL	8	8 (100.0) [63.1, 100.0]	11	8 (72.7) [39.0, 94.0]	1.375 [0.958, 1.975]	7.000 + [0.312, 157.257]	27.3 [-9.8, 64.4]	0.228	
150 - < 300 cells/uL	12	6 (50.0) [21.1, 78.9]	12	9 (75.0) [42.8, 94.5]	0.667 [0.347, 1.281]	0.333 [0.059, 1.877]	-25.0 [-70.8, 20.8]	0.400	
>= 300 cells/uL	11	8 (72.7) [39.0, 94.0]	11	10 (90.9) [58.7, 99.8]	0.800 [0.532, 1.202]	0.267 [0.023, 3.080]	-18.2 [-58.6, 22.2]	0.586	
Screening eosinophils (cat. C)								0.192	
< 150 cells/uL	9	8 (88.9) [51.8, 99.7]	9	6 (66.7) [29.9, 92.5]	1.333 [0.795, 2.235]	4.000 [0.329, 48.656]	22.2 [-25.9, 70.3]	0.576	
150 - < 300 cells/uL	9	6 (66.7) [29.9, 92.5]	13	11 (84.6) [54.6, 98.1]	0.788 [0.470, 1.321]	0.364 [0.047, 2.817]	-17.9 [-63.9, 28.0]	0.609	
>= 300 cells/uL	12	7 (58.3) [27.7, 84.8]	12	10 (83.3) [51.6, 97.9]	0.700 [0.408, 1.202]	0.280 [0.042, 1.878]	-25.0 [-68.3, 18.3]	0.371	
Total serum IgE (cat. C)								0.542	
Low (< 106.15 IU/ml)	15	12 (80.0) [51.9, 95.7]	13	11 (84.6) [54.6, 98.1]	0.945 [0.671, 1.333]	0.727 [0.102, 5.201]	-4.6 [-40.0, 30.7]	1.000	
High (>= 106.15 IU/ml)	15	9 (60.0) [32.3, 83.7]	21	16 (76.2) [52.8, 91.8]	0.788 [0.489, 1.269]	0.469 [0.111, 1.980]	-16.2 [-52.7, 20.3]	0.465	
Baseline IL-5								0.045	i
Low (< 0.5425 pg/ml)	15	13 (86.7) [59.5, 98.3]	19	14 (73.7) [48.8, 90.9]	1.176 [0.842, 1.643]	2.321 [0.382, 14.118]	13.0 [-19.2, 45.2]	0.426	
High (>= 0.5425 pg/ml)	16	9 (56.3) [29.9, 80.2]	15	13 (86.7) [59.5, 98.3]	0.649 [0.403, 1.044]	0.198 [0.033, 1.181]	-30.4 [-66.7, 5.8]	0.113	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table CT1AAN_SLSIC: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related non-severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline IL-13								0.664
Low (< 0.034 pg/ml)	13	10 (76.9) [46.2, 95.0]	20	16 (80.0) [56.3, 94.3]	0.962 [0.664, 1.392]	0.833 [0.153, 4.528]	-3.1 [-38.3, 32.1]	1.000
High (>= 0.034 pg/ml)	18	12 (66.7) [41.0, 86.7]	14	11 (78.6) [49.2, 95.3]	0.848 [0.554, 1.299]	0.545 [0.109, 2.727]	-11.9 [-48.9, 25.0]	0.694

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 07FEB2022

Table MT1AAC_SLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	446	38 (8.5) [6.1, 11.5]	436	26 (6.0) [3.9, 8.6]	1.429 [0.883, 2.311]	1.469 [0.876, 2.464]	2.6 [-1.1, 6.2]	0.155

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 02FEB2022

Table NT1AAC_SLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	395	27 (6.8) [4.6, 9.8]	391	22 (5.6) [3.6, 8.4]	1.215 [0.704, 2.096]	1.231 [0.688, 2.200]	1.2 [-2.4, 4.8]	0.556

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAC_TLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL - adult

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	380	27 (7.1) [4.7, 10.2]	371	21 (5.7) [3.5, 8.5]	1.255 [0.723, 2.180]	1.275 [0.707, 2.298]	1.4 [-2.3, 5.2]	0.458

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAC_JLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL - adolescents

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	15	0 (0.0) [0.0, 21.8]	20	1 (5.0) [0.1, 24.9]	0.438 + [0.019, 10.046]	0.419 + [0.016, 11.027]	-5.0 [-20.4, 10.4]	1.000

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table PT3AAC_SLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	66	11 (16.7) [8.6, 27.9]	65	5 (7.7) [2.5, 17.0]	2.167 [0.797, 5.890]	2.400 [0.784, 7.346]	9.0 [-3.6, 21.6]	0.181

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table ST1AAC_SLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	73	9 (12.3) [5.8, 22.1]	76	7 (9.2) [3.8, 18.1]	1.339 [0.526, 3.406]	1.386 [0.488, 3.940]	3.1 [-8.2, 14.4]	0.603

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table DT1AAC_ULMI0: Incidence of non-disease related severe TEAEs during study period
DSAFNL - LTE

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	310	27 (8.7) [5.8, 12.4]	149	12 (8.1) [4.2, 13.6]	1.081 [0.564, 2.074]	1.089 [0.536, 2.215]	0.7 [-5.2, 6.5]	0.860

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table CT1AAC_SLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	31	1 (3.2) [0.1, 16.7]	34	6 (17.6) [6.8, 34.5]	0.183 [0.023, 1.435]	0.156 [0.018, 1.374]	-14.4 [-31.7, 2.9]	0.107

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table MT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.204
Male	154	10 (6.5) [3.2, 11.6]	156	11 (7.1) [3.6, 12.3]	0.921 [0.403, 2.105]	0.915 [0.377, 2.222]	-0.6 [-6.8, 5.7]	1.000
Female	292	28 (9.6) [6.5, 13.6]	280	15 (5.4) [3.0, 8.7]	1.790 [0.977, 3.279]	1.874 [0.978, 3.589]	4.2 [-0.4, 8.9]	0.058
Age								0.967
< 65 years	361	32 (8.9) [6.1, 12.3]	373	23 (6.2) [3.9, 9.1]	1.438 [0.858, 2.408]	1.480 [0.848, 2.582]	2.7 [-1.4, 6.8]	0.207
>= 65 years	85	6 (7.1) [2.6, 14.7]	63	3 (4.8) [1.0, 13.3]	1.482 [0.385, 5.701]	1.519 [0.365, 6.322]	2.3 [-6.7, 11.2]	0.733
Exacerbations in the year before study								0.741
<= 2	248	16 (6.5) [3.7, 10.3]	259	13 (5.0) [2.7, 8.4]	1.285 [0.631, 2.617]	1.305 [0.614, 2.772]	1.4 [-3.0, 5.9]	0.568
> 2	198	22 (11.1) [7.1, 16.3]	177	13 (7.3) [4.0, 12.2]	1.513 [0.786, 2.912]	1.577 [0.769, 3.233]	3.8 [-2.6, 10.1]	0.220

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race								0.669
White	299	26 (8.7) [5.8, 12.5]	293	19 (6.5) [3.9, 9.9]	1.341 [0.759, 2.369]	1.373 [0.743, 2.540]	2.2 [-2.4, 6.8]	0.353
Black or African American	23	4 (17.4) [5.0, 38.8]	21	1 (4.8) [0.1, 23.8]	3.652 [0.443, 30.122]	4.211 [0.431, 41.144]	12.6 [-9.9, 35.2]	0.348
Asian	110	6 (5.5) [2.0, 11.5]	106	3 (2.8) [0.6, 8.0]	1.927 [0.495, 7.509]	1.981 [0.482, 8.133]	2.6 [-3.6, 8.8]	0.499
Other	14	2 (14.3) [1.8, 42.8]	16	3 (18.8) [4.0, 45.6]	0.762 [0.148, 3.924]	0.722 [0.102, 5.095]	-4.5 [-37.7, 28.7]	1.000
Region								0.744
Europe	104	15 (14.4) [8.3, 22.7]	96	13 (13.5) [7.4, 22.0]	1.065 [0.535, 2.121]	1.076 [0.483, 2.396]	0.9 [-9.7, 11.5]	1.000
America	146	11 (7.5) [3.8, 13.1]	138	5 (3.6) [1.2, 8.3]	2.079 [0.741, 5.832]	2.167 [0.733, 6.407]	3.9 [-2.1, 9.9]	0.200
Asia/Pacific	107	5 (4.7) [1.5, 10.6]	107	3 (2.8) [0.6, 8.0]	1.667 [0.409, 6.800]	1.699 [0.396, 7.297]	1.9 [-4.1, 7.9]	0.721
Rest of the world	89	7 (7.9) [3.2, 15.5]	95	5 (5.3) [1.7, 11.9]	1.494 [0.492, 4.537]	1.537 [0.469, 5.031]	2.6 [-5.7, 10.9]	0.558
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	0 (0.0) [0.0, 70.8]	3	0 (0.0) [0.0, 70.8]				
18.5 - < 25.0 kg/m**2	124	7 (5.6) [2.3, 11.3]	129	7 (5.4) [2.2, 10.9]				
25.0 - < 30.0 kg/m**2	151	11 (7.3) [3.7, 12.7]	146	5 (3.4) [1.1, 7.8]				
>= 30.0 kg/m**2	168	20 (11.9) [7.4, 17.8]	158	14 (8.9) [4.9, 14.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils - Low								0.382
< 150 cells/uL	107	14 (13.1) [7.3, 21.0]	101	12 (11.9) [6.3, 19.8]	1.101 [0.535, 2.266]	1.116 [0.490, 2.545]	1.2 [-8.7, 11.1]	0.836
>= 150 cells/uL	339	24 (7.1) [4.6, 10.4]	335	14 (4.2) [2.3, 6.9]	1.694 [0.892, 3.218]	1.747 [0.888, 3.439]	2.9 [-0.9, 6.7]	0.132
Baseline eosinophils - High								0.313
< 300 cells/uL	250	22 (8.8) [5.6, 13.0]	241	18 (7.5) [4.5, 11.5]	1.178 [0.648, 2.141]	1.195 [0.624, 2.289]	1.3 [-3.9, 6.6]	0.624
>= 300 cells/uL	196	16 (8.2) [4.7, 12.9]	195	8 (4.1) [1.8, 7.9]	1.990 [0.872, 4.541]	2.078 [0.868, 4.974]	4.1 [-1.2, 9.3]	0.139
Baseline FENO								0.241
< 25 ppb	194	22 (11.3) [7.2, 16.7]	175	10 (5.7) [2.8, 10.3]	1.985 [0.967, 4.073]	2.110 [0.970, 4.592]	5.6 [-0.6, 11.8]	0.064
>= 25 ppb	249	16 (6.4) [3.7, 10.2]	256	15 (5.9) [3.3, 9.5]	1.097 [0.554, 2.170]	1.103 [0.533, 2.283]	0.6 [-4.0, 5.2]	0.854

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status								0.561
All negative	164	16 (9.8) [5.7, 15.4]	158	13 (8.2) [4.5, 13.7]	1.186 [0.590, 2.384]	1.206 [0.560, 2.596]	1.5 [-5.3, 8.4]	0.699
Any positive	275	21 (7.6) [4.8, 11.4]	269	13 (4.8) [2.6, 8.1]	1.580 [0.808, 3.091]	1.628 [0.798, 3.322]	2.8 [-1.6, 7.2]	0.216
Total serum IgE								0.895
Low	138	15 (10.9) [6.2, 17.3]	135	9 (6.7) [3.1, 12.3]	1.630 [0.739, 3.598]	1.707 [0.720, 4.046]	4.2 [-3.2, 11.6]	0.286
Normal	275	22 (8.0) [5.1, 11.9]	256	16 (6.3) [3.6, 10.0]	1.280 [0.688, 2.382]	1.304 [0.669, 2.543]	1.8 [-3.0, 6.5]	0.502
High	33	1 (3.0) [0.1, 15.8]	45	1 (2.2) [0.1, 11.8]	1.364 [0.088, 21.017]	1.375 [0.083, 22.815]	0.8 [-9.1, 10.7]	1.000
OCS at baseline								0.874
Yes	55	8 (14.5) [6.5, 26.7]	55	6 (10.9) [4.1, 22.2]	1.333 [0.495, 3.589]	1.390 [0.448, 4.310]	3.6 [-10.6, 17.9]	0.776
No	391	30 (7.7) [5.2, 10.8]	381	20 (5.2) [3.2, 8.0]	1.462 [0.845, 2.528]	1.500 [0.836, 2.691]	2.4 [-1.3, 6.1]	0.190

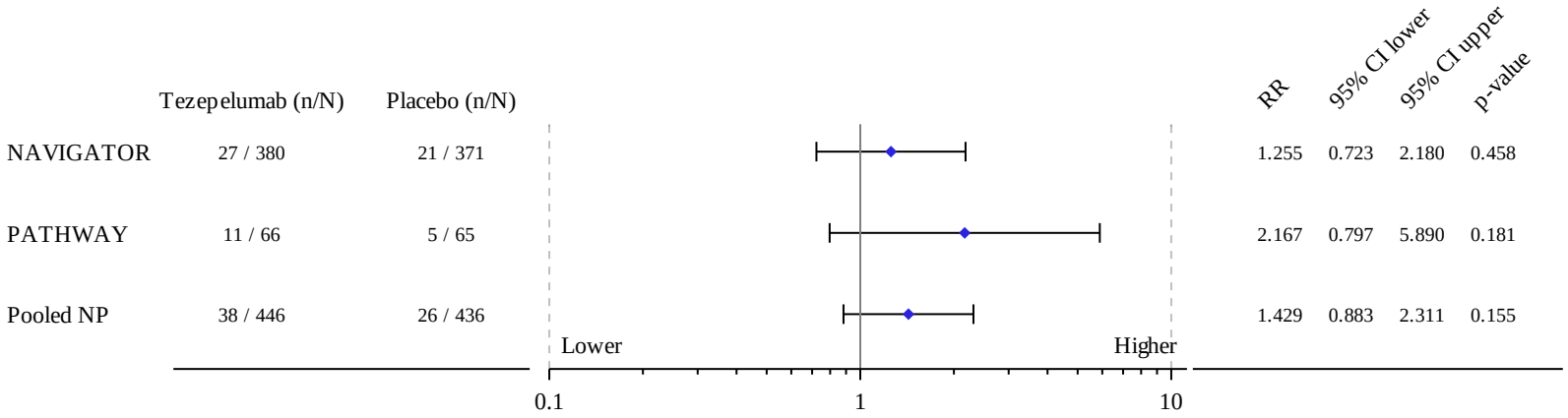
Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.983
Yes	119	11 (9.2) [4.7, 15.9]	107	7 (6.5) [2.7, 13.0]	1.413 [0.568, 3.514]	1.455 [0.543, 3.900]	2.7 [-5.2, 10.6]	0.474
No	327	27 (8.3) [5.5, 11.8]	329	19 (5.8) [3.5, 8.9]	1.430 [0.811, 2.520]	1.468 [0.799, 2.697]	2.5 [-1.7, 6.7]	0.225
Tiotropium use at baseline								0.684
Yes	109	9 (8.3) [3.8, 15.1]	102	7 (6.9) [2.8, 13.6]	1.203 [0.465, 3.111]	1.221 [0.437, 3.411]	1.4 [-6.7, 9.5]	0.798
No	337	29 (8.6) [5.8, 12.1]	334	19 (5.7) [3.5, 8.7]	1.513 [0.866, 2.644]	1.561 [0.857, 2.843]	2.9 [-1.3, 7.1]	0.177
Montelukast/ Cromoglicic acid use at baseline								0.942
Yes	180	17 (9.4) [5.6, 14.7]	162	11 (6.8) [3.4, 11.8]	1.391 [0.672, 2.881]	1.432 [0.650, 3.155]	2.7 [-3.7, 9.0]	0.432
No	266	21 (7.9) [5.0, 11.8]	274	15 (5.5) [3.1, 8.9]	1.442 [0.760, 2.737]	1.480 [0.746, 2.937]	2.4 [-2.2, 7.0]	0.302

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Figure MF1AAC_SLMF0: Forest plot for non-disease related severe TEAEs during study period
DSAFL



Test for heterogeneity - p-value: 0.349, I-square: 0.0 %

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of affected patients. RR = relative risk. CI = confidence interval.
Heterogeneity was investigated with Cochran Q test. NE = not evaluable.
Source tables: NT1AAC_TLMI0, PT3AAC_SLMI0, MT1AAC_SLMI0

Table NT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.299
Male	143	7 (4.9) [2.0, 9.8]	147	9 (6.1) [2.8, 11.3]	0.800 [0.306, 2.089]	0.789 [0.286, 2.179]	-1.2 [-7.2, 4.7]	0.798
Female	252	20 (7.9) [4.9, 12.0]	244	13 (5.3) [2.9, 8.9]	1.490 [0.758, 2.928]	1.532 [0.744, 3.152]	2.6 [-2.2, 7.4]	0.282
Age								0.880
< 65 years	319	23 (7.2) [4.6, 10.6]	338	20 (5.9) [3.7, 9.0]	1.218 [0.683, 2.175]	1.235 [0.665, 2.296]	1.3 [-2.8, 5.4]	0.531
>= 65 years	76	4 (5.3) [1.5, 12.9]	53	2 (3.8) [0.5, 13.0]	1.395 [0.265, 7.341]	1.417 [0.250, 8.030]	1.5 [-7.3, 10.3]	1.000
Exacerbations in the year before study								0.500
<= 2	211	11 (5.2) [2.6, 9.1]	226	12 (5.3) [2.8, 9.1]	0.982 [0.443, 2.177]	0.981 [0.423, 2.273]	-0.1 [-4.7, 4.6]	1.000
> 2	184	16 (8.7) [5.1, 13.7]	165	10 (6.1) [2.9, 10.9]	1.435 [0.670, 3.073]	1.476 [0.650, 3.351]	2.6 [-3.4, 8.7]	0.417
Race								0.792
White	251	17 (6.8) [4.0, 10.6]	252	16 (6.3) [3.7, 10.1]	1.067 [0.551, 2.064]	1.072 [0.529, 2.171]	0.4 [-4.3, 5.1]	0.859
Black or African American	21	3 (14.3) [3.0, 36.3]	21	1 (4.8) [0.1, 23.8]	3.000 [0.339, 26.561]	3.333 [0.318, 34.989]	9.5 [-12.8, 31.8]	0.606
Asian	108	5 (4.6) [1.5, 10.5]	104	3 (2.9) [0.6, 8.2]	1.605 [0.393, 6.546]	1.634 [0.381, 7.019]	1.7 [-4.3, 7.8]	0.722
Other	15	2 (13.3) [1.7, 40.5]	14	2 (14.3) [1.8, 42.8]	0.933 [0.151, 5.758]	0.923 [0.112, 7.623]	-1.0 [-33.0, 31.1]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.640
Europe	65	7 (10.8) [4.4, 20.9]	61	9 (14.8) [7.0, 26.2]	0.730 [0.290, 1.839]	0.697 [0.242, 2.005]	-4.0 [-17.2, 9.3]	0.596
America	151	10 (6.6) [3.2, 11.8]	152	6 (3.9) [1.5, 8.4]	1.678 [0.625, 4.500]	1.726 [0.611, 4.874]	2.7 [-3.0, 8.4]	0.318
Asia/Pacific	105	4 (3.8) [1.0, 9.5]	105	3 (2.9) [0.6, 8.1]	1.333 [0.306, 5.812]	1.347 [0.294, 6.169]	1.0 [-4.9, 6.8]	1.000
Rest of the world	74	6 (8.1) [3.0, 16.8]	73	4 (5.5) [1.5, 13.4]	1.480 [0.435, 5.028]	1.522 [0.411, 5.634]	2.6 [-6.9, 12.1]	0.745
BMI								0.583
< 18.5 kg/m**2	5	0 (0.0) [0.0, 52.2]	7	0 (0.0) [0.0, 41.0]	1.333 + [0.031, 58.090]	1.364 + [0.023, 79.964]	2.1 + [-40.3, 44.4]	NE
18.5 - < 25.0 kg/m**2	117	5 (4.3) [1.4, 9.7]	119	7 (5.9) [2.4, 11.7]	0.726 [0.237, 2.224]	0.714 [0.220, 2.318]	-1.6 [-8.1, 4.8]	0.769
25.0 - < 30.0 kg/m**2	130	9 (6.9) [3.2, 12.7]	130	4 (3.1) [0.8, 7.7]	2.250 [0.711, 7.123]	2.343 [0.703, 7.810]	3.8 [-2.2, 9.9]	0.254
>= 30.0 kg/m**2	143	13 (9.1) [4.9, 15.0]	135	11 (8.1) [4.1, 14.1]	1.116 [0.518, 2.404]	1.127 [0.487, 2.611]	0.9 [-6.4, 8.3]	0.833
Baseline eosinophils - Low								0.921
< 150 cells/uL	96	10 (10.4) [5.1, 18.3]	89	8 (9.0) [4.0, 16.9]	1.159 [0.479, 2.805]	1.177 [0.443, 3.131]	1.4 [-8.2, 11.0]	0.808
>= 150 cells/uL	299	17 (5.7) [3.3, 8.9]	302	14 (4.6) [2.6, 7.7]	1.226 [0.616, 2.443]	1.240 [0.600, 2.564]	1.0 [-2.8, 4.9]	0.585
Baseline eosinophils - High								0.593
< 300 cells/uL	225	16 (7.1) [4.1, 11.3]	211	14 (6.6) [3.7, 10.9]	1.072 [0.536, 2.142]	1.077 [0.512, 2.265]	0.5 [-4.7, 5.7]	0.853
>= 300 cells/uL	170	11 (6.5) [3.3, 11.3]	180	8 (4.4) [1.9, 8.6]	1.456 [0.600, 3.532]	1.487 [0.583, 3.792]	2.0 [-3.3, 7.4]	0.482

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.717
< 25 ppb	158	12 (7.6) [4.0, 12.9]	151	8 (5.3) [2.3, 10.2]	1.434 [0.603, 3.409]	1.469 [0.583, 3.701]	2.3 [-3.8, 8.4]	0.491
>= 25 ppb	234	15 (6.4) [3.6, 10.4]	236	13 (5.5) [3.0, 9.2]	1.164 [0.566, 2.392]	1.175 [0.546, 2.527]	0.9 [-3.8, 5.6]	0.701
Baseline specific perennial FEIA status								0.430
All negative	140	11 (7.9) [4.0, 13.6]	131	11 (8.4) [4.3, 14.5]	0.936 [0.420, 2.085]	0.930 [0.389, 2.225]	-0.5 [-7.8, 6.7]	1.000
Any positive	253	16 (6.3) [3.7, 10.1]	253	11 (4.3) [2.2, 7.6]	1.455 [0.689, 3.072]	1.485 [0.675, 3.267]	2.0 [-2.3, 6.3]	0.429
Total serum IgE								0.605
Low	116	10 (8.6) [4.2, 15.3]	125	9 (7.2) [3.3, 13.2]	1.197 [0.504, 2.842]	1.216 [0.476, 3.107]	1.4 [-6.2, 9.1]	0.812
Normal	247	17 (6.9) [4.1, 10.8]	220	11 (5.0) [2.5, 8.8]	1.377 [0.659, 2.875]	1.404 [0.643, 3.067]	1.9 [-2.8, 6.6]	0.439
High	32	0 (0.0) [0.0, 10.9]	46	2 (4.3) [0.5, 14.8]	0.285 + [0.014, 5.742]	0.274 + [0.013, 5.898]	-4.3 [-12.9, 4.2]	0.510
OCS at baseline								0.824
Yes	47	6 (12.8) [4.8, 25.7]	42	5 (11.9) [4.0, 25.6]	1.072 [0.353, 3.259]	1.083 [0.305, 3.846]	0.9 [-15.1, 16.8]	1.000
No	348	21 (6.0) [3.8, 9.1]	349	17 (4.9) [2.9, 7.7]	1.239 [0.665, 2.307]	1.254 [0.650, 2.420]	1.2 [-2.5, 4.8]	0.510

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.694
Yes	115	9 (7.8) [3.6, 14.3]	110	6 (5.5) [2.0, 11.5]	1.435 [0.528, 3.898]	1.472 [0.506, 4.281]	2.4 [-5.0, 9.7]	0.596
No	280	18 (6.4) [3.9, 10.0]	281	16 (5.7) [3.3, 9.1]	1.129 [0.588, 2.169]	1.138 [0.568, 2.279]	0.7 [-3.6, 5.0]	0.728
Tiotropium use at baseline								0.930
Yes	106	7 (6.6) [2.7, 13.1]	106	6 (5.7) [2.1, 11.9]	1.167 [0.406, 3.356]	1.178 [0.382, 3.631]	0.9 [-6.5, 8.3]	1.000
No	289	20 (6.9) [4.3, 10.5]	285	16 (5.6) [3.2, 9.0]	1.233 [0.652, 2.330]	1.250 [0.634, 2.464]	1.3 [-3.0, 5.6]	0.606
Montelukast/ Cromoglicic acid use at baseline								0.338
Yes	168	12 (7.1) [3.7, 12.1]	149	6 (4.0) [1.5, 8.6]	1.774 [0.683, 4.609]	1.833 [0.670, 5.013]	3.1 [-2.5, 8.8]	0.331
No	227	15 (6.6) [3.7, 10.7]	242	16 (6.6) [3.8, 10.5]	0.999 [0.506, 1.974]	0.999 [0.482, 2.072]	-0.0 [-4.9, 4.9]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_TLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.237
Male	135	7 (5.2) [2.1, 10.4]	136	9 (6.6) [3.1, 12.2]	0.784 [0.300, 2.043]	0.772 [0.279, 2.135]	-1.4 [-7.8, 4.9]	0.798
Female	245	20 (8.2) [5.1, 12.3]	235	12 (5.1) [2.7, 8.7]	1.599 [0.799, 3.197]	1.652 [0.789, 3.460]	3.1 [-1.8, 7.9]	0.203
Age								0.914
< 65 years	304	23 (7.6) [4.9, 11.1]	318	19 (6.0) [3.6, 9.2]	1.266 [0.704, 2.277]	1.288 [0.687, 2.416]	1.6 [-2.7, 5.9]	0.523
>= 65 years	76	4 (5.3) [1.5, 12.9]	53	2 (3.8) [0.5, 13.0]	1.395 [0.265, 7.341]	1.417 [0.250, 8.030]	1.5 [-7.3, 10.3]	1.000
Exacerbations in the year before study								0.381
<= 2	204	11 (5.4) [2.7, 9.4]	214	12 (5.6) [2.9, 9.6]	0.962 [0.434, 2.130]	0.959 [0.414, 2.226]	-0.2 [-5.1, 4.6]	1.000
> 2	176	16 (9.1) [5.3, 14.3]	157	9 (5.7) [2.7, 10.6]	1.586 [0.721, 3.487]	1.644 [0.705, 3.835]	3.4 [-2.8, 9.6]	0.300
Race								0.862
White	239	17 (7.1) [4.2, 11.1]	235	15 (6.4) [3.6, 10.3]	1.114 [0.570, 2.179]	1.123 [0.547, 2.305]	0.7 [-4.2, 5.7]	0.855
Black or African American	21	3 (14.3) [3.0, 36.3]	19	1 (5.3) [0.1, 26.0]	2.714 [0.308, 23.926]	3.000 [0.285, 31.633]	9.0 [-14.0, 32.1]	0.607
Asian	107	5 (4.7) [1.5, 10.6]	103	3 (2.9) [0.6, 8.3]	1.604 [0.393, 6.542]	1.634 [0.380, 7.020]	1.8 [-4.3, 7.9]	0.722
Other	13	2 (15.4) [1.9, 45.4]	14	2 (14.3) [1.8, 42.8]	1.077 [0.176, 6.572]	1.091 [0.130, 9.124]	1.1 [-33.2, 35.4]	1.000

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_TLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.563
Europe	64	7 (10.9) [4.5, 21.2]	60	9 (15.0) [7.1, 26.6]	0.729 [0.290, 1.835]	0.696 [0.242, 2.004]	-4.1 [-17.5, 9.4]	0.596
America	140	10 (7.1) [3.5, 12.7]	134	5 (3.7) [1.2, 8.5]	1.914 [0.672, 5.454]	1.985 [0.660, 5.967]	3.4 [-2.7, 9.5]	0.290
Asia/Pacific	104	4 (3.8) [1.1, 9.6]	104	3 (2.9) [0.6, 8.2]	1.333 [0.306, 5.811]	1.347 [0.294, 6.171]	1.0 [-4.9, 6.8]	1.000
Rest of the world	72	6 (8.3) [3.1, 17.3]	73	4 (5.5) [1.5, 13.4]	1.521 [0.448, 5.165]	1.568 [0.423, 5.808]	2.9 [-6.8, 12.5]	0.533
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	0 (0.0) [0.0, 70.8]	3	0 (0.0) [0.0, 70.8]				
18.5 - < 25.0 kg/m**2	109	5 (4.6) [1.5, 10.4]	108	6 (5.6) [2.1, 11.7]				
25.0 - < 30.0 kg/m**2	127	9 (7.1) [3.3, 13.0]	126	4 (3.2) [0.9, 7.9]				
>= 30.0 kg/m**2	141	13 (9.2) [5.0, 15.3]	134	11 (8.2) [4.2, 14.2]				
Baseline eosinophils - Low								0.822
< 150 cells/uL	95	10 (10.5) [5.2, 18.5]	87	8 (9.2) [4.1, 17.3]	1.145 [0.473, 2.768]	1.162 [0.437, 3.092]	1.3 [-8.4, 11.1]	0.808
>= 150 cells/uL	285	17 (6.0) [3.5, 9.4]	284	13 (4.6) [2.5, 7.7]	1.303 [0.645, 2.632]	1.322 [0.630, 2.776]	1.4 [-2.6, 5.4]	0.574
Baseline eosinophils - High								0.539
< 300 cells/uL	216	16 (7.4) [4.3, 11.8]	207	14 (6.8) [3.7, 11.1]	1.095 [0.549, 2.187]	1.103 [0.524, 2.321]	0.6 [-4.7, 6.0]	0.851
>= 300 cells/uL	164	11 (6.7) [3.4, 11.7]	164	7 (4.3) [1.7, 8.6]	1.571 [0.625, 3.953]	1.613 [0.609, 4.268]	2.4 [-3.1, 8.0]	0.468

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_TLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.842
< 25 ppb	155	12 (7.7) [4.1, 13.1]	145	8 (5.5) [2.4, 10.6]	1.403 [0.591, 3.334]	1.437 [0.570, 3.623]	2.2 [-4.1, 8.5]	0.494
>= 25 ppb	222	15 (6.8) [3.8, 10.9]	222	12 (5.4) [2.8, 9.3]	1.250 [0.599, 2.609]	1.268 [0.580, 2.775]	1.4 [-3.5, 6.2]	0.692
Baseline specific perennial FEIA status								0.373
All negative	137	11 (8.0) [4.1, 13.9]	129	11 (8.5) [4.3, 14.7]	0.942 [0.423, 2.096]	0.937 [0.391, 2.241]	-0.5 [-7.9, 6.9]	1.000
Any positive	241	16 (6.6) [3.8, 10.6]	235	10 (4.3) [2.1, 7.7]	1.560 [0.723, 3.368]	1.600 [0.711, 3.602]	2.4 [-2.1, 6.9]	0.314
Total serum IgE								0.754
Low	115	10 (8.7) [4.2, 15.4]	121	9 (7.4) [3.5, 13.7]	1.169 [0.493, 2.773]	1.185 [0.463, 3.031]	1.3 [-6.5, 9.1]	0.813
Normal	235	17 (7.2) [4.3, 11.3]	212	11 (5.2) [2.6, 9.1]	1.394 [0.668, 2.909]	1.425 [0.652, 3.115]	2.0 [-2.9, 7.0]	0.437
High	30	0 (0.0) [0.0, 11.6]	38	1 (2.6) [0.1, 13.8]	0.419 + [0.018, 9.941]	0.410 + [0.016, 10.424]	-2.6 [-10.7, 5.4]	1.000
OCS at baseline								0.800
Yes	46	6 (13.0) [4.9, 26.3]	42	5 (11.9) [4.0, 25.6]	1.096 [0.361, 3.327]	1.110 [0.312, 3.946]	1.1 [-14.9, 17.2]	1.000
No	334	21 (6.3) [3.9, 9.5]	329	16 (4.9) [2.8, 7.8]	1.293 [0.687, 2.433]	1.313 [0.672, 2.562]	1.4 [-2.4, 5.2]	0.500

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAC_TLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.803
Yes	112	9 (8.0) [3.7, 14.7]	104	6 (5.8) [2.1, 12.1]	1.393 [0.513, 3.778]	1.427 [0.490, 4.158]	2.3 [-5.4, 9.9]	0.598
No	268	18 (6.7) [4.0, 10.4]	267	15 (5.6) [3.2, 9.1]	1.196 [0.615, 2.322]	1.210 [0.596, 2.453]	1.1 [-3.4, 5.5]	0.720
Tiotropium use at baseline								0.823
Yes	103	7 (6.8) [2.8, 13.5]	100	6 (6.0) [2.2, 12.6]	1.133 [0.394, 3.253]	1.142 [0.370, 3.525]	0.8 [-6.9, 8.5]	1.000
No	277	20 (7.2) [4.5, 10.9]	271	15 (5.5) [3.1, 9.0]	1.304 [0.682, 2.494]	1.328 [0.665, 2.652]	1.7 [-2.8, 6.1]	0.486
Montelukast/ Cromoglicic acid use at baseline								0.415
Yes	163	12 (7.4) [3.9, 12.5]	141	6 (4.3) [1.6, 9.0]	1.730 [0.667, 4.490]	1.788 [0.653, 4.895]	3.1 [-2.8, 9.0]	0.332
No	217	15 (6.9) [3.9, 11.1]	230	15 (6.5) [3.7, 10.5]	1.060 [0.531, 2.116]	1.064 [0.507, 2.233]	0.4 [-4.7, 5.5]	1.000

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table PT3AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.653
Male	19	3 (15.8) [3.4, 39.6]	20	2 (10.0) [1.2, 31.7]	1.579 [0.296, 8.433]	1.688 [0.249, 11.416]	5.8 [-20.4, 31.9]	0.661
Female	47	8 (17.0) [7.6, 30.8]	45	3 (6.7) [1.4, 18.3]	2.553 [0.723, 9.022]	2.872 [0.711, 11.607]	10.4 [-4.8, 25.5]	0.199
Age								0.985
< 65 years	57	9 (15.8) [7.5, 27.9]	55	4 (7.3) [2.0, 17.6]	2.171 [0.710, 6.641]	2.391 [0.690, 8.278]	8.5 [-5.0, 22.0]	0.238
>= 65 years	9	2 (22.2) [2.8, 60.0]	10	1 (10.0) [0.3, 44.5]	2.222 [0.240, 20.566]	2.571 [0.192, 34.473]	12.2 [-31.2, 55.7]	0.582
Exacerbations in the year before study								0.277
<= 2	44	5 (11.4) [3.8, 24.6]	45	1 (2.2) [0.1, 11.8]	5.114 [0.622, 42.029]	5.641 [0.631, 50.397]	9.1 [-3.4, 21.7]	0.110
> 2	22	6 (27.3) [10.7, 50.2]	20	4 (20.0) [5.7, 43.7]	1.364 [0.449, 4.141]	1.500 [0.355, 6.347]	7.3 [-23.1, 37.6]	0.723
Race		N<10 any level						NE
White	60	9 (15.0) [7.1, 26.6]	58	4 (6.9) [1.9, 16.7]				
Black or African American	2	1 (50.0) [1.3, 98.7]	2	0 (0.0) [0.0, 84.2]				
Asian	3	1 (33.3) [0.8, 90.6]	3	0 (0.0) [0.0, 70.8]				
Other	1	0 (0.0) [0.0, 97.5]	2	1 (50.0) [1.3, 98.7]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		N<10 any level						NE
Europe	40	8 (20.0) [9.1, 35.6]	36	4 (11.1) [3.1, 26.1]				
America	6	1 (16.7) [0.4, 64.1]	4	0 (0.0) [0.0, 60.2]				
Asia/Pacific	3	1 (33.3) [0.8, 90.6]	3	0 (0.0) [0.0, 70.8]				
Rest of the world	17	1 (5.9) [0.1, 28.7]	22	1 (4.5) [0.1, 22.8]				
BMI								0.952
18.5 - < 25.0 kg/m**2	15	2 (13.3) [1.7, 40.5]	21	1 (4.8) [0.1, 23.8]	2.800 [0.279, 28.129]	3.077 [0.253, 37.483]	8.6 [-16.6, 33.8]	0.559
25.0 - < 30.0 kg/m**2	24	2 (8.3) [1.0, 27.0]	20	1 (5.0) [0.1, 24.9]	1.667 [0.163, 17.061]	1.727 [0.145, 20.578]	3.3 [-15.9, 22.5]	1.000
>= 30.0 kg/m**2	27	7 (25.9) [11.1, 46.3]	24	3 (12.5) [2.7, 32.4]	2.074 [0.603, 7.136]	2.450 [0.555, 10.813]	13.4 [-11.7, 38.5]	0.300
Baseline eosinophils - Low		n<10 all levels						NE
< 150 cells/uL	12	4 (33.3) [9.9, 65.1]	14	4 (28.6) [8.4, 58.1]				
>= 150 cells/uL	54	7 (13.0) [5.4, 24.9]	51	1 (2.0) [0.0, 10.4]				
Baseline eosinophils - High								0.338
< 300 cells/uL	34	6 (17.6) [6.8, 34.5]	34	4 (11.8) [3.3, 27.5]	1.500 [0.464, 4.845]	1.607 [0.410, 6.299]	5.9 [-13.8, 25.6]	0.734
>= 300 cells/uL	32	5 (15.6) [5.3, 32.8]	31	1 (3.2) [0.1, 16.7]	4.844 [0.599, 39.140]	5.556 [0.610, 50.597]	12.4 [-4.8, 29.6]	0.196

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.099
< 25 ppb	39	10 (25.6) [13.0, 42.1]	30	2 (6.7) [0.8, 22.1]	3.846 [0.910, 16.260]	4.828 [0.970, 24.020]	19.0 [-0.3, 38.3]	0.055
>= 25 ppb	27	1 (3.7) [0.1, 19.0]	34	3 (8.8) [1.9, 23.7]	0.420 [0.046, 3.811]	0.397 [0.039, 4.054]	-5.1 [-20.3, 10.1]	0.623
Baseline specific perennial FEIA status		n<10 all levels						NE
All negative	27	5 (18.5) [6.3, 38.1]	29	2 (6.9) [0.8, 22.8]				
Any positive	34	5 (14.7) [5.0, 31.1]	34	3 (8.8) [1.9, 23.7]				
Total serum IgE								0.337
Low	23	5 (21.7) [7.5, 43.7]	14	0 (0.0) [0.0, 23.2]	6.875 + [0.409, 115.603]	8.622 + [0.440, 168.988]	21.7 [-0.9, 44.3]	0.135
Normal	40	5 (12.5) [4.2, 26.8]	44	5 (11.4) [3.8, 24.6]	1.100 [0.344, 3.520]	1.114 [0.297, 4.175]	1.1 [-15.1, 17.4]	1.000
High	3	1 (33.3) [0.8, 90.6]	7	0 (0.0) [0.0, 41.0]	6.000 + [0.309, 116.606]	9.000 + [0.270, 299.860]	33.3 [-43.8, 100.0]	0.300
OCS at baseline								0.789
Yes	9	2 (22.2) [2.8, 60.0]	13	1 (7.7) [0.2, 36.0]	2.889 [0.306, 27.271]	3.429 [0.261, 45.026]	14.5 [-25.7, 54.7]	0.544
No	57	9 (15.8) [7.5, 27.9]	52	4 (7.7) [2.1, 18.5]	2.053 [0.672, 6.267]	2.250 [0.649, 7.805]	8.1 [-5.7, 21.9]	0.244

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
LAMA use at baseline								0.383	
Yes	7	2 (28.6) [3.7, 71.0]	3	1 (33.3) [0.8, 90.6]	0.857 [0.118, 6.228]	0.800 [0.044, 14.643]	-4.8 [-91.5, 82.0]	1.000	
No	59	9 (15.3) [7.2, 27.0]	62	4 (6.5) [1.8, 15.7]	2.364 [0.769, 7.265]	2.610 [0.758, 8.992]	8.8 [-3.9, 21.5]	0.148	
Tiotropium use at baseline		N<10 any level						NE	
Yes	6	2 (33.3) [4.3, 77.7]	2	1 (50.0) [1.3, 98.7]					
No	60	9 (15.0) [7.1, 26.6]	63	4 (6.3) [1.8, 15.5]					
Montelukast/ Cromoglicic acid use at baseline								0.147	
Yes	17	5 (29.4) [10.3, 56.0]	21	5 (23.8) [8.2, 47.2]	1.235 [0.427, 3.572]	1.333 [0.313, 5.673]	5.6 [-28.0, 39.2]	0.727	
No	49	6 (12.2) [4.6, 24.8]	44	0 (0.0) [0.0, 8.0]	11.700 + [0.678, 201.885]	13.299 + [0.727, 243.305]	12.2 [0.9, 23.6]	0.028	*

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	25	4 (16.0) [4.5, 36.1]	31	3 (9.7) [2.0, 25.8]				
Female	48	5 (10.4) [3.5, 22.7]	45	4 (8.9) [2.5, 21.2]				
Age								0.233
< 65 years	58	5 (8.6) [2.9, 19.0]	62	6 (9.7) [3.6, 19.9]	0.891 [0.287, 2.762]	0.881 [0.254, 3.057]	-1.1 [-13.0, 10.9]	1.000
>= 65 years	15	4 (26.7) [7.8, 55.1]	14	1 (7.1) [0.2, 33.9]	3.733 [0.473, 29.489]	4.727 [0.458, 48.771]	19.5 [-13.5, 52.6]	0.330
Exacerbations in the year before study								0.832
<= 2	60	7 (11.7) [4.8, 22.6]	55	5 (9.1) [3.0, 20.0]	1.283 [0.432, 3.808]	1.321 [0.393, 4.433]	2.6 [-10.3, 15.4]	0.765
> 2	13	2 (15.4) [1.9, 45.4]	21	2 (9.5) [1.2, 30.4]	1.615 [0.258, 10.109]	1.727 [0.212, 14.048]	5.9 [-23.7, 35.4]	0.627
Race		N<10 any level						NE
White	61	8 (13.1) [5.8, 24.2]	64	6 (9.4) [3.5, 19.3]				
Black or African American	1	0 (0.0) [0.0, 97.5]	0					
Asian	11	1 (9.1) [0.2, 41.3]	11	0 (0.0) [0.0, 28.5]				
Other	0		1	1 (100.0) [2.5, 100.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		n<10 all levels						NE
Europe	27	5 (18.5) [6.3, 38.1]	32	3 (9.4) [2.0, 25.0]				
America	21	3 (14.3) [3.0, 36.3]	17	4 (23.5) [6.8, 49.9]				
Asia/Pacific	11	1 (9.1) [0.2, 41.3]	10	0 (0.0) [0.0, 30.8]				
Rest of the world	14	0 (0.0) [0.0, 23.2]	17	0 (0.0) [0.0, 19.5]				
BMI		n<10 all levels						NE
18.5 - < 25.0 kg/m**2	20	1 (5.0) [0.1, 24.9]	23	3 (13.0) [2.8, 33.6]				
25.0 - < 30.0 kg/m**2	22	3 (13.6) [2.9, 34.9]	24	1 (4.2) [0.1, 21.1]				
>= 30.0 kg/m**2	31	5 (16.1) [5.5, 33.7]	29	3 (10.3) [2.2, 27.4]				
Baseline eosinophils - Low								0.866
< 150 cells/uL	27	6 (22.2) [8.6, 42.3]	24	4 (16.7) [4.7, 37.4]	1.333 [0.427, 4.167]	1.429 [0.350, 5.825]	5.6 [-20.0, 31.1]	0.731
>= 150 cells/uL	46	3 (6.5) [1.4, 17.9]	52	3 (5.8) [1.2, 15.9]	1.130 [0.240, 5.328]	1.140 [0.218, 5.945]	0.8 [-10.8, 12.3]	1.000
Baseline eosinophils - High								0.511
< 300 cells/uL	46	6 (13.0) [4.9, 26.3]	52	4 (7.7) [2.1, 18.5]	1.696 [0.510, 5.637]	1.800 [0.475, 6.826]	5.4 [-8.8, 19.5]	0.508
>= 300 cells/uL	27	3 (11.1) [2.4, 29.2]	24	3 (12.5) [2.7, 32.4]	0.889 [0.198, 3.995]	0.875 [0.159, 4.809]	-1.4 [-23.1, 20.3]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO		n<10 all levels						NE
< 25 ppb	31	5 (16.1) [5.5, 33.7]	26	2 (7.7) [0.9, 25.1]				
>= 25 ppb	36	4 (11.1) [3.1, 26.1]	43	4 (9.3) [2.6, 22.1]				
Baseline specific perennial FEIA status								0.074
All negative	43	8 (18.6) [8.4, 33.4]	39	2 (5.1) [0.6, 17.3]	3.628 [0.820, 16.059]	4.229 [0.839, 21.302]	13.5 [-2.5, 29.5]	0.092
Any positive	25	1 (4.0) [0.1, 20.4]	34	4 (11.8) [3.3, 27.5]	0.340 [0.040, 2.860]	0.313 [0.033, 2.983]	-7.8 [-24.5, 9.0]	0.384
Total serum IgE		N<10 any level						NE
Low	30	4 (13.3) [3.8, 30.7]	31	4 (12.9) [3.6, 29.8]				
Normal	39	4 (10.3) [2.9, 24.2]	43	3 (7.0) [1.5, 19.1]				
High	3	1 (33.3) [0.8, 90.6]	2	0 (0.0) [0.0, 84.2]				
LAMA use at baseline								0.656
Yes	34	3 (8.8) [1.9, 23.7]	40	2 (5.0) [0.6, 16.9]	1.765 [0.313, 9.952]	1.839 [0.289, 11.706]	3.8 [-10.6, 18.2]	0.656
No	39	6 (15.4) [5.9, 30.5]	36	5 (13.9) [4.7, 29.5]	1.108 [0.370, 3.318]	1.127 [0.312, 4.071]	1.5 [-17.2, 20.2]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAC_SLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline								0.656
Yes	34	3 (8.8) [1.9, 23.7]	40	2 (5.0) [0.6, 16.9]	1.765 [0.313, 9.952]	1.839 [0.289, 11.706]	3.8 [-10.6, 18.2]	0.656
No	39	6 (15.4) [5.9, 30.5]	36	5 (13.9) [4.7, 29.5]	1.108 [0.370, 3.318]	1.127 [0.312, 4.071]	1.5 [-17.2, 20.2]	1.000
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	30	4 (13.3) [3.8, 30.7]	37	3 (8.1) [1.7, 21.9]				
No	43	5 (11.6) [3.9, 25.1]	39	4 (10.3) [2.9, 24.2]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table DT1AAC_ULSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.738
Male	115	8 (7.0) [3.1, 13.2]	56	3 (5.4) [1.1, 14.9]	1.299 [0.358, 4.707]	1.321 [0.337, 5.183]	1.6 [-7.2, 10.4]	1.000
Female	195	19 (9.7) [6.0, 14.8]	93	9 (9.7) [4.5, 17.6]	1.007 [0.474, 2.139]	1.008 [0.437, 2.321]	0.1 [-8.0, 8.2]	1.000
Age								0.217
< 65 years	250	21 (8.4) [5.3, 12.6]	127	8 (6.3) [2.8, 12.0]	1.334 [0.608, 2.926]	1.364 [0.587, 3.172]	2.1 [-3.9, 8.1]	0.544
>= 65 years	60	6 (10.0) [3.8, 20.5]	22	4 (18.2) [5.2, 40.3]	0.550 [0.171, 1.767]	0.500 [0.127, 1.974]	-8.2 [-29.1, 12.7]	0.446
Exacerbations in the year before study								0.847
<= 2	173	14 (8.1) [4.5, 13.2]	88	7 (8.0) [3.3, 15.7]	1.017 [0.426, 2.429]	1.019 [0.396, 2.624]	0.1 [-7.7, 8.0]	1.000
> 2	137	13 (9.5) [5.1, 15.7]	61	5 (8.2) [2.7, 18.1]	1.158 [0.432, 3.104]	1.174 [0.399, 3.453]	1.3 [-8.3, 10.9]	1.000
Race								0.242
White	226	17 (7.5) [4.4, 11.8]	99	11 (11.1) [5.7, 19.0]	0.677 [0.329, 1.392]	0.651 [0.293, 1.446]	-3.6 [-11.4, 4.2]	0.290
Black or African American	16	4 (25.0) [7.3, 52.4]	14	0 (0.0) [0.0, 23.2]	7.941 + [0.465, 135.654]	10.440 + [0.510, 213.519]	25.0 [-2.9, 52.9]	0.103
Asian	56	4 (7.1) [2.0, 17.3]	30	0 (0.0) [0.0, 11.6]	4.895 + [0.272, 87.968]	5.229 + [0.272, 100.460]	7.1 [-2.2, 16.4]	0.293
Other	12	2 (16.7) [2.1, 48.4]	6	1 (16.7) [0.4, 64.1]	1.000 [0.112, 8.947]	1.000 [0.072, 13.868]	0.0 [-49.0, 49.0]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_ULSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.429
Europe	53	7 (13.2) [5.5, 25.3]	24	3 (12.5) [2.7, 32.4]	1.057 [0.299, 3.738]	1.065 [0.250, 4.531]	0.7 [-18.4, 19.8]	1.000
America	133	9 (6.8) [3.1, 12.5]	62	7 (11.3) [4.7, 21.9]	0.599 [0.234, 1.535]	0.570 [0.202, 1.609]	-4.5 [-14.7, 5.6]	0.279
Asia/Pacific	52	4 (7.7) [2.1, 18.5]	26	0 (0.0) [0.0, 13.2]	4.585 + [0.256, 82.066]	4.918 + [0.255, 94.885]	7.7 [-2.4, 17.8]	0.295
Rest of the world	72	7 (9.7) [4.0, 19.0]	37	2 (5.4) [0.7, 18.2]	1.799 [0.393, 8.229]	1.885 [0.371, 9.564]	4.3 [-7.7, 16.4]	0.715
BMI		N<10 any level						NE
< 18.5 kg/m**2	4	0 (0.0) [0.0, 60.2]	2	0 (0.0) [0.0, 84.2]				
18.5 - < 25.0 kg/m**2	83	2 (2.4) [0.3, 8.4]	45	2 (4.4) [0.5, 15.1]				
25.0 - < 30.0 kg/m**2	104	10 (9.6) [4.7, 17.0]	48	4 (8.3) [2.3, 20.0]				
>= 30.0 kg/m**2	119	15 (12.6) [7.2, 19.9]	54	6 (11.1) [4.2, 22.6]				
Baseline eosinophils - Low								0.431
< 150 cells/uL	74	10 (13.5) [6.7, 23.5]	36	3 (8.3) [1.8, 22.5]	1.622 [0.475, 5.532]	1.719 [0.443, 6.676]	5.2 [-8.8, 19.2]	0.540
>= 150 cells/uL	236	17 (7.2) [4.3, 11.3]	113	9 (8.0) [3.7, 14.6]	0.904 [0.416, 1.966]	0.897 [0.387, 2.080]	-0.8 [-7.4, 5.9]	0.829
Baseline eosinophils - High								0.892
< 300 cells/uL	180	18 (10.0) [6.0, 15.3]	83	8 (9.6) [4.3, 18.1]	1.038 [0.470, 2.289]	1.042 [0.434, 2.503]	0.4 [-8.2, 9.0]	1.000
>= 300 cells/uL	130	9 (6.9) [3.2, 12.7]	66	4 (6.1) [1.7, 14.8]	1.142 [0.365, 3.571]	1.153 [0.341, 3.893]	0.9 [-7.5, 9.2]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_ULSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.982
< 25 ppb	127	13 (10.2) [5.6, 16.9]	64	6 (9.4) [3.5, 19.3]	1.092 [0.435, 2.738]	1.102 [0.398, 3.050]	0.9 [-9.2, 10.9]	1.000
>= 25 ppb	180	14 (7.8) [4.3, 12.7]	83	6 (7.2) [2.7, 15.1]	1.076 [0.429, 2.701]	1.082 [0.401, 2.924]	0.5 [-7.1, 8.2]	1.000
Baseline specific perennial FEIA status								0.352
All negative	116	12 (10.3) [5.5, 17.4]	53	7 (13.2) [5.5, 25.3]	0.783 [0.327, 1.876]	0.758 [0.280, 2.050]	-2.9 [-14.9, 9.2]	0.605
Any positive	193	15 (7.8) [4.4, 12.5]	94	5 (5.3) [1.7, 12.0]	1.461 [0.547, 3.900]	1.500 [0.528, 4.259]	2.5 [-4.2, 9.1]	0.622
Total serum IgE								0.967
Low	93	11 (11.8) [6.1, 20.2]	49	6 (12.2) [4.6, 24.8]	0.966 [0.380, 2.455]	0.961 [0.333, 2.778]	-0.4 [-13.3, 12.4]	1.000
Normal	193	16 (8.3) [4.8, 13.1]	81	6 (7.4) [2.8, 15.4]	1.119 [0.454, 2.757]	1.130 [0.426, 3.000]	0.9 [-6.9, 8.7]	1.000
High	24	0 (0.0) [0.0, 14.2]	19	0 (0.0) [0.0, 17.6]	0.800 + [0.017, 38.568]	0.796 + [0.015, 41.953]	-0.5 + [-13.8, 12.8]	NE
OCS at baseline								0.640
Yes	28	4 (14.3) [4.0, 32.7]	12	1 (8.3) [0.2, 38.5]	1.714 [0.213, 13.782]	1.833 [0.183, 18.370]	6.0 [-20.3, 32.2]	1.000
No	282	23 (8.2) [5.2, 12.0]	137	11 (8.0) [4.1, 13.9]	1.016 [0.510, 2.023]	1.017 [0.481, 2.152]	0.1 [-6.0, 6.2]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_ULSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.120
Yes	83	11 (13.3) [6.8, 22.5]	42	2 (4.8) [0.6, 16.2]	2.783 [0.646, 11.987]	3.056 [0.645, 14.474]	8.5 [-3.0, 20.0]	0.216
No	227	16 (7.0) [4.1, 11.2]	107	10 (9.3) [4.6, 16.5]	0.754 [0.354, 1.606]	0.736 [0.322, 1.680]	-2.3 [-9.4, 4.8]	0.513
Tiotropium use at baseline								0.153
Yes	76	10 (13.2) [6.5, 22.9]	40	2 (5.0) [0.6, 16.9]	2.632 [0.606, 11.435]	2.879 [0.599, 13.834]	8.2 [-3.9, 20.2]	0.214
No	234	17 (7.3) [4.3, 11.4]	109	10 (9.2) [4.5, 16.2]	0.792 [0.375, 1.672]	0.776 [0.343, 1.755]	-1.9 [-8.9, 5.1]	0.526
Montelukast/ Cromoglicic acid use at baseline								0.818
Yes	123	11 (8.9) [4.5, 15.4]	55	5 (9.1) [3.0, 20.0]	0.984 [0.359, 2.696]	0.982 [0.324, 2.976]	-0.1 [-10.6, 10.3]	1.000
No	187	16 (8.6) [5.0, 13.5]	94	7 (7.4) [3.0, 14.7]	1.149 [0.490, 2.696]	1.163 [0.461, 2.932]	1.1 [-6.3, 8.6]	0.822

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table NT1AAC_SLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.712
Western Europe	72	7 (9.7) [4.0, 19.0]	72	9 (12.5) [5.9, 22.4]	0.778 [0.306, 1.976]	0.754 [0.265, 2.147]	-2.8 [-14.4, 8.9]	0.792
North America	77	7 (9.1) [3.7, 17.8]	77	5 (6.5) [2.1, 14.5]	1.400 [0.464, 4.220]	1.440 [0.436, 4.752]	2.6 [-7.2, 12.4]	0.765
South America	74	3 (4.1) [0.8, 11.4]	75	1 (1.3) [0.0, 7.2]	3.041 [0.324, 28.569]	3.127 [0.318, 30.768]	2.7 [-3.8, 9.3]	0.367
Central/Eastern Europe	20	0 (0.0) [0.0, 16.8]	18	1 (5.6) [0.1, 27.3]	0.302 + [0.013, 6.967]	0.285 + [0.011, 7.439]	-5.6 [-21.4, 10.3]	0.474
Asia Pacific	98	4 (4.1) [1.1, 10.1]	94	3 (3.2) [0.7, 9.0]	1.279 [0.294, 5.562]	1.291 [0.281, 5.928]	0.9 [-5.4, 7.2]	1.000
Rest of the world	54	6 (11.1) [4.2, 22.6]	55	3 (5.5) [1.1, 15.1]	2.037 [0.537, 7.734]	2.167 [0.513, 9.148]	5.7 [-6.5, 17.8]	0.320
Baseline eosinophils (cat. N)								0.819
< 150 cells/uL	96	10 (10.4) [5.1, 18.3]	89	8 (9.0) [4.0, 16.9]	1.159 [0.479, 2.805]	1.177 [0.443, 3.131]	1.4 [-8.2, 11.0]	0.808
150 - < 300 cells/uL	129	6 (4.7) [1.7, 9.8]	122	6 (4.9) [1.8, 10.4]	0.946 [0.313, 2.853]	0.943 [0.296, 3.007]	-0.3 [-6.3, 5.8]	1.000
300 - < 450 cells/uL	70	3 (4.3) [0.9, 12.0]	75	1 (1.3) [0.0, 7.2]	3.214 [0.342, 30.181]	3.313 [0.336, 32.628]	3.0 [-3.8, 9.7]	0.353
>= 450 cells/uL	100	8 (8.0) [3.5, 15.2]	105	7 (6.7) [2.7, 13.3]	1.200 [0.452, 3.187]	1.217 [0.425, 3.491]	1.3 [-6.8, 9.5]	0.792
Baseline eosinophils (cat. Q)								0.688
Q1: < 140 cells/uL	89	10 (11.2) [5.5, 19.7]	81	6 (7.4) [2.8, 15.4]	1.517 [0.577, 3.987]	1.582 [0.548, 4.568]	3.8 [-6.0, 13.7]	0.441
Q2: 140 - < 250 cells/uL	99	2 (2.0) [0.2, 7.1]	94	4 (4.3) [1.2, 10.5]	0.475 [0.089, 2.531]	0.464 [0.083, 2.595]	-2.2 [-8.2, 3.7]	0.435
Q3: 250 - < 430 cells/uL	103	7 (6.8) [2.8, 13.5]	103	5 (4.9) [1.6, 11.0]	1.400 [0.459, 4.268]	1.429 [0.438, 4.659]	1.9 [-5.4, 9.3]	0.768
Q4: >= 430 cells/uL	104	8 (7.7) [3.4, 14.6]	113	7 (6.2) [2.5, 12.3]	1.242 [0.467, 3.305]	1.262 [0.441, 3.611]	1.5 [-6.2, 9.2]	0.791

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAC_SLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline FENO (cat. N)								0.056	
< 25 ppb	158	12 (7.6) [4.0, 12.9]	151	8 (5.3) [2.3, 10.2]	1.434 [0.603, 3.409]	1.469 [0.583, 3.701]	2.3 [-3.8, 8.4]	0.491	
25 - < 50 ppb	114	9 (7.9) [3.7, 14.5]	116	2 (1.7) [0.2, 6.1]	4.579 [1.011, 20.732]	4.886 [1.032, 23.133]	6.2 [-0.2, 12.5]	0.033	*
>= 50 ppb	120	6 (5.0) [1.9, 10.6]	120	11 (9.2) [4.7, 15.8]	0.545 [0.208, 1.427]	0.522 [0.186, 1.459]	-4.2 [-11.5, 3.1]	0.314	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAC_SLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.096
Q1: < 16 ppb	94	6 (6.4) [2.4, 13.4]	85	7 (8.2) [3.4, 16.2]	0.775 [0.271, 2.215]	0.760 [0.245, 2.357]	-1.9 [-10.6, 6.9]	0.775
Q2: 16 - < 30 ppb	88	6 (6.8) [2.5, 14.3]	99	1 (1.0) [0.0, 5.5]	6.750 [0.829, 54.981]	7.171 [0.846, 60.779]	5.8 [-0.9, 12.5]	0.053
Q3: 30 - < 56 ppb	106	10 (9.4) [4.6, 16.7]	96	4 (4.2) [1.1, 10.3]	2.264 [0.734, 6.982]	2.396 [0.726, 7.909]	5.3 [-2.6, 13.1]	0.172
Q4: >= 56 ppb	104	5 (4.8) [1.6, 10.9]	107	9 (8.4) [3.9, 15.4]	0.572 [0.198, 1.649]	0.550 [0.178, 1.700]	-3.6 [-11.2, 4.0]	0.408
Total serum IgE (cat. N)								0.892
Q1: < 53.1 IU/ml	94	9 (9.6) [4.5, 17.4]	99	7 (7.1) [2.9, 14.0]	1.354 [0.526, 3.489]	1.392 [0.496, 3.901]	2.5 [-6.3, 11.3]	0.607
Q2: 53.1 - < 195.6 IU/ml	101	7 (6.9) [2.8, 13.8]	101	7 (6.9) [2.8, 13.8]	1.000 [0.364, 2.747]	1.000 [0.338, 2.962]	0.0 [-8.0, 8.0]	1.000
Q3: 195.6 - < 572.4 IU/ml	108	10 (9.3) [4.5, 16.4]	87	6 (6.9) [2.6, 14.4]	1.343 [0.508, 3.549]	1.378 [0.480, 3.953]	2.4 [-6.3, 11.0]	0.609
Q4: >= 572.4 IU/ml	92	1 (1.1) [0.0, 5.9]	104	2 (1.9) [0.2, 6.8]	0.565 [0.052, 6.132]	0.560 [0.050, 6.284]	-0.8 [-5.2, 3.6]	1.000
Nasal polyps last 2 years								0.858
Yes	33	3 (9.1) [1.9, 24.3]	31	2 (6.5) [0.8, 21.4]	1.409 [0.252, 7.875]	1.450 [0.226, 9.320]	2.6 [-13.6, 18.8]	1.000
No	362	24 (6.6) [4.3, 9.7]	360	20 (5.6) [3.4, 8.4]	1.193 [0.671, 2.121]	1.207 [0.654, 2.226]	1.1 [-2.7, 4.8]	0.641

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAC_TLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL - adult

	Tezepelumab		Placebo					
Non-disease related severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.617
Western Europe	71	7 (9.9) [4.1, 19.3]	71	9 (12.7) [6.0, 22.7]	0.778 [0.306, 1.974]	0.753 [0.264, 2.148]	-2.8 [-14.6, 9.0]	0.792
North America	75	7 (9.3) [3.8, 18.3]	71	5 (7.0) [2.3, 15.7]	1.325 [0.441, 3.985]	1.359 [0.411, 4.496]	2.3 [-8.0, 12.5]	0.766
South America	65	3 (4.6) [1.0, 12.9]	63	0 (0.0) [0.0, 5.7]	6.788 + [0.358, 128.806]	7.112 + [0.360, 140.538]	4.6 [-2.0, 11.3]	0.244
Central/Eastern Europe	19	0 (0.0) [0.0, 17.6]	18	1 (5.6) [0.1, 27.3]	0.317 + [0.014, 7.305]	0.299 + [0.011, 7.832]	-5.6 [-21.5, 10.4]	0.486
Asia Pacific	97	4 (4.1) [1.1, 10.2]	93	3 (3.2) [0.7, 9.1]	1.278 [0.294, 5.558]	1.290 [0.281, 5.928]	0.9 [-5.5, 7.3]	1.000
Rest of the world	53	6 (11.3) [4.3, 23.0]	55	3 (5.5) [1.1, 15.1]	2.075 [0.547, 7.876]	2.213 [0.524, 9.348]	5.9 [-6.4, 18.1]	0.316
Baseline eosinophils (cat. N)								0.686
< 150 cells/uL	95	10 (10.5) [5.2, 18.5]	87	8 (9.2) [4.1, 17.3]	1.145 [0.473, 2.768]	1.162 [0.437, 3.092]	1.3 [-8.4, 11.1]	0.808
150 - < 300 cells/uL	121	6 (5.0) [1.8, 10.5]	120	6 (5.0) [1.9, 10.6]	0.992 [0.329, 2.988]	0.991 [0.310, 3.165]	-0.0 [-6.4, 6.3]	1.000
300 - < 450 cells/uL	70	3 (4.3) [0.9, 12.0]	69	0 (0.0) [0.0, 5.2]	6.901 + [0.363, 131.166]	7.207 + [0.365, 142.190]	4.3 [-1.9, 10.5]	0.245
>= 450 cells/uL	94	8 (8.5) [3.7, 16.1]	95	7 (7.4) [3.0, 14.6]	1.155 [0.436, 3.057]	1.169 [0.406, 3.365]	1.1 [-7.6, 9.9]	0.795
Baseline eosinophils (cat. Q)								0.665
Q1: < 140 cells/uL	89	10 (11.2) [5.5, 19.7]	79	6 (7.6) [2.8, 15.8]	1.479 [0.563, 3.886]	1.540 [0.533, 4.450]	3.6 [-6.3, 13.6]	0.446
Q2: 140 - < 250 cells/uL	93	2 (2.2) [0.3, 7.6]	92	4 (4.3) [1.2, 10.8]	0.495 [0.093, 2.635]	0.484 [0.086, 2.707]	-2.2 [-8.4, 4.0]	0.444
Q3: 250 - < 430 cells/uL	100	7 (7.0) [2.9, 13.9]	98	4 (4.1) [1.1, 10.1]	1.715 [0.518, 5.674]	1.769 [0.501, 6.245]	2.9 [-4.4, 10.3]	0.537
Q4: >= 430 cells/uL	98	8 (8.2) [3.6, 15.5]	102	7 (6.9) [2.8, 13.6]	1.190 [0.448, 3.156]	1.206 [0.420, 3.463]	1.3 [-7.0, 9.6]	0.793

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAC_TLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.090
< 25 ppb	155	12 (7.7) [4.1, 13.1]	145	8 (5.5) [2.4, 10.6]	1.403 [0.591, 3.334]	1.437 [0.570, 3.623]	2.2 [-4.1, 8.5]	0.494
25 - < 50 ppb	111	9 (8.1) [3.8, 14.8]	109	2 (1.8) [0.2, 6.5]	4.419 [0.977, 19.987]	4.721 [0.996, 22.375]	6.3 [-0.3, 12.9]	0.059
>= 50 ppb	111	6 (5.4) [2.0, 11.4]	113	10 (8.8) [4.3, 15.7]	0.611 [0.230, 1.624]	0.589 [0.206, 1.679]	-3.4 [-11.1, 4.2]	0.438

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAC_TLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.071
Q1: < 16 ppb	93	6 (6.5) [2.4, 13.5]	81	7 (8.6) [3.5, 17.0]	0.747 [0.262, 2.131]	0.729 [0.235, 2.265]	-2.2 [-11.2, 6.9]	0.774
Q2: 16 - < 30 ppb	86	6 (7.0) [2.6, 14.6]	96	1 (1.0) [0.0, 5.7]	6.698 [0.823, 54.525]	7.125 [0.840, 60.425]	5.9 [-0.9, 12.8]	0.053
Q3: 30 - < 56 ppb	102	10 (9.8) [4.8, 17.3]	89	3 (3.4) [0.7, 9.5]	2.908 [0.826, 10.238]	3.116 [0.830, 11.703]	6.4 [-1.5, 14.4]	0.091
Q4: >= 56 ppb	96	5 (5.2) [1.7, 11.7]	101	9 (8.9) [4.2, 16.2]	0.584 [0.203, 1.682]	0.562 [0.181, 1.740]	-3.7 [-11.8, 4.4]	0.409
Total serum IgE (cat. N)								0.967
Q1: < 53.1 IU/ml	93	9 (9.7) [4.5, 17.6]	96	7 (7.3) [3.0, 14.4]	1.327 [0.516, 3.417]	1.362 [0.485, 3.822]	2.4 [-6.6, 11.4]	0.609
Q2: 53.1 - < 195.6 IU/ml	100	7 (7.0) [2.9, 13.9]	99	7 (7.1) [2.9, 14.0]	0.990 [0.361, 2.718]	0.989 [0.334, 2.932]	-0.1 [-8.2, 8.0]	1.000
Q3: 195.6 - < 572.4 IU/ml	103	10 (9.7) [4.8, 17.1]	85	6 (7.1) [2.6, 14.7]	1.375 [0.521, 3.630]	1.416 [0.493, 4.069]	2.6 [-6.3, 11.6]	0.605
Q4: >= 572.4 IU/ml	84	1 (1.2) [0.0, 6.5]	91	1 (1.1) [0.0, 6.0]	1.083 [0.069, 17.046]	1.084 [0.067, 17.615]	0.1 [-4.2, 4.4]	1.000
Nasal polyps last 2 years								0.922
Yes	32	3 (9.4) [2.0, 25.0]	29	2 (6.9) [0.8, 22.8]	1.359 [0.244, 7.570]	1.397 [0.216, 9.011]	2.5 [-14.5, 19.4]	1.000
No	348	24 (6.9) [4.5, 10.1]	342	19 (5.6) [3.4, 8.5]	1.241 [0.693, 2.224]	1.259 [0.677, 2.344]	1.3 [-2.6, 5.2]	0.530

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table DT1AAC_ULSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Age (cat. N)								0.499
< 18 years	14	0 (0.0) [0.0, 23.2]	12	0 (0.0) [0.0, 26.5]	0.867 + [0.018, 40.684]	0.862 + [0.016, 46.704]	-0.5 + [-21.5, 20.5]	NE
18 - < 65 years	236	21 (8.9) [5.6, 13.3]	115	8 (7.0) [3.1, 13.2]	1.279 [0.584, 2.799]	1.306 [0.560, 3.046]	1.9 [-4.6, 8.5]	0.680
>= 65 years	60	6 (10.0) [3.8, 20.5]	22	4 (18.2) [5.2, 40.3]	0.550 [0.171, 1.767]	0.500 [0.127, 1.974]	-8.2 [-29.1, 12.7]	0.446
Region (cat. N)								0.643
Western Europe	58	7 (12.1) [5.0, 23.3]	25	3 (12.0) [2.5, 31.2]	1.006 [0.283, 3.576]	1.007 [0.238, 4.257]	0.1 [-18.0, 18.2]	1.000
North America	62	4 (6.5) [1.8, 15.7]	26	4 (15.4) [4.4, 34.9]	0.419 [0.113, 1.551]	0.379 [0.087, 1.650]	-8.9 [-26.8, 9.0]	0.228
South America	71	5 (7.0) [2.3, 15.7]	36	3 (8.3) [1.8, 22.5]	0.845 [0.214, 3.339]	0.833 [0.188, 3.702]	-1.3 [-14.2, 11.6]	1.000
Central/Eastern Europe	20	0 (0.0) [0.0, 16.8]	12	0 (0.0) [0.0, 26.5]	0.619 + [0.013, 29.337]	0.610 + [0.011, 32.715]	-1.5 + [-20.0, 17.1]	NE
Asia Pacific	47	4 (8.5) [2.4, 20.4]	25	0 (0.0) [0.0, 13.7]	4.875 + [0.273, 87.062]	5.276 + [0.273, 102.053]	8.5 [-2.5, 19.6]	0.291
Rest of the world	52	7 (13.5) [5.6, 25.8]	25	2 (8.0) [1.0, 26.0]	1.683 [0.376, 7.521]	1.789 [0.344, 9.313]	5.5 [-11.6, 22.5]	0.710

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_ULSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline eosinophils (cat. N)								0.797	
< 150 cells/uL	74	10 (13.5) [6.7, 23.5]	36	3 (8.3) [1.8, 22.5]	1.622 [0.475, 5.532]	1.719 [0.443, 6.676]	5.2 [-8.8, 19.2]	0.540	
150 - < 300 cells/uL	106	8 (7.5) [3.3, 14.3]	47	5 (10.6) [3.5, 23.1]	0.709 [0.245, 2.054]	0.686 [0.212, 2.219]	-3.1 [-14.8, 8.6]	0.539	
300 - < 450 cells/uL	58	2 (3.4) [0.4, 11.9]	31	1 (3.2) [0.1, 16.7]	1.069 [0.101, 11.327]	1.071 [0.093, 12.306]	0.2 [-10.0, 10.5]	1.000	
>= 450 cells/uL	72	7 (9.7) [4.0, 19.0]	35	3 (8.6) [1.8, 23.1]	1.134 [0.312, 4.124]	1.149 [0.278, 4.739]	1.2 [-12.5, 14.8]	1.000	
Baseline eosinophils (cat. Q)								0.098	
Q1: < 140 cells/uL	67	10 (14.9) [7.4, 25.7]	33	2 (6.1) [0.7, 20.2]	2.463 [0.572, 10.603]	2.719 [0.560, 13.201]	8.9 [-5.2, 22.9]	0.327	
Q2: 140 - < 250 cells/uL	85	2 (2.4) [0.3, 8.2]	40	5 (12.5) [4.2, 26.8]	0.188 [0.038, 0.929]	0.169 [0.031, 0.911]	-10.1 [-22.7, 2.4]	0.034	*
Q3: 250 - < 430 cells/uL	83	8 (9.6) [4.3, 18.1]	37	2 (5.4) [0.7, 18.2]	1.783 [0.398, 7.994]	1.867 [0.377, 9.251]	4.2 [-7.4, 15.9]	0.722	
Q4: >= 430 cells/uL	75	7 (9.3) [3.8, 18.3]	39	3 (7.7) [1.6, 20.9]	1.213 [0.332, 4.434]	1.235 [0.301, 5.068]	1.6 [-11.0, 14.2]	1.000	

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_ULSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								1.000
< 25 ppb	127	13 (10.2) [5.6, 16.9]	64	6 (9.4) [3.5, 19.3]	1.092 [0.435, 2.738]	1.102 [0.398, 3.050]	0.9 [-9.2, 10.9]	1.000
25 - < 50 ppb	89	7 (7.9) [3.2, 15.5]	41	3 (7.3) [1.5, 19.9]	1.075 [0.293, 3.948]	1.081 [0.265, 4.412]	0.5 [-11.0, 12.1]	1.000
>= 50 ppb	91	7 (7.7) [3.1, 15.2]	42	3 (7.1) [1.5, 19.5]	1.077 [0.293, 3.960]	1.083 [0.266, 4.414]	0.5 [-10.7, 11.8]	1.000
Baseline FENO (cat. Q)								0.729
Q1: < 16 ppb	72	6 (8.3) [3.1, 17.3]	38	4 (10.5) [2.9, 24.8]	0.792 [0.238, 2.635]	0.773 [0.204, 2.925]	-2.2 [-15.9, 11.5]	0.735
Q2: 16 - < 30 ppb	74	8 (10.8) [4.8, 20.2]	38	4 (10.5) [2.9, 24.8]	1.027 [0.330, 3.194]	1.030 [0.289, 3.667]	0.3 [-13.8, 14.3]	1.000
Q3: 30 - < 56 ppb	83	6 (7.2) [2.7, 15.1]	37	3 (8.1) [1.7, 21.9]	0.892 [0.236, 3.373]	0.883 [0.209, 3.740]	-0.9 [-13.2, 11.5]	1.000
Q4: >= 56 ppb	78	7 (9.0) [3.7, 17.6]	34	1 (2.9) [0.1, 15.3]	3.051 [0.390, 23.850]	3.254 [0.384, 27.531]	6.0 [-4.6, 16.7]	0.431

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_ULSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Total serum IgE (cat. N)								0.823
Q1: < 53.1 IU/ml	75	7 (9.3) [3.8, 18.3]	36	4 (11.1) [3.1, 26.1]	0.840 [0.263, 2.686]	0.824 [0.225, 3.017]	-1.8 [-16.0, 12.5]	0.745
Q2: 53.1 - < 195.6 IU/ml	73	9 (12.3) [5.8, 22.1]	42	5 (11.9) [4.0, 25.6]	1.036 [0.372, 2.887]	1.041 [0.324, 3.339]	0.4 [-13.8, 14.7]	1.000
Q3: 195.6 - < 572.4 IU/ml	86	10 (11.6) [5.7, 20.3]	31	2 (6.5) [0.8, 21.4]	1.802 [0.418, 7.773]	1.908 [0.394, 9.238]	5.2 [-8.0, 18.4]	0.512
Q4: >= 572.4 IU/ml	76	1 (1.3) [0.0, 7.1]	40	1 (2.5) [0.1, 13.2]	0.526 [0.034, 8.194]	0.520 [0.032, 8.540]	-1.2 [-8.6, 6.2]	1.000
Nasal polyps last 2 years								0.755
Yes	28	3 (10.7) [2.3, 28.2]	14	1 (7.1) [0.2, 33.9]	1.500 [0.171, 13.142]	1.560 [0.147, 16.527]	3.6 [-19.5, 26.6]	1.000
No	282	24 (8.5) [5.5, 12.4]	135	11 (8.1) [4.1, 14.1]	1.044 [0.527, 2.069]	1.049 [0.498, 2.209]	0.4 [-5.8, 6.6]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table PT3AAC_SLSIP: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race (cat. P)								0.955
White	60	9 (15.0) [7.1, 26.6]	58	4 (6.9) [1.9, 16.7]	2.175 [0.709, 6.674]	2.382 [0.691, 8.219]	8.1 [-4.7, 20.9]	0.240
Non-white	6	2 (33.3) [4.3, 77.7]	7	1 (14.3) [0.4, 57.9]	2.333 [0.275, 19.802]	3.000 [0.199, 45.244]	19.0 [-42.2, 80.3]	0.559
Region (cat. P)								0.974
North America/Western EU	6	1 (16.7) [0.4, 64.1]	4	0 (0.0) [0.0, 60.2]	2.143 + [0.108, 42.518]	2.455 + [0.079, 76.132]	16.7 [-34.0, 67.3]	1.000
Rest of world	60	10 (16.7) [8.3, 28.5]	61	5 (8.2) [2.7, 18.1]	2.033 [0.739, 5.597]	2.240 [0.717, 6.999]	8.5 [-4.9, 21.8]	0.179
Baseline eosinophils (cat. P)		n<10 all levels						NE
< 250 cells/uL	30	5 (16.7) [5.6, 34.7]	29	2 (6.9) [0.8, 22.8]				
>= 250 cells/uL	36	6 (16.7) [6.4, 32.8]	36	3 (8.3) [1.8, 22.5]				
Baseline FENO (cat. P)								0.090
< 24 ppb	38	10 (26.3) [13.4, 43.1]	30	2 (6.7) [0.8, 22.1]	3.947 [0.935, 16.673]	5.000 [1.003, 24.914]	19.6 [0.1, 39.2]	0.053
>= 24 ppb	28	1 (3.6) [0.1, 18.3]	34	3 (8.8) [1.9, 23.7]	0.405 [0.045, 3.679]	0.383 [0.038, 3.899]	-5.3 [-20.3, 9.8]	0.620

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAC_SLSIP: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. M)								0.148
< 22.0 ppb	34	9 (26.5) [12.9, 44.4]	29	2 (6.9) [0.8, 22.8]	3.838 [0.900, 16.361]	4.860 [0.956, 24.703]	19.6 [-1.1, 40.2]	0.052
>= 22.0 ppb	32	2 (6.3) [0.8, 20.8]	35	3 (8.6) [1.8, 23.1]	0.729 [0.130, 4.087]	0.711 [0.111, 4.555]	-2.3 [-17.8, 13.2]	1.000
Baseline all FEIA status		n<10 all levels						NE
All negative	25	5 (20.0) [6.8, 40.7]	22	1 (4.5) [0.1, 22.8]				
Any positive	35	5 (14.3) [4.8, 30.3]	41	4 (9.8) [2.7, 23.1]				
Th2 status								0.478
Low	41	8 (19.5) [8.8, 34.9]	30	2 (6.7) [0.8, 22.1]	2.927 [0.669, 12.809]	3.394 [0.665, 17.310]	12.8 [-5.1, 30.8]	0.174
High	25	3 (12.0) [2.5, 31.2]	34	3 (8.8) [1.9, 23.7]	1.360 [0.299, 6.185]	1.409 [0.260, 7.644]	3.2 [-16.2, 22.6]	0.691
Baseline Periostin		n<10 all levels						NE
Low (< 20.9 ng/ml)	27	4 (14.8) [4.2, 33.7]	32	4 (12.5) [3.5, 29.0]				
High (>= 20.9 ng/ml)	39	7 (17.9) [7.5, 33.5]	33	1 (3.0) [0.1, 15.8]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAC_SLSIP: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Current post-BD FEV1 reversibility								0.008	i
Yes	57	10 (17.5) [8.7, 29.9]	60	2 (3.3) [0.4, 11.5]	5.263 [1.205, 22.989]	6.170 [1.289, 29.544]	14.2 [1.6, 26.8]	0.014	*
No	9	1 (11.1) [0.3, 48.2]	5	3 (60.0) [14.7, 94.7]	0.185 [0.026, 1.343]	0.083 [0.005, 1.294]	-48.9 [-100.0, 14.3]	0.095	
Maintenance OCS use at baseline								0.622	
Yes	9	2 (22.2) [2.8, 60.0]	14	2 (14.3) [1.8, 42.8]	1.556 [0.264, 9.151]	1.714 [0.196, 15.019]	7.9 [-34.0, 49.8]	1.000	
No	57	9 (15.8) [7.5, 27.9]	51	3 (5.9) [1.2, 16.2]	2.684 [0.768, 9.377]	3.000 [0.765, 11.765]	9.9 [-3.4, 23.2]	0.131	
No chronic OCS use and current post-BD FEV1 reversibility								0.226	
Yes	51	8 (15.7) [7.0, 28.6]	49	2 (4.1) [0.5, 14.0]	3.843 [0.858, 17.208]	4.372 [0.879, 21.736]	11.6 [-1.8, 25.0]	0.092	
No	15	3 (20.0) [4.3, 48.1]	16	3 (18.8) [4.0, 45.6]	1.067 [0.253, 4.488]	1.083 [0.182, 6.439]	1.3 [-33.1, 35.6]	1.000	

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAC_SLSIS: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFL

Non-disease related severe TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. S)								0.629
Western Europe/North America	22	6 (27.3) [10.7, 50.2]	24	6 (25.0) [9.8, 46.7]	1.091 [0.413, 2.885]	1.125 [0.301, 4.198]	2.3 [-27.5, 32.1]	1.000
Central/Eastern Europe	30	1 (3.3) [0.1, 17.2]	31	1 (3.2) [0.1, 16.7]	1.033 [0.068, 15.780]	1.034 [0.062, 17.328]	0.1 [-12.1, 12.3]	1.000
Rest of world	21	2 (9.5) [1.2, 30.4]	21	0 (0.0) [0.0, 16.1]	5.000 + [0.254, 98.272]	5.513 + [0.249, 122.081]	9.5 [-7.8, 26.8]	0.488
BMI (cat. S)		n<10 all levels						NE
< 30 kg/m**2	42	4 (9.5) [2.7, 22.6]	47	4 (8.5) [2.4, 20.4]				
>= 30.0 kg/m**2	31	5 (16.1) [5.5, 33.7]	29	3 (10.3) [2.2, 27.4]				
OCS dose at baseline								0.587
<= 10 mg	56	7 (12.5) [5.2, 24.1]	56	6 (10.7) [4.0, 21.9]	1.167 [0.418, 3.254]	1.190 [0.373, 3.795]	1.8 [-11.9, 15.4]	1.000
> 10 mg	17	2 (11.8) [1.5, 36.4]	20	1 (5.0) [0.1, 24.9]	2.353 [0.233, 23.746]	2.533 [0.209, 30.680]	6.8 [-16.7, 30.3]	0.584

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table MT1AAS_SLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	446	40 (9.0) [6.5, 12.0]	436	31 (7.1) [4.9, 9.9]	1.261 [0.804, 1.978]	1.287 [0.790, 2.098]	1.9 [-2.0, 5.7]	0.325

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 02FEB2022

Table NT1AAS_SLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	395	33 (8.4) [5.8, 11.5]	391	26 (6.6) [4.4, 9.6]	1.256 [0.766, 2.060]	1.280 [0.750, 2.183]	1.7 [-2.2, 5.6]	0.417

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAS_TLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL - adult

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	380	33 (8.7) [6.1, 12.0]	371	26 (7.0) [4.6, 10.1]	1.239 [0.756, 2.030]	1.262 [0.739, 2.155]	1.7 [-2.4, 5.8]	0.418

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table NT1AAS_JLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL - adolescents

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	15	0 (0.0) [0.0, 21.8]	20	0 (0.0) [0.0, 16.8]				

Note: DSAFL - adolescents = Dossier Label Safety Set - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 01FEB2022

Table PT3AAS_SLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	66	7 (10.6) [4.4, 20.6]	65	5 (7.7) [2.5, 17.0]	1.379 [0.461, 4.123]	1.424 [0.428, 4.739]	2.9 [-8.5, 14.3]	0.763

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table ST1AAS_SLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	73	8 (11.0) [4.9, 20.5]	76	7 (9.2) [3.8, 18.1]	1.190 [0.455, 3.114]	1.213 [0.416, 3.535]	1.7 [-9.3, 12.8]	0.790

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: AAE, created on: 07FEB2022

Table DT1AAS_ULMI0: Incidence of non-disease related serious TEAEs during study period
DSAFNL - LTE

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	310	43 (13.9) [10.2, 18.2]	149	16 (10.7) [6.3, 16.9]	1.292 [0.753, 2.216]	1.339 [0.727, 2.465]	3.1 [-3.7, 9.9]	0.376

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table CT1AAS_SLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFL

	Tezepelumab		Placebo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	31	0 (0.0) [0.0, 11.2]	34	3 (8.8) [1.9, 23.7]	0.156 + [0.008, 2.909]	0.143 + [0.007, 2.881]	-8.8 [-21.4, 3.8]	0.240

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: ASL, created on: 07FEB2022

Table MT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.957
Male	154	16 (10.4) [6.1, 16.3]	156	13 (8.3) [4.5, 13.8]	1.247 [0.621, 2.504]	1.275 [0.592, 2.750]	2.1 [-5.1, 9.2]	0.564
Female	292	24 (8.2) [5.3, 12.0]	280	18 (6.4) [3.9, 10.0]	1.279 [0.710, 2.304]	1.303 [0.691, 2.458]	1.8 [-2.8, 6.4]	0.428
Age								0.589
< 65 years	361	31 (8.6) [5.9, 12.0]	373	27 (7.2) [4.8, 10.4]	1.186 [0.723, 1.947]	1.204 [0.703, 2.061]	1.3 [-2.8, 5.5]	0.584
>= 65 years	85	9 (10.6) [5.0, 19.2]	63	4 (6.3) [1.8, 15.5]	1.668 [0.538, 5.172]	1.747 [0.513, 5.951]	4.2 [-6.0, 14.5]	0.559
Exacerbations in the year before study								0.770
<= 2	248	14 (5.6) [3.1, 9.3]	259	13 (5.0) [2.7, 8.4]	1.125 [0.540, 2.344]	1.132 [0.521, 2.459]	0.6 [-3.7, 4.9]	0.844
> 2	198	26 (13.1) [8.8, 18.6]	177	18 (10.2) [6.1, 15.6]	1.291 [0.733, 2.274]	1.335 [0.705, 2.528]	3.0 [-4.1, 10.0]	0.423

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race								0.771
White	299	26 (8.7) [5.8, 12.5]	293	19 (6.5) [3.9, 9.9]	1.341 [0.759, 2.369]	1.373 [0.743, 2.540]	2.2 [-2.4, 6.8]	0.353
Black or African American	23	3 (13.0) [2.8, 33.6]	21	1 (4.8) [0.1, 23.8]	2.739 [0.308, 24.340]	3.000 [0.287, 31.347]	8.3 [-12.8, 29.3]	0.609
Asian	110	10 (9.1) [4.4, 16.1]	106	9 (8.5) [4.0, 15.5]	1.071 [0.453, 2.531]	1.078 [0.420, 2.767]	0.6 [-7.9, 9.1]	1.000
Other	14	1 (7.1) [0.2, 33.9]	16	2 (12.5) [1.6, 38.3]	0.571 [0.058, 5.647]	0.538 [0.043, 6.668]	-5.4 [-33.1, 22.4]	1.000
Region								0.749
Europe	104	17 (16.3) [9.8, 24.9]	96	9 (9.4) [4.4, 17.1]	1.744 [0.816, 3.724]	1.889 [0.799, 4.468]	7.0 [-3.2, 17.2]	0.206
America	146	8 (5.5) [2.4, 10.5]	138	8 (5.8) [2.5, 11.1]	0.945 [0.365, 2.449]	0.942 [0.344, 2.583]	-0.3 [-6.4, 5.8]	1.000
Asia/Pacific	107	11 (10.3) [5.2, 17.7]	107	10 (9.3) [4.6, 16.5]	1.100 [0.488, 2.481]	1.111 [0.451, 2.738]	0.9 [-8.0, 9.8]	1.000
Rest of the world	89	4 (4.5) [1.2, 11.1]	95	4 (4.2) [1.2, 10.4]	1.067 [0.275, 4.140]	1.071 [0.260, 4.416]	0.3 [-6.7, 7.3]	1.000
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	0 (0.0) [0.0, 70.8]	3	0 (0.0) [0.0, 70.8]				
18.5 - < 25.0 kg/m**2	124	9 (7.3) [3.4, 13.3]	129	9 (7.0) [3.2, 12.8]				
25.0 - < 30.0 kg/m**2	151	15 (9.9) [5.7, 15.9]	146	8 (5.5) [2.4, 10.5]				
>= 30.0 kg/m**2	168	16 (9.5) [5.5, 15.0]	158	14 (8.9) [4.9, 14.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils - Low								0.431
< 150 cells/uL	107	15 (14.0) [8.1, 22.1]	101	14 (13.9) [7.8, 22.2]	1.011 [0.515, 1.988]	1.013 [0.462, 2.222]	0.2 [-10.2, 10.5]	1.000
>= 150 cells/uL	339	25 (7.4) [4.8, 10.7]	335	17 (5.1) [3.0, 8.0]	1.453 [0.800, 2.641]	1.489 [0.789, 2.812]	2.3 [-1.6, 6.2]	0.265
Baseline eosinophils - High								0.262
< 300 cells/uL	250	21 (8.4) [5.3, 12.6]	241	20 (8.3) [5.1, 12.5]	1.012 [0.563, 1.819]	1.013 [0.535, 1.921]	0.1 [-5.2, 5.4]	1.000
>= 300 cells/uL	196	19 (9.7) [5.9, 14.7]	195	11 (5.6) [2.8, 9.9]	1.718 [0.840, 3.515]	1.796 [0.831, 3.881]	4.1 [-1.7, 9.8]	0.183
Baseline FENO								0.728
< 25 ppb	194	17 (8.8) [5.2, 13.7]	175	11 (6.3) [3.2, 11.0]	1.394 [0.672, 2.894]	1.432 [0.651, 3.148]	2.5 [-3.4, 8.4]	0.434
>= 25 ppb	249	23 (9.2) [5.9, 13.5]	256	20 (7.8) [4.8, 11.8]	1.182 [0.666, 2.098]	1.201 [0.642, 2.247]	1.4 [-3.8, 6.7]	0.634

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status								0.541
All negative	164	18 (11.0) [6.6, 16.8]	158	16 (10.1) [5.9, 15.9]	1.084 [0.573, 2.049]	1.094 [0.537, 2.230]	0.8 [-6.5, 8.2]	0.857
Any positive	275	22 (8.0) [5.1, 11.9]	269	15 (5.6) [3.2, 9.0]	1.435 [0.761, 2.706]	1.472 [0.747, 2.904]	2.4 [-2.2, 7.0]	0.308
Total serum IgE								0.552
Low	138	15 (10.9) [6.2, 17.3]	135	13 (9.6) [5.2, 15.9]	1.129 [0.558, 2.282]	1.144 [0.523, 2.506]	1.2 [-6.7, 9.2]	0.843
Normal	275	22 (8.0) [5.1, 11.9]	256	17 (6.6) [3.9, 10.4]	1.205 [0.655, 2.216]	1.223 [0.634, 2.359]	1.4 [-3.4, 6.2]	0.619
High	33	3 (9.1) [1.9, 24.3]	45	1 (2.2) [0.1, 11.8]	4.091 [0.445, 37.597]	4.400 [0.437, 44.339]	6.9 [-6.5, 20.2]	0.305
OCS at baseline								0.881
Yes	55	12 (21.8) [11.8, 35.0]	55	9 (16.4) [7.8, 28.8]	1.333 [0.612, 2.907]	1.426 [0.547, 3.722]	5.5 [-11.0, 21.9]	0.628
No	391	28 (7.2) [4.8, 10.2]	381	22 (5.8) [3.7, 8.6]	1.240 [0.723, 2.129]	1.259 [0.707, 2.242]	1.4 [-2.3, 5.1]	0.467

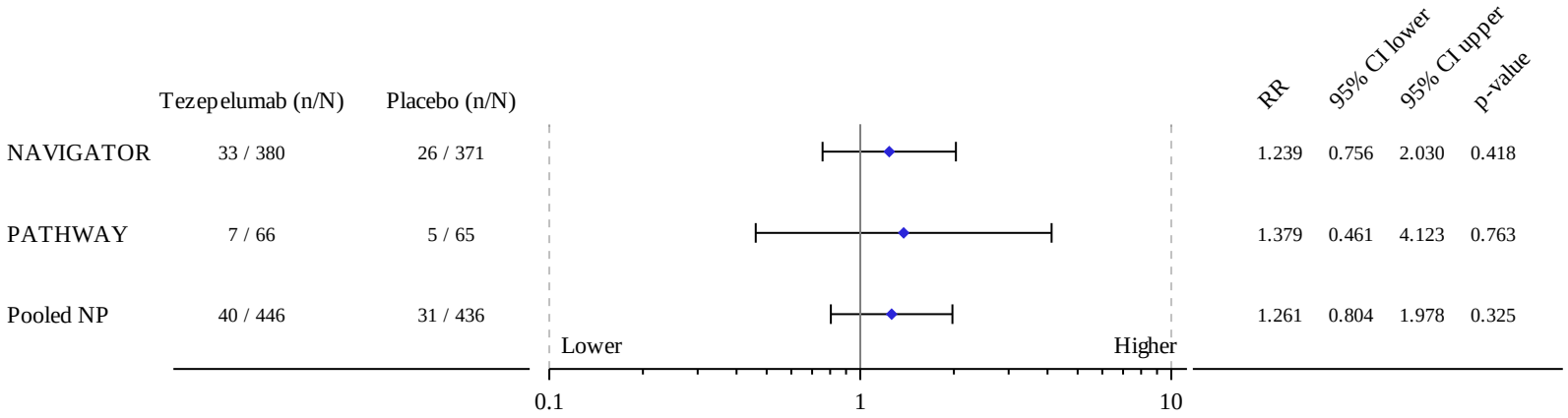
Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table MT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.865
Yes	119	16 (13.4) [7.9, 20.9]	107	11 (10.3) [5.2, 17.7]	1.308 [0.635, 2.692]	1.356 [0.599, 3.067]	3.2 [-6.1, 12.5]	0.540
No	327	24 (7.3) [4.8, 10.7]	329	20 (6.1) [3.8, 9.2]	1.207 [0.681, 2.142]	1.224 [0.662, 2.262]	1.3 [-2.9, 5.4]	0.537
Tiotropium use at baseline								0.717
Yes	109	15 (13.8) [7.9, 21.7]	102	10 (9.8) [4.8, 17.3]	1.404 [0.661, 2.981]	1.468 [0.627, 3.436]	4.0 [-5.7, 13.6]	0.402
No	337	25 (7.4) [4.9, 10.8]	334	21 (6.3) [3.9, 9.5]	1.180 [0.674, 2.066]	1.194 [0.655, 2.178]	1.1 [-3.0, 5.3]	0.647
Montelukast/ Cromoglicic acid use at baseline								0.434
Yes	180	23 (12.8) [8.3, 18.6]	162	14 (8.6) [4.8, 14.1]	1.479 [0.788, 2.775]	1.549 [0.768, 3.123]	4.1 [-3.0, 11.2]	0.229
No	266	17 (6.4) [3.8, 10.0]	274	17 (6.2) [3.7, 9.7]	1.030 [0.537, 1.975]	1.032 [0.515, 2.067]	0.2 [-4.3, 4.7]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Figure MF1AAS_SLMF0: Forest plot for non-disease related serious TEAEs during study period
DSAFL



Test for heterogeneity - p-value: 0.862, I-square: 0.0 %

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of affected patients. RR = relative risk. CI = confidence interval.
Heterogeneity was investigated with Cochran Q test. NE = not evaluable.
Source tables: NT1AAS_TLMI0, PT3AAS_SLMI0, MT1AAS_SLMI0

Table NT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.663
Male	143	14 (9.8) [5.5, 15.9]	147	10 (6.8) [3.3, 12.2]	1.439 [0.661, 3.134]	1.487 [0.638, 3.466]	3.0 [-4.0, 10.0]	0.399
Female	252	19 (7.5) [4.6, 11.5]	244	16 (6.6) [3.8, 10.4]	1.150 [0.605, 2.183]	1.162 [0.583, 2.316]	1.0 [-3.9, 5.9]	0.728
Age								0.500
< 65 years	319	25 (7.8) [5.1, 11.4]	338	23 (6.8) [4.4, 10.0]	1.152 [0.668, 1.987]	1.165 [0.647, 2.097]	1.0 [-3.3, 5.3]	0.654
>= 65 years	76	8 (10.5) [4.7, 19.7]	53	3 (5.7) [1.2, 15.7]	1.860 [0.517, 6.687]	1.961 [0.495, 7.765]	4.9 [-6.0, 15.8]	0.524
Exacerbations in the year before study								0.658
<= 2	211	12 (5.7) [3.0, 9.7]	226	12 (5.3) [2.8, 9.1]	1.071 [0.492, 2.332]	1.075 [0.472, 2.449]	0.4 [-4.4, 5.1]	1.000
> 2	184	21 (11.4) [7.2, 16.9]	165	14 (8.5) [4.7, 13.8]	1.345 [0.707, 2.558]	1.390 [0.682, 2.831]	2.9 [-3.9, 9.8]	0.379
Race								0.791
White	251	20 (8.0) [4.9, 12.0]	252	15 (6.0) [3.4, 9.6]	1.339 [0.701, 2.555]	1.368 [0.684, 2.737]	2.0 [-2.8, 6.9]	0.387
Black or African American	21	3 (14.3) [3.0, 36.3]	21	1 (4.8) [0.1, 23.8]	3.000 [0.339, 26.561]	3.333 [0.318, 34.989]	9.5 [-12.8, 31.8]	0.606
Asian	108	9 (8.3) [3.9, 15.2]	104	9 (8.7) [4.0, 15.8]	0.963 [0.398, 2.331]	0.960 [0.365, 2.521]	-0.3 [-8.8, 8.1]	1.000
Other	15	1 (6.7) [0.2, 31.9]	14	1 (7.1) [0.2, 33.9]	0.933 [0.064, 13.537]	0.929 [0.053, 16.423]	-0.5 [-25.9, 24.9]	1.000

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.859
Europe	65	11 (16.9) [8.8, 28.3]	61	6 (9.8) [3.7, 20.2]	1.721 [0.678, 4.366]	1.867 [0.645, 5.407]	7.1 [-6.3, 20.5]	0.302
America	151	8 (5.3) [2.3, 10.2]	152	7 (4.6) [1.9, 9.3]	1.150 [0.428, 3.093]	1.159 [0.409, 3.280]	0.7 [-4.9, 6.2]	0.798
Asia/Pacific	105	10 (9.5) [4.7, 16.8]	105	10 (9.5) [4.7, 16.8]	1.000 [0.434, 2.302]	1.000 [0.398, 2.513]	0.0 [-8.9, 8.9]	1.000
Rest of the world	74	4 (5.4) [1.5, 13.3]	73	3 (4.1) [0.9, 11.5]	1.315 [0.305, 5.673]	1.333 [0.288, 6.177]	1.3 [-6.9, 9.5]	1.000
BMI								0.276
< 18.5 kg/m**2	5	0 (0.0) [0.0, 52.2]	7	0 (0.0) [0.0, 41.0]	1.333 + [0.031, 58.090]	1.364 + [0.023, 79.964]	2.1 + [-40.3, 44.4]	NE
18.5 - < 25.0 kg/m**2	117	7 (6.0) [2.4, 11.9]	119	8 (6.7) [2.9, 12.8]	0.890 [0.333, 2.375]	0.883 [0.310, 2.518]	-0.7 [-7.8, 6.3]	1.000
25.0 - < 30.0 kg/m**2	130	14 (10.8) [6.0, 17.4]	130	5 (3.8) [1.3, 8.7]	2.800 [1.039, 7.549]	3.017 [1.054, 8.639]	6.9 [-0.1, 14.0]	0.054
>= 30.0 kg/m**2	143	12 (8.4) [4.4, 14.2]	135	13 (9.6) [5.2, 15.9]	0.871 [0.412, 1.842]	0.860 [0.378, 1.957]	-1.2 [-8.7, 6.2]	0.835
Baseline eosinophils - Low								0.511
< 150 cells/uL	96	12 (12.5) [6.6, 20.8]	89	11 (12.4) [6.3, 21.0]	1.011 [0.470, 2.175]	1.013 [0.423, 2.428]	0.1 [-10.5, 10.7]	1.000
>= 150 cells/uL	299	21 (7.0) [4.4, 10.5]	302	15 (5.0) [2.8, 8.1]	1.414 [0.743, 2.690]	1.445 [0.730, 2.861]	2.1 [-2.1, 6.2]	0.307
Baseline eosinophils - High								0.270
< 300 cells/uL	225	18 (8.0) [4.8, 12.3]	211	17 (8.1) [4.8, 12.6]	0.993 [0.526, 1.875]	0.992 [0.497, 1.981]	-0.1 [-5.6, 5.5]	1.000
>= 300 cells/uL	170	15 (8.8) [5.0, 14.1]	180	9 (5.0) [2.3, 9.3]	1.765 [0.793, 3.925]	1.839 [0.782, 4.321]	3.8 [-2.1, 9.7]	0.204

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.966
< 25 ppb	158	12 (7.6) [4.0, 12.9]	151	9 (6.0) [2.8, 11.0]	1.274 [0.553, 2.937]	1.297 [0.530, 3.172]	1.6 [-4.6, 7.9]	0.654
>= 25 ppb	234	21 (9.0) [5.6, 13.4]	236	17 (7.2) [4.3, 11.3]	1.246 [0.675, 2.301]	1.270 [0.652, 2.474]	1.8 [-3.6, 7.1]	0.503
Baseline specific perennial FEIA status								0.621
All negative	140	15 (10.7) [6.1, 17.1]	131	13 (9.9) [5.4, 16.4]	1.080 [0.534, 2.182]	1.089 [0.497, 2.386]	0.8 [-7.2, 8.8]	0.845
Any positive	253	18 (7.1) [4.3, 11.0]	253	13 (5.1) [2.8, 8.6]	1.385 [0.693, 2.765]	1.414 [0.678, 2.951]	2.0 [-2.6, 6.5]	0.459
Total serum IgE								0.346
Low	116	12 (10.3) [5.5, 17.4]	125	11 (8.8) [4.5, 15.2]	1.176 [0.540, 2.560]	1.196 [0.506, 2.827]	1.5 [-6.7, 9.8]	0.827
Normal	247	18 (7.3) [4.4, 11.3]	220	15 (6.8) [3.9, 11.0]	1.069 [0.552, 2.069]	1.074 [0.528, 2.186]	0.5 [-4.6, 5.5]	0.859
High	32	3 (9.4) [2.0, 25.0]	46	0 (0.0) [0.0, 7.7]	9.970 + [0.533, 186.627]	11.034 + [0.550, 221.375]	9.4 [-3.4, 22.1]	0.065
OCS at baseline								0.472
Yes	47	11 (23.4) [12.3, 38.0]	42	6 (14.3) [5.4, 28.5]	1.638 [0.664, 4.044]	1.833 [0.612, 5.490]	9.1 [-9.2, 27.5]	0.296
No	348	22 (6.3) [4.0, 9.4]	349	20 (5.7) [3.5, 8.7]	1.103 [0.613, 1.984]	1.110 [0.594, 2.073]	0.6 [-3.2, 4.4]	0.753

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.586
Yes	115	14 (12.2) [6.8, 19.6]	110	9 (8.2) [3.8, 15.0]	1.488 [0.672, 3.297]	1.556 [0.644, 3.756]	4.0 [-4.8, 12.8]	0.382
No	280	19 (6.8) [4.1, 10.4]	281	17 (6.0) [3.6, 9.5]	1.122 [0.596, 2.112]	1.130 [0.575, 2.223]	0.7 [-3.7, 5.1]	0.734
Tiotropium use at baseline								0.674
Yes	106	13 (12.3) [6.7, 20.1]	106	9 (8.5) [4.0, 15.5]	1.444 [0.645, 3.234]	1.507 [0.615, 3.692]	3.8 [-5.4, 12.9]	0.500
No	289	20 (6.9) [4.3, 10.5]	285	17 (6.0) [3.5, 9.4]	1.160 [0.621, 2.169]	1.172 [0.601, 2.287]	1.0 [-3.4, 5.3]	0.735
Montelukast/ Cromoglicic acid use at baseline								0.251
Yes	168	19 (11.3) [6.9, 17.1]	149	10 (6.7) [3.3, 12.0]	1.685 [0.809, 3.508]	1.772 [0.797, 3.944]	4.6 [-2.3, 11.5]	0.176
No	227	14 (6.2) [3.4, 10.1]	242	16 (6.6) [3.8, 10.5]	0.933 [0.466, 1.867]	0.928 [0.442, 1.948]	-0.4 [-5.3, 4.4]	0.853

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_TLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.677
Male	135	14 (10.4) [5.8, 16.8]	136	10 (7.4) [3.6, 13.1]	1.410 [0.649, 3.064]	1.458 [0.624, 3.407]	3.0 [-4.5, 10.5]	0.402
Female	245	19 (7.8) [4.7, 11.8]	235	16 (6.8) [3.9, 10.8]	1.139 [0.600, 2.161]	1.151 [0.577, 2.295]	0.9 [-4.1, 6.0]	0.728
Age								0.488
< 65 years	304	25 (8.2) [5.4, 11.9]	318	23 (7.2) [4.6, 10.7]	1.137 [0.660, 1.959]	1.149 [0.637, 2.072]	1.0 [-3.5, 5.5]	0.655
>= 65 years	76	8 (10.5) [4.7, 19.7]	53	3 (5.7) [1.2, 15.7]	1.860 [0.517, 6.687]	1.961 [0.495, 7.765]	4.9 [-6.0, 15.8]	0.524
Exacerbations in the year before study								0.636
<= 2	204	12 (5.9) [3.1, 10.0]	214	12 (5.6) [2.9, 9.6]	1.049 [0.482, 2.281]	1.052 [0.461, 2.399]	0.3 [-4.7, 5.2]	1.000
> 2	176	21 (11.9) [7.5, 17.7]	157	14 (8.9) [5.0, 14.5]	1.338 [0.705, 2.540]	1.384 [0.678, 2.824]	3.0 [-4.1, 10.2]	0.475
Race								0.837
White	239	20 (8.4) [5.2, 12.6]	235	15 (6.4) [3.6, 10.3]	1.311 [0.688, 2.498]	1.339 [0.668, 2.684]	2.0 [-3.1, 7.1]	0.483
Black or African American	21	3 (14.3) [3.0, 36.3]	19	1 (5.3) [0.1, 26.0]	2.714 [0.308, 23.926]	3.000 [0.285, 31.633]	9.0 [-14.0, 32.1]	0.607
Asian	107	9 (8.4) [3.9, 15.4]	103	9 (8.7) [4.1, 15.9]	0.963 [0.398, 2.329]	0.959 [0.365, 2.521]	-0.3 [-8.9, 8.2]	1.000
Other	13	1 (7.7) [0.2, 36.0]	14	1 (7.1) [0.2, 33.9]	1.077 [0.075, 15.505]	1.083 [0.061, 19.313]	0.5 [-26.7, 27.8]	1.000

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_TLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.848
Europe	64	11 (17.2) [8.9, 28.7]	60	6 (10.0) [3.8, 20.5]	1.719 [0.678, 4.357]	1.868 [0.644, 5.416]	7.2 [-6.4, 20.8]	0.301
America	140	8 (5.7) [2.5, 10.9]	134	7 (5.2) [2.1, 10.5]	1.094 [0.408, 2.933]	1.100 [0.387, 3.121]	0.5 [-5.6, 6.6]	1.000
Asia/Pacific	104	10 (9.6) [4.7, 17.0]	104	10 (9.6) [4.7, 17.0]	1.000 [0.435, 2.301]	1.000 [0.398, 2.514]	0.0 [-9.0, 9.0]	1.000
Rest of the world	72	4 (5.6) [1.5, 13.6]	73	3 (4.1) [0.9, 11.5]	1.352 [0.314, 5.828]	1.373 [0.296, 6.362]	1.4 [-6.9, 9.8]	0.719
BMI		N<10 any level						NE
< 18.5 kg/m**2	3	0 (0.0) [0.0, 70.8]	3	0 (0.0) [0.0, 70.8]				
18.5 - < 25.0 kg/m**2	109	7 (6.4) [2.6, 12.8]	108	8 (7.4) [3.3, 14.1]				
25.0 - < 30.0 kg/m**2	127	14 (11.0) [6.2, 17.8]	126	5 (4.0) [1.3, 9.0]				
>= 30.0 kg/m**2	141	12 (8.5) [4.5, 14.4]	134	13 (9.7) [5.3, 16.0]				
Baseline eosinophils - Low								0.512
< 150 cells/uL	95	12 (12.6) [6.7, 21.0]	87	11 (12.6) [6.5, 21.5]	0.999 [0.465, 2.146]	0.999 [0.416, 2.397]	-0.0 [-10.8, 10.8]	1.000
>= 150 cells/uL	285	21 (7.4) [4.6, 11.0]	284	15 (5.3) [3.0, 8.6]	1.395 [0.734, 2.651]	1.427 [0.720, 2.827]	2.1 [-2.3, 6.4]	0.390
Baseline eosinophils - High								0.340
< 300 cells/uL	216	18 (8.3) [5.0, 12.9]	207	17 (8.2) [4.9, 12.8]	1.015 [0.538, 1.914]	1.016 [0.509, 2.030]	0.1 [-5.6, 5.8]	1.000
>= 300 cells/uL	164	15 (9.1) [5.2, 14.6]	164	9 (5.5) [2.5, 10.2]	1.667 [0.751, 3.700]	1.734 [0.736, 4.083]	3.7 [-2.6, 9.9]	0.289

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_TLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.985
< 25 ppb	155	12 (7.7) [4.1, 13.1]	145	9 (6.2) [2.9, 11.5]	1.247 [0.542, 2.872]	1.268 [0.518, 3.105]	1.5 [-4.9, 8.0]	0.656
>= 25 ppb	222	21 (9.5) [6.0, 14.1]	222	17 (7.7) [4.5, 12.0]	1.235 [0.670, 2.278]	1.260 [0.646, 2.458]	1.8 [-3.9, 7.5]	0.611
Baseline specific perennial FEIA status								0.666
All negative	137	15 (10.9) [6.3, 17.4]	129	13 (10.1) [5.5, 16.6]	1.086 [0.538, 2.194]	1.097 [0.500, 2.405]	0.9 [-7.3, 9.0]	0.844
Any positive	241	18 (7.5) [4.5, 11.5]	235	13 (5.5) [3.0, 9.3]	1.350 [0.677, 2.693]	1.378 [0.660, 2.881]	1.9 [-2.9, 6.8]	0.459
Total serum IgE								0.390
Low	115	12 (10.4) [5.5, 17.5]	121	11 (9.1) [4.6, 15.7]	1.148 [0.528, 2.497]	1.165 [0.492, 2.756]	1.3 [-7.1, 9.8]	0.827
Normal	235	18 (7.7) [4.6, 11.8]	212	15 (7.1) [4.0, 11.4]	1.083 [0.560, 2.094]	1.089 [0.535, 2.220]	0.6 [-4.7, 5.9]	0.858
High	30	3 (10.0) [2.1, 26.5]	38	0 (0.0) [0.0, 9.3]	8.806 + [0.472, 164.170]	9.800 + [0.486, 197.493]	10.0 [-3.7, 23.7]	0.081
OCS at baseline								0.428
Yes	46	11 (23.9) [12.6, 38.8]	42	6 (14.3) [5.4, 28.5]	1.674 [0.679, 4.127]	1.886 [0.629, 5.655]	9.6 [-8.9, 28.2]	0.290
No	334	22 (6.6) [4.2, 9.8]	329	20 (6.1) [3.8, 9.2]	1.084 [0.603, 1.947]	1.089 [0.583, 2.037]	0.5 [-3.5, 4.5]	0.874

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table NT1AAS_TLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.615
Yes	112	14 (12.5) [7.0, 20.1]	104	9 (8.7) [4.0, 15.8]	1.444 [0.653, 3.195]	1.508 [0.623, 3.649]	3.8 [-5.2, 12.9]	0.386
No	268	19 (7.1) [4.3, 10.8]	267	17 (6.4) [3.8, 10.0]	1.113 [0.592, 2.095]	1.122 [0.570, 2.209]	0.7 [-3.9, 5.3]	0.863
Tiotropium use at baseline								0.704
Yes	103	13 (12.6) [6.9, 20.6]	100	9 (9.0) [4.2, 16.4]	1.402 [0.628, 3.134]	1.460 [0.595, 3.587]	3.6 [-5.9, 13.1]	0.500
No	277	20 (7.2) [4.5, 10.9]	271	17 (6.3) [3.7, 9.9]	1.151 [0.616, 2.149]	1.163 [0.595, 2.271]	0.9 [-3.6, 5.5]	0.735
Montelukast/ Cromoglicic acid use at baseline								0.266
Yes	163	19 (11.7) [7.2, 17.6]	141	10 (7.1) [3.5, 12.7]	1.644 [0.791, 3.417]	1.728 [0.776, 3.852]	4.6 [-2.6, 11.7]	0.240
No	217	14 (6.5) [3.6, 10.6]	230	16 (7.0) [4.0, 11.1]	0.927 [0.464, 1.854]	0.922 [0.439, 1.938]	-0.5 [-5.6, 4.6]	0.852

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11APR2022

Table PT3AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	19	2 (10.5) [1.3, 33.1]	20	3 (15.0) [3.2, 37.9]				
Female	47	5 (10.6) [3.5, 23.1]	45	2 (4.4) [0.5, 15.1]				
Age								0.858
< 65 years	57	6 (10.5) [4.0, 21.5]	55	4 (7.3) [2.0, 17.6]	1.447 [0.432, 4.852]	1.500 [0.399, 5.634]	3.3 [-9.0, 15.6]	0.743
>= 65 years	9	1 (11.1) [0.3, 48.2]	10	1 (10.0) [0.3, 44.5]	1.111 [0.081, 15.284]	1.125 [0.060, 21.087]	1.1 [-37.1, 39.4]	1.000
Exacerbations in the year before study		n<10 all levels						NE
<= 2	44	2 (4.5) [0.6, 15.5]	45	1 (2.2) [0.1, 11.8]				
> 2	22	5 (22.7) [7.8, 45.4]	20	4 (20.0) [5.7, 43.7]				
Race		N<10 any level						NE
White	60	6 (10.0) [3.8, 20.5]	58	4 (6.9) [1.9, 16.7]				
Black or African American	2	0 (0.0) [0.0, 84.2]	2	0 (0.0) [0.0, 84.2]				
Asian	3	1 (33.3) [0.8, 90.6]	3	0 (0.0) [0.0, 70.8]				
Other	1	0 (0.0) [0.0, 97.5]	2	1 (50.0) [1.3, 98.7]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		N<10 any level						NE
Europe	40	6 (15.0) [5.7, 29.8]	36	3 (8.3) [1.8, 22.5]				
America	6	0 (0.0) [0.0, 45.9]	4	1 (25.0) [0.6, 80.6]				
Asia/Pacific	3	1 (33.3) [0.8, 90.6]	3	0 (0.0) [0.0, 70.8]				
Rest of the world	17	0 (0.0) [0.0, 19.5]	22	1 (4.5) [0.1, 22.8]				
BMI		n<10 all levels						NE
18.5 - < 25.0 kg/m**2	15	2 (13.3) [1.7, 40.5]	21	1 (4.8) [0.1, 23.8]				
25.0 - < 30.0 kg/m**2	24	1 (4.2) [0.1, 21.1]	20	3 (15.0) [3.2, 37.9]				
>= 30.0 kg/m**2	27	4 (14.8) [4.2, 33.7]	24	1 (4.2) [0.1, 21.1]				
Baseline eosinophils - Low		n<10 all levels						NE
< 150 cells/uL	12	3 (25.0) [5.5, 57.2]	14	3 (21.4) [4.7, 50.8]				
>= 150 cells/uL	54	4 (7.4) [2.1, 17.9]	51	2 (3.9) [0.5, 13.5]				
Baseline eosinophils - High		n<10 all levels						NE
< 300 cells/uL	34	3 (8.8) [1.9, 23.7]	34	3 (8.8) [1.9, 23.7]				
>= 300 cells/uL	32	4 (12.5) [3.5, 29.0]	31	2 (6.5) [0.8, 21.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO		n<10 all levels						NE
< 25 ppb	39	5 (12.8) [4.3, 27.4]	30	2 (6.7) [0.8, 22.1]				
>= 25 ppb	27	2 (7.4) [0.9, 24.3]	34	3 (8.8) [1.9, 23.7]				
Baseline specific perennial FEIA status		n<10 all levels						NE
All negative	27	3 (11.1) [2.4, 29.2]	29	3 (10.3) [2.2, 27.4]				
Any positive	34	4 (11.8) [3.3, 27.5]	34	2 (5.9) [0.7, 19.7]				
Total serum IgE		n<10 all levels						NE
Low	23	3 (13.0) [2.8, 33.6]	14	2 (14.3) [1.8, 42.8]				
Normal	40	4 (10.0) [2.8, 23.7]	44	2 (4.5) [0.6, 15.5]				
High	3	0 (0.0) [0.0, 70.8]	7	1 (14.3) [0.4, 57.9]				
OCS at baseline		n<10 all levels						NE
Yes	9	1 (11.1) [0.3, 48.2]	13	3 (23.1) [5.0, 53.8]				
No	57	6 (10.5) [4.0, 21.5]	52	2 (3.8) [0.5, 13.2]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline		n<10 all levels						NE
Yes	7	2 (28.6) [3.7, 71.0]	3	2 (66.7) [9.4, 99.2]				
No	59	5 (8.5) [2.8, 18.7]	62	3 (4.8) [1.0, 13.5]				
Tiotropium use at baseline		N<10 any level						NE
Yes	6	2 (33.3) [4.3, 77.7]	2	1 (50.0) [1.3, 98.7]				
No	60	5 (8.3) [2.8, 18.4]	63	4 (6.3) [1.8, 15.5]				
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	17	4 (23.5) [6.8, 49.9]	21	4 (19.0) [5.4, 41.9]				
No	49	3 (6.1) [1.3, 16.9]	44	1 (2.3) [0.1, 12.0]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.096
Male	25	4 (16.0) [4.5, 36.1]	31	1 (3.2) [0.1, 16.7]	4.960 [0.591, 41.614]	5.714 [0.596, 54.824]	12.8 [-6.5, 32.0]	0.161
Female	48	4 (8.3) [2.3, 20.0]	45	6 (13.3) [5.1, 26.8]	0.625 [0.189, 2.071]	0.591 [0.155, 2.249]	-5.0 [-19.8, 9.8]	0.515
Age								0.771
< 65 years	58	6 (10.3) [3.9, 21.2]	62	5 (8.1) [2.7, 17.8]	1.283 [0.414, 3.977]	1.315 [0.379, 4.568]	2.3 [-9.7, 14.3]	0.757
>= 65 years	15	2 (13.3) [1.7, 40.5]	14	2 (14.3) [1.8, 42.8]	0.933 [0.151, 5.758]	0.923 [0.112, 7.623]	-1.0 [-33.0, 31.1]	1.000
Exacerbations in the year before study								0.815
<= 2	60	6 (10.0) [3.8, 20.5]	55	4 (7.3) [2.0, 17.6]	1.375 [0.410, 4.616]	1.417 [0.378, 5.313]	2.7 [-9.2, 14.7]	0.745
> 2	13	2 (15.4) [1.9, 45.4]	21	3 (14.3) [3.0, 36.3]	1.077 [0.207, 5.608]	1.091 [0.157, 7.592]	1.1 [-29.8, 32.0]	1.000
Race		N<10 any level						NE
White	61	7 (11.5) [4.7, 22.2]	64	6 (9.4) [3.5, 19.3]				
Black or African American	1	0 (0.0) [0.0, 97.5]	0					
Asian	11	1 (9.1) [0.2, 41.3]	11	1 (9.1) [0.2, 41.3]				
Other	0		1	0 (0.0) [0.0, 97.5]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region		n<10 all levels						NE
Europe	27	4 (14.8) [4.2, 33.7]	32	3 (9.4) [2.0, 25.0]				
America	21	2 (9.5) [1.2, 30.4]	17	2 (11.8) [1.5, 36.4]				
Asia/Pacific	11	1 (9.1) [0.2, 41.3]	10	1 (10.0) [0.3, 44.5]				
Rest of the world	14	1 (7.1) [0.2, 33.9]	17	1 (5.9) [0.1, 28.7]				
BMI		n<10 all levels						NE
18.5 - < 25.0 kg/m**2	20	0 (0.0) [0.0, 16.8]	23	2 (8.7) [1.1, 28.0]				
25.0 - < 30.0 kg/m**2	22	3 (13.6) [2.9, 34.9]	24	2 (8.3) [1.0, 27.0]				
>= 30.0 kg/m**2	31	5 (16.1) [5.5, 33.7]	29	3 (10.3) [2.2, 27.4]				
Baseline eosinophils - Low		n<10 all levels						NE
< 150 cells/uL	27	5 (18.5) [6.3, 38.1]	24	4 (16.7) [4.7, 37.4]				
>= 150 cells/uL	46	3 (6.5) [1.4, 17.9]	52	3 (5.8) [1.2, 15.9]				
Baseline eosinophils - High		n<10 all levels						NE
< 300 cells/uL	46	5 (10.9) [3.6, 23.6]	52	4 (7.7) [2.1, 18.5]				
>= 300 cells/uL	27	3 (11.1) [2.4, 29.2]	24	3 (12.5) [2.7, 32.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO		n<10 all levels						NE
< 25 ppb	31	4 (12.9) [3.6, 29.8]	26	3 (11.5) [2.4, 30.2]				
>= 25 ppb	36	3 (8.3) [1.8, 22.5]	43	3 (7.0) [1.5, 19.1]				
Baseline specific perennial FEIA status								0.634
All negative	43	7 (16.3) [6.8, 30.7]	39	5 (12.8) [4.3, 27.4]	1.270 [0.439, 3.675]	1.322 [0.383, 4.568]	3.5 [-14.2, 21.1]	0.760
Any positive	25	1 (4.0) [0.1, 20.4]	34	2 (5.9) [0.7, 19.7]	0.680 [0.065, 7.089]	0.667 [0.057, 7.788]	-1.9 [-16.4, 12.6]	1.000
Total serum IgE		N<10 any level						NE
Low	30	3 (10.0) [2.1, 26.5]	31	7 (22.6) [9.6, 41.1]				
Normal	39	4 (10.3) [2.9, 24.2]	43	0 (0.0) [0.0, 8.2]				
High	3	1 (33.3) [0.8, 90.6]	2	0 (0.0) [0.0, 84.2]				
LAMA use at baseline								0.118
Yes	34	1 (2.9) [0.1, 15.3]	40	4 (10.0) [2.8, 23.7]	0.294 [0.034, 2.508]	0.273 [0.029, 2.566]	-7.1 [-20.7, 6.6]	0.366
No	39	7 (17.9) [7.5, 33.5]	36	3 (8.3) [1.8, 22.5]	2.154 [0.602, 7.703]	2.406 [0.572, 10.128]	9.6 [-8.1, 27.3]	0.313

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table ST1AAS_SLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related serious TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline								0.118
Yes	34	1 (2.9) [0.1, 15.3]	40	4 (10.0) [2.8, 23.7]	0.294 [0.034, 2.508]	0.273 [0.029, 2.566]	-7.1 [-20.7, 6.6]	0.366
No	39	7 (17.9) [7.5, 33.5]	36	3 (8.3) [1.8, 22.5]	2.154 [0.602, 7.703]	2.406 [0.572, 10.128]	9.6 [-8.1, 27.3]	0.313
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	30	3 (10.0) [2.1, 26.5]	37	3 (8.1) [1.7, 21.9]				
No	43	5 (11.6) [3.9, 25.1]	39	4 (10.3) [2.9, 24.2]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table DT1AAS_ULSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.597
Male	115	19 (16.5) [10.3, 24.6]	56	6 (10.7) [4.0, 21.9]	1.542 [0.652, 3.646]	1.649 [0.619, 4.392]	5.8 [-6.1, 17.7]	0.364
Female	195	24 (12.3) [8.0, 17.8]	93	10 (10.8) [5.3, 18.9]	1.145 [0.571, 2.294]	1.165 [0.532, 2.549]	1.6 [-7.0, 10.2]	0.846
Age								0.773
< 65 years	250	31 (12.4) [8.6, 17.1]	127	12 (9.4) [5.0, 15.9]	1.312 [0.698, 2.467]	1.357 [0.671, 2.741]	3.0 [-4.2, 10.1]	0.493
>= 65 years	60	12 (20.0) [10.8, 32.3]	22	4 (18.2) [5.2, 40.3]	1.100 [0.396, 3.053]	1.125 [0.321, 3.945]	1.8 [-20.3, 24.0]	1.000
Exacerbations in the year before study								0.766
<= 2	173	21 (12.1) [7.7, 18.0]	88	9 (10.2) [4.8, 18.5]	1.187 [0.568, 2.481]	1.213 [0.530, 2.772]	1.9 [-6.9, 10.8]	0.838
> 2	137	22 (16.1) [10.3, 23.3]	61	7 (11.5) [4.7, 22.2]	1.399 [0.632, 3.100]	1.476 [0.594, 3.666]	4.6 [-6.7, 15.9]	0.515
Race								0.603
White	226	27 (11.9) [8.0, 16.9]	99	11 (11.1) [5.7, 19.0]	1.075 [0.556, 2.080]	1.085 [0.515, 2.286]	0.8 [-7.4, 9.1]	1.000
Black or African American	16	4 (25.0) [7.3, 52.4]	14	0 (0.0) [0.0, 23.2]	7.941 + [0.465, 135.654]	10.440 + [0.510, 213.519]	25.0 [-2.9, 52.9]	0.103
Asian	56	9 (16.1) [7.6, 28.3]	30	4 (13.3) [3.8, 30.7]	1.205 [0.405, 3.589]	1.245 [0.349, 4.439]	2.7 [-15.3, 20.8]	1.000
Other	12	3 (25.0) [5.5, 57.2]	6	1 (16.7) [0.4, 64.1]	1.500 [0.195, 11.536]	1.667 [0.135, 20.578]	8.3 [-42.8, 59.4]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_ULSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.518
Europe	53	12 (22.6) [12.3, 36.2]	24	2 (8.3) [1.0, 27.0]	2.717 [0.659, 11.208]	3.220 [0.660, 15.694]	14.3 [-4.5, 33.1]	0.203
America	133	10 (7.5) [3.7, 13.4]	62	6 (9.7) [3.6, 19.9]	0.777 [0.296, 2.042]	0.759 [0.263, 2.191]	-2.2 [-12.0, 7.6]	0.587
Asia/Pacific	52	9 (17.3) [8.2, 30.3]	26	4 (15.4) [4.4, 34.9]	1.125 [0.382, 3.311]	1.151 [0.318, 4.161]	1.9 [-18.2, 22.1]	1.000
Rest of the world	72	12 (16.7) [8.9, 27.3]	37	4 (10.8) [3.0, 25.4]	1.542 [0.534, 4.449]	1.650 [0.493, 5.526]	5.9 [-9.4, 21.1]	0.570
BMI		N<10 any level						NE
< 18.5 kg/m**2	4	1 (25.0) [0.6, 80.6]	2	0 (0.0) [0.0, 84.2]				
18.5 - < 25.0 kg/m**2	83	7 (8.4) [3.5, 16.6]	45	5 (11.1) [3.7, 24.1]				
25.0 - < 30.0 kg/m**2	104	14 (13.5) [7.6, 21.6]	48	5 (10.4) [3.5, 22.7]				
>= 30.0 kg/m**2	119	21 (17.6) [11.3, 25.7]	54	6 (11.1) [4.2, 22.6]				
Baseline eosinophils - Low								0.549
< 150 cells/uL	74	11 (14.9) [7.7, 25.0]	36	3 (8.3) [1.8, 22.5]	1.784 [0.530, 5.999]	1.921 [0.501, 7.366]	6.5 [-7.7, 20.7]	0.543
>= 150 cells/uL	236	32 (13.6) [9.5, 18.6]	113	13 (11.5) [6.3, 18.9]	1.179 [0.644, 2.157]	1.207 [0.607, 2.400]	2.1 [-5.9, 10.0]	0.733
Baseline eosinophils - High								0.754
< 300 cells/uL	180	27 (15.0) [10.1, 21.1]	83	9 (10.8) [5.1, 19.6]	1.383 [0.681, 2.808]	1.451 [0.649, 3.242]	4.2 [-5.2, 13.5]	0.442
>= 300 cells/uL	130	16 (12.3) [7.2, 19.2]	66	7 (10.6) [4.4, 20.6]	1.160 [0.502, 2.681]	1.183 [0.461, 3.035]	1.7 [-8.8, 12.2]	0.818

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_ULSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.666
< 25 ppb	127	16 (12.6) [7.4, 19.7]	64	5 (7.8) [2.6, 17.3]	1.613 [0.619, 4.204]	1.701 [0.594, 4.874]	4.8 [-5.1, 14.7]	0.463
>= 25 ppb	180	27 (15.0) [10.1, 21.1]	83	10 (12.0) [5.9, 21.0]	1.245 [0.632, 2.451]	1.288 [0.592, 2.803]	3.0 [-6.7, 12.6]	0.573
Baseline specific perennial FEIA status								0.883
All negative	116	24 (20.7) [13.7, 29.2]	53	9 (17.0) [8.1, 29.8]	1.218 [0.609, 2.438]	1.275 [0.547, 2.972]	3.7 [-10.2, 17.6]	0.678
Any positive	193	19 (9.8) [6.0, 14.9]	94	7 (7.4) [3.0, 14.7]	1.322 [0.576, 3.034]	1.357 [0.550, 3.351]	2.4 [-5.2, 10.0]	0.662
Total serum IgE								0.484
Low	93	18 (19.4) [11.9, 28.9]	49	6 (12.2) [4.6, 24.8]	1.581 [0.671, 3.723]	1.720 [0.635, 4.662]	7.1 [-6.6, 20.9]	0.351
Normal	193	21 (10.9) [6.9, 16.2]	81	9 (11.1) [5.2, 20.0]	0.979 [0.469, 2.045]	0.977 [0.427, 2.235]	-0.2 [-9.2, 8.8]	1.000
High	24	4 (16.7) [4.7, 37.4]	19	1 (5.3) [0.1, 26.0]	3.167 [0.385, 26.042]	3.600 [0.368, 35.265]	11.4 [-11.3, 34.1]	0.363
OCS at baseline								0.289
Yes	28	8 (28.6) [13.2, 48.7]	12	1 (8.3) [0.2, 38.5]	3.429 [0.480, 24.482]	4.400 [0.485, 39.917]	20.2 [-8.6, 49.1]	0.233
No	282	35 (12.4) [8.8, 16.8]	137	15 (10.9) [6.3, 17.4]	1.134 [0.641, 2.003]	1.152 [0.606, 2.191]	1.5 [-5.6, 8.5]	0.749

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_ULSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
LAMA use at baseline								0.058	
Yes	83	16 (19.3) [11.4, 29.4]	42	2 (4.8) [0.6, 16.2]	4.048 [0.976, 16.787]	4.776 [1.043, 21.865]	14.5 [2.1, 27.0]	0.032	*
No	227	27 (11.9) [8.0, 16.8]	107	14 (13.1) [7.3, 21.0]	0.909 [0.497, 1.662]	0.897 [0.449, 1.789]	-1.2 [-9.5, 7.2]	0.858	
Tiotropium use at baseline								0.029	i
Yes	76	16 (21.1) [12.5, 31.9]	40	1 (2.5) [0.1, 13.2]	8.421 [1.158, 61.216]	10.400 [1.325, 81.607]	18.6 [6.3, 30.8]	0.006	*
No	234	27 (11.5) [7.7, 16.3]	109	15 (13.8) [7.9, 21.7]	0.838 [0.465, 1.511]	0.817 [0.416, 1.608]	-2.2 [-10.5, 6.1]	0.597	
Montelukast/ Cromoglicic acid use at baseline								0.640	
Yes	123	20 (16.3) [10.2, 24.0]	55	8 (14.5) [6.5, 26.7]	1.118 [0.525, 2.380]	1.141 [0.469, 2.777]	1.7 [-11.0, 14.4]	0.828	
No	187	23 (12.3) [8.0, 17.9]	94	8 (8.5) [3.7, 16.1]	1.445 [0.672, 3.107]	1.508 [0.647, 3.512]	3.8 [-4.4, 11.9]	0.422	

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table NT1AAS_SLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.756
Western Europe	72	12 (16.7) [8.9, 27.3]	72	7 (9.7) [4.0, 19.0]	1.714 [0.716, 4.104]	1.857 [0.686, 5.028]	6.9 [-5.4, 19.3]	0.325
North America	77	8 (10.4) [4.6, 19.4]	77	6 (7.8) [2.9, 16.2]	1.333 [0.485, 3.662]	1.372 [0.453, 4.160]	2.6 [-7.8, 13.0]	0.780
South America	74	0 (0.0) [0.0, 4.9]	75	1 (1.3) [0.0, 7.2]	0.338 + [0.014, 8.160]	0.333 + [0.013, 8.315]	-1.3 [-5.3, 2.6]	1.000
Central/Eastern Europe	20	0 (0.0) [0.0, 16.8]	18	1 (5.6) [0.1, 27.3]	0.302 + [0.013, 6.967]	0.285 + [0.011, 7.439]	-5.6 [-21.4, 10.3]	0.474
Asia Pacific	98	9 (9.2) [4.3, 16.7]	94	9 (9.6) [4.5, 17.4]	0.959 [0.398, 2.311]	0.955 [0.362, 2.521]	-0.4 [-9.7, 8.9]	1.000
Rest of the world	54	4 (7.4) [2.1, 17.9]	55	2 (3.6) [0.4, 12.5]	2.037 [0.389, 10.663]	2.120 [0.372, 12.088]	3.8 [-6.6, 14.2]	0.438
Baseline eosinophils (cat. N)								0.419
< 150 cells/uL	96	12 (12.5) [6.6, 20.8]	89	11 (12.4) [6.3, 21.0]	1.011 [0.470, 2.175]	1.013 [0.423, 2.428]	0.1 [-10.5, 10.7]	1.000
150 - < 300 cells/uL	129	6 (4.7) [1.7, 9.8]	122	6 (4.9) [1.8, 10.4]	0.946 [0.313, 2.853]	0.943 [0.296, 3.007]	-0.3 [-6.3, 5.8]	1.000
300 - < 450 cells/uL	70	6 (8.6) [3.2, 17.7]	75	1 (1.3) [0.0, 7.2]	6.429 [0.794, 52.068]	6.938 [0.814, 59.158]	7.2 [-1.2, 15.7]	0.056
>= 450 cells/uL	100	9 (9.0) [4.2, 16.4]	105	8 (7.6) [3.3, 14.5]	1.181 [0.474, 2.941]	1.199 [0.444, 3.241]	1.4 [-7.2, 9.9]	0.803
Baseline eosinophils (cat. Q)								0.689
Q1: < 140 cells/uL	89	12 (13.5) [7.2, 22.4]	81	10 (12.3) [6.1, 21.5]	1.092 [0.499, 2.391]	1.106 [0.450, 2.719]	1.1 [-10.1, 12.4]	1.000
Q2: 140 - < 250 cells/uL	99	2 (2.0) [0.2, 7.1]	94	3 (3.2) [0.7, 9.0]	0.633 [0.108, 3.704]	0.625 [0.102, 3.829]	-1.2 [-6.7, 4.4]	0.676
Q3: 250 - < 430 cells/uL	103	10 (9.7) [4.8, 17.1]	103	5 (4.9) [1.6, 11.0]	2.000 [0.708, 5.648]	2.108 [0.694, 6.397]	4.9 [-3.2, 12.9]	0.283
Q4: >= 430 cells/uL	104	9 (8.7) [4.0, 15.8]	113	8 (7.1) [3.1, 13.5]	1.222 [0.490, 3.050]	1.243 [0.461, 3.353]	1.6 [-6.5, 9.7]	0.802

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAS_SLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.369
< 25 ppb	158	12 (7.6) [4.0, 12.9]	151	9 (6.0) [2.8, 11.0]	1.274 [0.553, 2.937]	1.297 [0.530, 3.172]	1.6 [-4.6, 7.9]	0.654
25 - < 50 ppb	114	12 (10.5) [5.6, 17.7]	116	6 (5.2) [1.9, 10.9]	2.035 [0.791, 5.237]	2.157 [0.781, 5.960]	5.4 [-2.4, 13.2]	0.148
>= 50 ppb	120	9 (7.5) [3.5, 13.8]	120	11 (9.2) [4.7, 15.8]	0.818 [0.352, 1.902]	0.803 [0.320, 2.016]	-1.7 [-9.5, 6.2]	0.816

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAS_SLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.368
Q1: < 16 ppb	94	6 (6.4) [2.4, 13.4]	85	6 (7.1) [2.6, 14.7]	0.904 [0.303, 2.697]	0.898 [0.278, 2.897]	-0.7 [-9.1, 7.8]	1.000
Q2: 16 - < 30 ppb	88	7 (8.0) [3.3, 15.7]	99	4 (4.0) [1.1, 10.0]	1.969 [0.596, 6.500]	2.052 [0.580, 7.263]	3.9 [-4.0, 11.8]	0.353
Q3: 30 - < 56 ppb	106	13 (12.3) [6.7, 20.1]	96	6 (6.3) [2.3, 13.1]	1.962 [0.776, 4.959]	2.097 [0.764, 5.756]	6.0 [-2.9, 14.9]	0.157
Q4: >= 56 ppb	104	7 (6.7) [2.7, 13.4]	107	10 (9.3) [4.6, 16.5]	0.720 [0.285, 1.821]	0.700 [0.256, 1.914]	-2.6 [-10.9, 5.7]	0.615
Total serum IgE (cat. N)								0.558
Q1: < 53.1 IU/ml	94	10 (10.6) [5.2, 18.7]	99	10 (10.1) [5.0, 17.8]	1.053 [0.459, 2.415]	1.060 [0.420, 2.674]	0.5 [-9.1, 10.2]	1.000
Q2: 53.1 - < 195.6 IU/ml	101	9 (8.9) [4.2, 16.2]	101	7 (6.9) [2.8, 13.8]	1.286 [0.498, 3.319]	1.314 [0.470, 3.675]	2.0 [-6.5, 10.4]	0.795
Q3: 195.6 - < 572.4 IU/ml	108	8 (7.4) [3.3, 14.1]	87	7 (8.0) [3.3, 15.9]	0.921 [0.348, 2.439]	0.914 [0.318, 2.629]	-0.6 [-9.2, 8.0]	1.000
Q4: >= 572.4 IU/ml	92	6 (6.5) [2.4, 13.7]	104	2 (1.9) [0.2, 6.8]	3.391 [0.702, 16.391]	3.558 [0.700, 18.085]	4.6 [-2.1, 11.3]	0.151
Nasal polyps last 2 years								0.458
Yes	33	3 (9.1) [1.9, 24.3]	31	1 (3.2) [0.1, 16.7]	2.818 [0.309, 25.675]	3.000 [0.295, 30.498]	5.9 [-8.9, 20.6]	0.614
No	362	30 (8.3) [5.7, 11.6]	360	25 (6.9) [4.5, 10.1]	1.193 [0.716, 1.988]	1.211 [0.697, 2.103]	1.3 [-2.8, 5.5]	0.575

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAS_TLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.755
Western Europe	71	12 (16.9) [9.0, 27.7]	71	7 (9.9) [4.1, 19.3]	1.714 [0.717, 4.101]	1.860 [0.686, 5.040]	7.0 [-5.5, 19.6]	0.324
North America	75	8 (10.7) [4.7, 19.9]	71	6 (8.5) [3.2, 17.5]	1.262 [0.461, 3.457]	1.294 [0.425, 3.933]	2.2 [-8.7, 13.1]	0.781
South America	65	0 (0.0) [0.0, 5.5]	63	1 (1.6) [0.0, 8.5]	0.323 + [0.013, 7.789]	0.318 + [0.013, 7.955]	-1.6 [-6.2, 3.1]	0.492
Central/Eastern Europe	19	0 (0.0) [0.0, 17.6]	18	1 (5.6) [0.1, 27.3]	0.317 + [0.014, 7.305]	0.299 + [0.011, 7.832]	-5.6 [-21.5, 10.4]	0.486
Asia Pacific	97	9 (9.3) [4.3, 16.9]	93	9 (9.7) [4.5, 17.6]	0.959 [0.398, 2.309]	0.955 [0.361, 2.521]	-0.4 [-9.8, 9.0]	1.000
Rest of the world	53	4 (7.5) [2.1, 18.2]	55	2 (3.6) [0.4, 12.5]	2.075 [0.397, 10.860]	2.163 [0.379, 12.340]	3.9 [-6.6, 14.4]	0.433
Baseline eosinophils (cat. N)								0.465
< 150 cells/uL	95	12 (12.6) [6.7, 21.0]	87	11 (12.6) [6.5, 21.5]	0.999 [0.465, 2.146]	0.999 [0.416, 2.397]	-0.0 [-10.8, 10.8]	1.000
150 - < 300 cells/uL	121	6 (5.0) [1.8, 10.5]	120	6 (5.0) [1.9, 10.6]	0.992 [0.329, 2.988]	0.991 [0.310, 3.165]	-0.0 [-6.4, 6.3]	1.000
300 - < 450 cells/uL	70	6 (8.6) [3.2, 17.7]	69	1 (1.4) [0.0, 7.8]	5.914 [0.731, 47.851]	6.375 [0.747, 54.420]	7.1 [-1.5, 15.7]	0.116
>= 450 cells/uL	94	9 (9.6) [4.5, 17.4]	95	8 (8.4) [3.7, 15.9]	1.137 [0.458, 2.821]	1.151 [0.424, 3.124]	1.2 [-8.1, 10.4]	0.805
Baseline eosinophils (cat. Q)								0.707
Q1: < 140 cells/uL	89	12 (13.5) [7.2, 22.4]	79	10 (12.7) [6.2, 22.0]	1.065 [0.487, 2.330]	1.075 [0.437, 2.645]	0.8 [-10.6, 12.2]	1.000
Q2: 140 - < 250 cells/uL	93	2 (2.2) [0.3, 7.6]	92	3 (3.3) [0.7, 9.2]	0.659 [0.113, 3.856]	0.652 [0.106, 3.996]	-1.1 [-6.9, 4.6]	0.682
Q3: 250 - < 430 cells/uL	100	10 (10.0) [4.9, 17.6]	98	5 (5.1) [1.7, 11.5]	1.960 [0.695, 5.527]	2.067 [0.680, 6.283]	4.9 [-3.4, 13.2]	0.283
Q4: >= 430 cells/uL	98	9 (9.2) [4.3, 16.7]	102	8 (7.8) [3.4, 14.9]	1.171 [0.471, 2.912]	1.188 [0.439, 3.215]	1.3 [-7.4, 10.1]	0.803

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAS_TLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.413
< 25 ppb	155	12 (7.7) [4.1, 13.1]	145	9 (6.2) [2.9, 11.5]	1.247 [0.542, 2.872]	1.268 [0.518, 3.105]	1.5 [-4.9, 8.0]	0.656
25 - < 50 ppb	111	12 (10.8) [5.7, 18.1]	109	6 (5.5) [2.0, 11.6]	1.964 [0.764, 5.046]	2.081 [0.752, 5.759]	5.3 [-2.8, 13.4]	0.218
>= 50 ppb	111	9 (8.1) [3.8, 14.8]	113	11 (9.7) [5.0, 16.8]	0.833 [0.359, 1.931]	0.818 [0.325, 2.059]	-1.6 [-10.0, 6.7]	0.816

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table NT1AAS_TLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL - adult

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.396
Q1: < 16 ppb	93	6 (6.5) [2.4, 13.5]	81	6 (7.4) [2.8, 15.4]	0.871 [0.292, 2.595]	0.862 [0.267, 2.786]	-1.0 [-9.7, 7.8]	1.000
Q2: 16 - < 30 ppb	86	7 (8.1) [3.3, 16.1]	96	4 (4.2) [1.1, 10.3]	1.953 [0.592, 6.444]	2.038 [0.575, 7.219]	4.0 [-4.2, 12.1]	0.354
Q3: 30 - < 56 ppb	102	13 (12.7) [7.0, 20.8]	89	6 (6.7) [2.5, 14.1]	1.891 [0.750, 4.766]	2.021 [0.734, 5.562]	6.0 [-3.4, 15.4]	0.226
Q4: >= 56 ppb	96	7 (7.3) [3.0, 14.4]	101	10 (9.9) [4.9, 17.5]	0.736 [0.292, 1.856]	0.716 [0.261, 1.963]	-2.6 [-11.4, 6.2]	0.615
Total serum IgE (cat. N)								0.589
Q1: < 53.1 IU/ml	93	10 (10.8) [5.3, 18.9]	96	10 (10.4) [5.1, 18.3]	1.032 [0.451, 2.365]	1.036 [0.410, 2.618]	0.3 [-9.5, 10.2]	1.000
Q2: 53.1 - < 195.6 IU/ml	100	9 (9.0) [4.2, 16.4]	99	7 (7.1) [2.9, 14.0]	1.273 [0.493, 3.284]	1.300 [0.464, 3.639]	1.9 [-6.6, 10.5]	0.795
Q3: 195.6 - < 572.4 IU/ml	103	8 (7.8) [3.4, 14.7]	85	7 (8.2) [3.4, 16.2]	0.943 [0.357, 2.495]	0.938 [0.326, 2.702]	-0.5 [-9.3, 8.4]	1.000
Q4: >= 572.4 IU/ml	84	6 (7.1) [2.7, 14.9]	91	2 (2.2) [0.3, 7.7]	3.250 [0.674, 15.662]	3.423 [0.671, 17.452]	4.9 [-2.5, 12.4]	0.156
Nasal polyps last 2 years								0.470
Yes	32	3 (9.4) [2.0, 25.0]	29	1 (3.4) [0.1, 17.8]	2.719 [0.299, 24.701]	2.897 [0.284, 29.533]	5.9 [-9.4, 21.3]	0.614
No	348	30 (8.6) [5.9, 12.1]	342	25 (7.3) [4.8, 10.6]	1.179 [0.709, 1.963]	1.196 [0.688, 2.080]	1.3 [-3.0, 5.6]	0.575

Note: DSAFL - adult = Dossier Label Safety Set - adult.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 09MAR2022

Table DT1AAS_ULSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Age (cat. N)								0.962
< 18 years	14	0 (0.0) [0.0, 23.2]	12	0 (0.0) [0.0, 26.5]	0.867 + [0.018, 40.684]	0.862 + [0.016, 46.704]	-0.5 + [-21.5, 20.5]	NE
18 - < 65 years	236	31 (13.1) [9.1, 18.1]	115	12 (10.4) [5.5, 17.5]	1.259 [0.672, 2.359]	1.298 [0.640, 2.633]	2.7 [-5.0, 10.4]	0.603
>= 65 years	60	12 (20.0) [10.8, 32.3]	22	4 (18.2) [5.2, 40.3]	1.100 [0.396, 3.053]	1.125 [0.321, 3.945]	1.8 [-20.3, 24.0]	1.000
Region (cat. N)								0.734
Western Europe	58	12 (20.7) [11.2, 33.4]	25	2 (8.0) [1.0, 26.0]	2.586 [0.624, 10.717]	3.000 [0.619, 14.542]	12.7 [-5.1, 30.4]	0.210
North America	62	5 (8.1) [2.7, 17.8]	26	3 (11.5) [2.4, 30.2]	0.699 [0.180, 2.713]	0.673 [0.148, 3.047]	-3.5 [-20.2, 13.3]	0.689
South America	71	5 (7.0) [2.3, 15.7]	36	3 (8.3) [1.8, 22.5]	0.845 [0.214, 3.339]	0.833 [0.188, 3.702]	-1.3 [-14.2, 11.6]	1.000
Central/Eastern Europe	20	3 (15.0) [3.2, 37.9]	12	0 (0.0) [0.0, 26.5]	4.333 + [0.243, 77.298]	5.000 + [0.237, 105.660]	15.0 [-7.3, 37.3]	0.274
Asia Pacific	47	9 (19.1) [9.1, 33.3]	25	4 (16.0) [4.5, 36.1]	1.197 [0.409, 3.500]	1.243 [0.341, 4.530]	3.1 [-18.2, 24.5]	1.000
Rest of the world	52	9 (17.3) [8.2, 30.3]	25	4 (16.0) [4.5, 36.1]	1.082 [0.369, 3.175]	1.099 [0.303, 3.985]	1.3 [-19.3, 21.9]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_ULSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. N)								0.875
< 150 cells/uL	74	11 (14.9) [7.7, 25.0]	36	3 (8.3) [1.8, 22.5]	1.784 [0.530, 5.999]	1.921 [0.501, 7.366]	6.5 [-7.7, 20.7]	0.543
150 - < 300 cells/uL	106	16 (15.1) [8.9, 23.4]	47	6 (12.8) [4.8, 25.7]	1.182 [0.494, 2.831]	1.215 [0.443, 3.330]	2.3 [-10.9, 15.6]	0.806
300 - < 450 cells/uL	58	6 (10.3) [3.9, 21.2]	31	2 (6.5) [0.8, 21.4]	1.603 [0.344, 7.478]	1.673 [0.317, 8.830]	3.9 [-10.3, 18.0]	0.708
>= 450 cells/uL	72	10 (13.9) [6.9, 24.1]	35	5 (14.3) [4.8, 30.3]	0.972 [0.360, 2.629]	0.968 [0.304, 3.083]	-0.4 [-16.6, 15.8]	1.000
Baseline eosinophils (cat. Q)								0.641
Q1: < 140 cells/uL	67	10 (14.9) [7.4, 25.7]	33	2 (6.1) [0.7, 20.2]	2.463 [0.572, 10.603]	2.719 [0.560, 13.201]	8.9 [-5.2, 22.9]	0.327
Q2: 140 - < 250 cells/uL	85	9 (10.6) [5.0, 19.2]	40	5 (12.5) [4.2, 26.8]	0.847 [0.303, 2.365]	0.829 [0.259, 2.655]	-1.9 [-15.9, 12.1]	0.767
Q3: 250 - < 430 cells/uL	83	14 (16.9) [9.5, 26.7]	37	4 (10.8) [3.0, 25.4]	1.560 [0.551, 4.421]	1.674 [0.511, 5.481]	6.1 [-8.7, 20.9]	0.581
Q4: >= 430 cells/uL	75	10 (13.3) [6.6, 23.2]	39	5 (12.8) [4.3, 27.4]	1.040 [0.382, 2.831]	1.046 [0.331, 3.307]	0.5 [-14.4, 15.5]	1.000

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_ULSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. N)								0.597
< 25 ppb	127	16 (12.6) [7.4, 19.7]	64	5 (7.8) [2.6, 17.3]	1.613 [0.619, 4.204]	1.701 [0.594, 4.874]	4.8 [-5.1, 14.7]	0.463
25 - < 50 ppb	89	12 (13.5) [7.2, 22.4]	41	6 (14.6) [5.6, 29.2]	0.921 [0.372, 2.283]	0.909 [0.315, 2.620]	-1.2 [-15.9, 13.6]	1.000
>= 50 ppb	91	15 (16.5) [9.5, 25.7]	42	4 (9.5) [2.7, 22.6]	1.731 [0.611, 4.900]	1.875 [0.582, 6.039]	7.0 [-6.5, 20.4]	0.425
Baseline FENO (cat. Q)								0.490
Q1: < 16 ppb	72	6 (8.3) [3.1, 17.3]	38	2 (5.3) [0.6, 17.7]	1.583 [0.336, 7.470]	1.636 [0.314, 8.529]	3.1 [-8.5, 14.6]	0.712
Q2: 16 - < 30 ppb	74	12 (16.2) [8.7, 26.6]	38	5 (13.2) [4.4, 28.1]	1.232 [0.469, 3.242]	1.277 [0.415, 3.937]	3.1 [-12.6, 18.7]	0.785
Q3: 30 - < 56 ppb	83	11 (13.3) [6.8, 22.5]	37	6 (16.2) [6.2, 32.0]	0.817 [0.327, 2.043]	0.789 [0.268, 2.325]	-3.0 [-18.9, 12.9]	0.778
Q4: >= 56 ppb	78	14 (17.9) [10.2, 28.3]	34	2 (5.9) [0.7, 19.7]	3.051 [0.733, 12.697]	3.500 [0.749, 16.345]	12.1 [-1.7, 25.8]	0.141

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_ULSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Total serum IgE (cat. N)								0.648
Q1: < 53.1 IU/ml	75	13 (17.3) [9.6, 27.8]	36	3 (8.3) [1.8, 22.5]	2.080 [0.632, 6.843]	2.306 [0.613, 8.673]	9.0 [-5.5, 23.5]	0.258
Q2: 53.1 - < 195.6 IU/ml	73	12 (16.4) [8.8, 27.0]	42	7 (16.7) [7.0, 31.4]	0.986 [0.421, 2.311]	0.984 [0.354, 2.729]	-0.2 [-16.2, 15.8]	1.000
Q3: 195.6 - < 572.4 IU/ml	86	11 (12.8) [6.6, 21.7]	31	2 (6.5) [0.8, 21.4]	1.983 [0.465, 8.449]	2.127 [0.444, 10.185]	6.3 [-7.0, 19.7]	0.509
Q4: >= 572.4 IU/ml	76	7 (9.2) [3.8, 18.1]	40	4 (10.0) [2.8, 23.7]	0.921 [0.287, 2.960]	0.913 [0.251, 3.326]	-0.8 [-14.0, 12.5]	1.000
Nasal polyps last 2 years								0.656
Yes	28	7 (25.0) [10.7, 44.9]	14	2 (14.3) [1.8, 42.8]	1.750 [0.417, 7.346]	2.000 [0.357, 11.215]	10.7 [-19.0, 40.4]	0.692
No	282	36 (12.8) [9.1, 17.2]	135	14 (10.4) [5.8, 16.8]	1.231 [0.688, 2.204]	1.265 [0.657, 2.434]	2.4 [-4.6, 9.4]	0.523

Note: DSAFNL - LTE = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table PT3AAS_SLSIP: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

	Tezepelumab		Placebo					
Non-disease related serious TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Race (cat. P)								0.880
White	60	6 (10.0) [3.8, 20.5]	58	4 (6.9) [1.9, 16.7]	1.450 [0.431, 4.875]	1.500 [0.401, 5.616]	3.1 [-8.6, 14.8]	0.743
Non-white	6	1 (16.7) [0.4, 64.1]	7	1 (14.3) [0.4, 57.9]	1.167 [0.091, 14.916]	1.200 [0.059, 24.472]	2.4 [-52.6, 57.4]	1.000
Region (cat. P)								0.220
North America/Western EU	6	0 (0.0) [0.0, 45.9]	4	1 (25.0) [0.6, 80.6]	0.238 + [0.012, 4.724]	0.179 + [0.006, 5.678]	-25.0 [-88.3, 38.3]	0.400
Rest of world	60	7 (11.7) [4.8, 22.6]	61	4 (6.6) [1.8, 15.9]	1.779 [0.549, 5.765]	1.882 [0.521, 6.797]	5.1 [-6.8, 17.0]	0.363
Baseline eosinophils (cat. P)		n<10 all levels						NE
< 250 cells/uL	30	3 (10.0) [2.1, 26.5]	29	1 (3.4) [0.1, 17.8]				
>= 250 cells/uL	36	4 (11.1) [3.1, 26.1]	36	4 (11.1) [3.1, 26.1]				
Baseline FENO (cat. P)		n<10 all levels						NE
< 24 ppb	38	5 (13.2) [4.4, 28.1]	30	2 (6.7) [0.8, 22.1]				
>= 24 ppb	28	2 (7.1) [0.9, 23.5]	34	3 (8.8) [1.9, 23.7]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAS_SLSIP: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. M)		n<10 all levels						NE
< 22.0 ppb	34	4 (11.8) [3.3, 27.5]	29	2 (6.9) [0.8, 22.8]				
>= 22.0 ppb	32	3 (9.4) [2.0, 25.0]	35	3 (8.6) [1.8, 23.1]				
Baseline all FEIA status		n<10 all levels						NE
All negative	25	3 (12.0) [2.5, 31.2]	22	3 (13.6) [2.9, 34.9]				
Any positive	35	4 (11.4) [3.2, 26.7]	41	2 (4.9) [0.6, 16.5]				
Th2 status		n<10 all levels						NE
Low	41	6 (14.6) [5.6, 29.2]	30	3 (10.0) [2.1, 26.5]				
High	25	1 (4.0) [0.1, 20.4]	34	2 (5.9) [0.7, 19.7]				
Baseline Periostin		n<10 all levels						NE
Low (< 20.9 ng/ml)	27	3 (11.1) [2.4, 29.2]	32	4 (12.5) [3.5, 29.0]				
High (>= 20.9 ng/ml)	39	4 (10.3) [2.9, 24.2]	33	1 (3.0) [0.1, 15.8]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table PT3AAS_SLSIP: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Current post-BD FEV1 reversibility								0.060
Yes	57	7 (12.3) [5.1, 23.7]	60	3 (5.0) [1.0, 13.9]	2.456 [0.667, 9.040]	2.660 [0.653, 10.839]	7.3 [-4.6, 19.1]	0.197
No	9	0 (0.0) [0.0, 33.6]	5	2 (40.0) [5.3, 85.3]	0.120 + [0.007, 2.101]	0.074 + [0.003, 1.947]	-40.0 [-98.5, 18.5]	0.110
Maintenance OCS use at baseline		n<10 all levels						NE
Yes	9	1 (11.1) [0.3, 48.2]	14	4 (28.6) [8.4, 58.1]				
No	57	6 (10.5) [4.0, 21.5]	51	1 (2.0) [0.0, 10.4]				
No chronic OCS use and current post-BD FEV1 reversibility		n<10 all levels						NE
Yes	51	6 (11.8) [4.4, 23.9]	49	1 (2.0) [0.1, 10.9]				
No	15	1 (6.7) [0.2, 31.9]	16	4 (25.0) [7.3, 52.4]				

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 04APR2022

Table ST1AAS_SLSIS: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFL

Non-disease related serious TEAEs during study period	Tezepelumab N	Tezepelumab n (%) [95 % CI]	Placebo N	Placebo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. S)		n<10 all levels						NE
Western Europe/North America	22	4 (18.2) [5.2, 40.3]	24	4 (16.7) [4.7, 37.4]				
Central/Eastern Europe	30	2 (6.7) [0.8, 22.1]	31	2 (6.5) [0.8, 21.4]				
Rest of world	21	2 (9.5) [1.2, 30.4]	21	1 (4.8) [0.1, 23.8]				
BMI (cat. S)		n<10 all levels						NE
< 30 kg/m**2	42	3 (7.1) [1.5, 19.5]	47	4 (8.5) [2.4, 20.4]				
>= 30.0 kg/m**2	31	5 (16.1) [5.5, 33.7]	29	3 (10.3) [2.2, 27.4]				
OCS dose at baseline								0.455
<= 10 mg	56	7 (12.5) [5.2, 24.1]	56	7 (12.5) [5.2, 24.1]	1.000 [0.375, 2.664]	1.000 [0.326, 3.065]	0.0 [-14.0, 14.0]	1.000
> 10 mg	17	1 (5.9) [0.1, 28.7]	20	0 (0.0) [0.0, 16.8]	3.500 + [0.152, 80.708]	3.727 + [0.142, 97.638]	5.9 [-10.7, 22.5]	0.459

Note: DSAFL = Dossier Label Safety Set.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 23FEB2022

Table DT1AA_QLMI0: Incidence of non-disease related TEAEs during study period
DSAFNL - LTE - adolescents

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related TEAEs during study period	14	7 (50.0) [23.0, 77.0]	12	6 (50.0) [21.1, 78.9]	1.000 [0.463, 2.162]	1.000 [0.214, 4.674]	0.0 [-46.3, 46.3]	1.000

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AA_QLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	7	3 (42.9) [9.9, 81.6]	6	2 (33.3) [4.3, 77.7]				
Female	7	4 (57.1) [18.4, 90.1]	6	4 (66.7) [22.3, 95.7]				
Exacerbations in the year before study		n<10 all levels						NE
<= 2	7	3 (42.9) [9.9, 81.6]	8	4 (50.0) [15.7, 84.3]				
> 2	7	4 (57.1) [18.4, 90.1]	4	2 (50.0) [6.8, 93.2]				
Race		N<10 any level						NE
White	12	6 (50.0) [21.1, 78.9]	10	4 (40.0) [12.2, 73.8]				
Black or African American	0		2	2 (100.0) [15.8, 100.0]				
Asian	1	1 (100.0) [2.5, 100.0]	0					
Other	1	0 (0.0) [0.0, 97.5]	0					
Region		N<10 any level						NE
Europe	1	1 (100.0) [2.5, 100.0]	0					
America	10	5 (50.0) [18.7, 81.3]	12	6 (50.0) [21.1, 78.9]				
Asia/Pacific	1	1 (100.0) [2.5, 100.0]	0					
Rest of the world	2	0 (0.0) [0.0, 84.2]	0					

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_QLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	2	1 (50.0) [1.3, 98.7]				
18.5 - < 25.0 kg/m**2	8	5 (62.5) [24.5, 91.5]	6	3 (50.0) [11.8, 88.2]				
25.0 - < 30.0 kg/m**2	2	0 (0.0) [0.0, 84.2]	3	1 (33.3) [0.8, 90.6]				
>= 30.0 kg/m**2	2	1 (50.0) [1.3, 98.7]	1	1 (100.0) [2.5, 100.0]				
Baseline eosinophils - Low		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	0					
>= 150 cells/uL	13	6 (46.2) [19.2, 74.9]	12	6 (50.0) [21.1, 78.9]				
Baseline eosinophils - High								0.599
< 300 cells/uL	8	3 (37.5) [8.5, 75.5]	2	0 (0.0) [0.0, 84.2]	2.333 + [0.163, 33.343]	3.182 + [0.115, 87.919]	37.5 [-27.3, 100.0]	1.000
>= 300 cells/uL	6	4 (66.7) [22.3, 95.7]	10	6 (60.0) [26.2, 87.8]	1.111 [0.520, 2.374]	1.333 [0.161, 11.075]	6.7 [-55.1, 68.4]	1.000
Baseline FENO		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	4	2 (50.0) [6.8, 93.2]				
>= 25 ppb	11	7 (63.6) [30.8, 89.1]	8	4 (50.0) [15.7, 84.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_QLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status		N<10 any level						NE
All negative	3	2 (66.7) [9.4, 99.2]	1	0 (0.0) [0.0, 97.5]				
Any positive	11	5 (45.5) [16.7, 76.6]	11	6 (54.5) [23.4, 83.3]				
Total serum IgE		N<10 any level						NE
Low	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
Normal	11	6 (54.5) [23.4, 83.3]	6	3 (50.0) [11.8, 88.2]				
High	2	1 (50.0) [1.3, 98.7]	5	3 (60.0) [14.7, 94.7]				
OCS at baseline		N<10 any level						NE
Yes	1	1 (100.0) [2.5, 100.0]	0					
No	13	6 (46.2) [19.2, 74.9]	12	6 (50.0) [21.1, 78.9]				
LAMA use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	4	3 (75.0) [19.4, 99.4]				
No	11	5 (45.5) [16.7, 76.6]	8	3 (37.5) [8.5, 75.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_QLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	4	3 (75.0) [19.4, 99.4]				
No	11	5 (45.5) [16.7, 76.6]	8	3 (37.5) [8.5, 75.5]				
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	5	3 (60.0) [14.7, 94.7]	5	3 (60.0) [14.7, 94.7]				
No	9	4 (44.4) [13.7, 78.8]	7	3 (42.9) [9.9, 81.6]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_QLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)		N<10 any level						NE
Western Europe	1	1 (100.0) [2.5, 100.0]	0					
North America	1	0 (0.0) [0.0, 97.5]	4	2 (50.0) [6.8, 93.2]				
South America	9	5 (55.6) [21.2, 86.3]	8	4 (50.0) [15.7, 84.3]				
Central/Eastern Europe	1	0 (0.0) [0.0, 97.5]	0					
Asia Pacific	1	1 (100.0) [2.5, 100.0]	0					
Rest of the world	1	0 (0.0) [0.0, 97.5]	0					
Baseline eosinophils (cat. N)		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	0					
150 - < 300 cells/uL	7	2 (28.6) [3.7, 71.0]	2	0 (0.0) [0.0, 84.2]				
300 - < 450 cells/uL	0		2	1 (50.0) [1.3, 98.7]				
>= 450 cells/uL	6	4 (66.7) [22.3, 95.7]	8	5 (62.5) [24.5, 91.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_QLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. Q)		N<10 any level						NE
Q2: 140 - < 250 cells/uL	6	2 (33.3) [4.3, 77.7]	2	0 (0.0) [0.0, 84.2]				
Q3: 250 - < 430 cells/uL	2	1 (50.0) [1.3, 98.7]	1	0 (0.0) [0.0, 97.5]				
Q4: >= 430 cells/uL	6	4 (66.7) [22.3, 95.7]	9	6 (66.7) [29.9, 92.5]				
Baseline FENO (cat. N)		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	4	2 (50.0) [6.8, 93.2]				
25 - < 50 ppb	3	3 (100.0) [29.2, 100.0]	4	2 (50.0) [6.8, 93.2]				
>= 50 ppb	8	4 (50.0) [15.7, 84.3]	4	2 (50.0) [6.8, 93.2]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_QLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)		N<10 any level						NE
Q1: < 16 ppb	1	0 (0.0) [0.0, 97.5]	3	2 (66.7) [9.4, 99.2]				
Q2: 16 - < 30 ppb	2	0 (0.0) [0.0, 84.2]	2	1 (50.0) [1.3, 98.7]				
Q3: 30 - < 56 ppb	4	3 (75.0) [19.4, 99.4]	3	1 (33.3) [0.8, 90.6]				
Q4: >= 56 ppb	7	4 (57.1) [18.4, 90.1]	4	2 (50.0) [6.8, 93.2]				
Total serum IgE (cat. N)		N<10 any level						NE
Q1: < 53.1 IU/ml	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
Q2: 53.1 - < 195.6 IU/ml	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Q3: 195.6 - < 572.4 IU/ml	4	2 (50.0) [6.8, 93.2]	2	1 (50.0) [1.3, 98.7]				
Q4: >= 572.4 IU/ml	8	4 (50.0) [15.7, 84.3]	8	4 (50.0) [15.7, 84.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_QLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years		N<10 any level						NE
Yes	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
No	13	7 (53.8) [25.1, 80.8]	11	6 (54.5) [23.4, 83.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_QLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFNL - LTE - adolescents

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	14	7 (50.0) [23.0, 77.0]	12	6 (50.0) [21.1, 78.9]	1.000 [0.463, 2.162]	1.000 [0.214, 4.674]	0.0 [-46.3, 46.3]	1.000

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AAN_QLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex		n<10 all levels						NE
Male	7	3 (42.9) [9.9, 81.6]	6	2 (33.3) [4.3, 77.7]				
Female	7	4 (57.1) [18.4, 90.1]	6	4 (66.7) [22.3, 95.7]				
Exacerbations in the year before study		n<10 all levels						NE
<= 2	7	3 (42.9) [9.9, 81.6]	8	4 (50.0) [15.7, 84.3]				
> 2	7	4 (57.1) [18.4, 90.1]	4	2 (50.0) [6.8, 93.2]				
Race		N<10 any level						NE
White	12	6 (50.0) [21.1, 78.9]	10	4 (40.0) [12.2, 73.8]				
Black or African American	0		2	2 (100.0) [15.8, 100.0]				
Asian	1	1 (100.0) [2.5, 100.0]	0					
Other	1	0 (0.0) [0.0, 97.5]	0					
Region		N<10 any level						NE
Europe	1	1 (100.0) [2.5, 100.0]	0					
America	10	5 (50.0) [18.7, 81.3]	12	6 (50.0) [21.1, 78.9]				
Asia/Pacific	1	1 (100.0) [2.5, 100.0]	0					
Rest of the world	2	0 (0.0) [0.0, 84.2]	0					

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_QLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	2	1 (50.0) [1.3, 98.7]				
18.5 - < 25.0 kg/m**2	8	5 (62.5) [24.5, 91.5]	6	3 (50.0) [11.8, 88.2]				
25.0 - < 30.0 kg/m**2	2	0 (0.0) [0.0, 84.2]	3	1 (33.3) [0.8, 90.6]				
>= 30.0 kg/m**2	2	1 (50.0) [1.3, 98.7]	1	1 (100.0) [2.5, 100.0]				
Baseline eosinophils - Low		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	0					
>= 150 cells/uL	13	6 (46.2) [19.2, 74.9]	12	6 (50.0) [21.1, 78.9]				
Baseline eosinophils - High								0.599
< 300 cells/uL	8	3 (37.5) [8.5, 75.5]	2	0 (0.0) [0.0, 84.2]	2.333 + [0.163, 33.343]	3.182 + [0.115, 87.919]	37.5 [-27.3, 100.0]	1.000
>= 300 cells/uL	6	4 (66.7) [22.3, 95.7]	10	6 (60.0) [26.2, 87.8]	1.111 [0.520, 2.374]	1.333 [0.161, 11.075]	6.7 [-55.1, 68.4]	1.000
Baseline FENO		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	4	2 (50.0) [6.8, 93.2]				
>= 25 ppb	11	7 (63.6) [30.8, 89.1]	8	4 (50.0) [15.7, 84.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_QLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline specific perennial FEIA status		N<10 any level						NE
All negative	3	2 (66.7) [9.4, 99.2]	1	0 (0.0) [0.0, 97.5]				
Any positive	11	5 (45.5) [16.7, 76.6]	11	6 (54.5) [23.4, 83.3]				
Total serum IgE		N<10 any level						NE
Low	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
Normal	11	6 (54.5) [23.4, 83.3]	6	3 (50.0) [11.8, 88.2]				
High	2	1 (50.0) [1.3, 98.7]	5	3 (60.0) [14.7, 94.7]				
OCS at baseline		N<10 any level						NE
Yes	1	1 (100.0) [2.5, 100.0]	0					
No	13	6 (46.2) [19.2, 74.9]	12	6 (50.0) [21.1, 78.9]				
LAMA use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	4	3 (75.0) [19.4, 99.4]				
No	11	5 (45.5) [16.7, 76.6]	8	3 (37.5) [8.5, 75.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_QLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Tiotropium use at baseline		N<10 any level						NE
Yes	3	2 (66.7) [9.4, 99.2]	4	3 (75.0) [19.4, 99.4]				
No	11	5 (45.5) [16.7, 76.6]	8	3 (37.5) [8.5, 75.5]				
Montelukast/ Cromoglicic acid use at baseline		n<10 all levels						NE
Yes	5	3 (60.0) [14.7, 94.7]	5	3 (60.0) [14.7, 94.7]				
No	9	4 (44.4) [13.7, 78.8]	7	3 (42.9) [9.9, 81.6]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_QLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)		N<10 any level						NE
Western Europe	1	1 (100.0) [2.5, 100.0]	0					
North America	1	0 (0.0) [0.0, 97.5]	4	2 (50.0) [6.8, 93.2]				
South America	9	5 (55.6) [21.2, 86.3]	8	4 (50.0) [15.7, 84.3]				
Central/Eastern Europe	1	0 (0.0) [0.0, 97.5]	0					
Asia Pacific	1	1 (100.0) [2.5, 100.0]	0					
Rest of the world	1	0 (0.0) [0.0, 97.5]	0					
Baseline eosinophils (cat. N)		N<10 any level						NE
< 150 cells/uL	1	1 (100.0) [2.5, 100.0]	0					
150 - < 300 cells/uL	7	2 (28.6) [3.7, 71.0]	2	0 (0.0) [0.0, 84.2]				
300 - < 450 cells/uL	0		2	1 (50.0) [1.3, 98.7]				
>= 450 cells/uL	6	4 (66.7) [22.3, 95.7]	8	5 (62.5) [24.5, 91.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_QLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. Q)		N<10 any level						NE
Q2: 140 - < 250 cells/uL	6	2 (33.3) [4.3, 77.7]	2	0 (0.0) [0.0, 84.2]				
Q3: 250 - < 430 cells/uL	2	1 (50.0) [1.3, 98.7]	1	0 (0.0) [0.0, 97.5]				
Q4: >= 430 cells/uL	6	4 (66.7) [22.3, 95.7]	9	6 (66.7) [29.9, 92.5]				
Baseline FENO (cat. N)		N<10 any level						NE
< 25 ppb	3	0 (0.0) [0.0, 70.8]	4	2 (50.0) [6.8, 93.2]				
25 - < 50 ppb	3	3 (100.0) [29.2, 100.0]	4	2 (50.0) [6.8, 93.2]				
>= 50 ppb	8	4 (50.0) [15.7, 84.3]	4	2 (50.0) [6.8, 93.2]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_QLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)		N<10 any level						NE
Q1: < 16 ppb	1	0 (0.0) [0.0, 97.5]	3	2 (66.7) [9.4, 99.2]				
Q2: 16 - < 30 ppb	2	0 (0.0) [0.0, 84.2]	2	1 (50.0) [1.3, 98.7]				
Q3: 30 - < 56 ppb	4	3 (75.0) [19.4, 99.4]	3	1 (33.3) [0.8, 90.6]				
Q4: >= 56 ppb	7	4 (57.1) [18.4, 90.1]	4	2 (50.0) [6.8, 93.2]				
Total serum IgE (cat. N)		N<10 any level						NE
Q1: < 53.1 IU/ml	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
Q2: 53.1 - < 195.6 IU/ml	1	1 (100.0) [2.5, 100.0]	1	1 (100.0) [2.5, 100.0]				
Q3: 195.6 - < 572.4 IU/ml	4	2 (50.0) [6.8, 93.2]	2	1 (50.0) [1.3, 98.7]				
Q4: >= 572.4 IU/ml	8	4 (50.0) [15.7, 84.3]	8	4 (50.0) [15.7, 84.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_QLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adolescents

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years		N<10 any level						NE
Yes	1	0 (0.0) [0.0, 97.5]	1	0 (0.0) [0.0, 97.5]				
No	13	7 (53.8) [25.1, 80.8]	11	6 (54.5) [23.4, 83.3]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_QLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFNL - LTE - adolescents

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	14	0 (0.0) [0.0, 23.2]	12	0 (0.0) [0.0, 26.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AAS_QLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFNL - LTE - adolescents

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	14	0 (0.0) [0.0, 23.2]	12	0 (0.0) [0.0, 26.5]				

Note: DSAFNL - LTE - adolescents = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adolescents.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AA_LLMI0: Incidence of non-disease related TEAEs during study period
DSAFNL - LTE - adult

	Teze+Teze		Pbo+Pbo					
		n (%)		n (%)	RR	OR	RD	
	N	[95 % CI]	N	[95 % CI]	[95 % CI]	[95 % CI]	[95 % CI]	p-value
Non-disease related TEAEs during study period	296	233 (78.7) [73.6, 83.2]	137	107 (78.1) [70.2, 84.7]	1.008 [0.906, 1.121]	1.037 [0.634, 1.695]	0.6 [-8.3, 9.5]	0.900

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AA_LLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Sex								0.033	i
Male	108	86 (79.6) [70.8, 86.8]	50	33 (66.0) [51.2, 78.8]	1.207 [0.968, 1.504]	2.014 [0.952, 4.261]	13.6 [-3.0, 30.3]	0.076	
Female	188	147 (78.2) [71.6, 83.9]	87	74 (85.1) [75.8, 91.8]	0.919 [0.819, 1.032]	0.630 [0.318, 1.248]	-6.9 [-17.2, 3.5]	0.196	
Age								0.649	
< 65 years	236	186 (78.8) [73.0, 83.8]	115	89 (77.4) [68.7, 84.7]	1.018 [0.904, 1.147]	1.087 [0.635, 1.859]	1.4 [-8.5, 11.3]	0.783	
>= 65 years	60	47 (78.3) [65.8, 87.9]	22	18 (81.8) [59.7, 94.8]	0.957 [0.755, 1.214]	0.803 [0.231, 2.791]	-3.5 [-25.8, 18.8]	1.000	
Exacerbations in the year before study								0.678	
<= 2	166	130 (78.3) [71.3, 84.3]	80	61 (76.3) [65.4, 85.1]	1.027 [0.887, 1.189]	1.125 [0.597, 2.119]	2.1 [-10.1, 14.2]	0.745	
> 2	130	103 (79.2) [71.2, 85.8]	57	46 (80.7) [68.1, 90.0]	0.982 [0.841, 1.146]	0.912 [0.417, 1.995]	-1.5 [-15.1, 12.2]	1.000	
Race								0.772	
White	214	172 (80.4) [74.4, 85.5]	89	70 (78.7) [68.7, 86.6]	1.022 [0.900, 1.160]	1.112 [0.605, 2.044]	1.7 [-9.1, 12.6]	0.754	
Black or African American	16	11 (68.8) [41.3, 89.0]	12	9 (75.0) [42.8, 94.5]	0.917 [0.576, 1.459]	0.733 [0.137, 3.938]	-6.3 [-46.9, 34.4]	1.000	
Asian	55	40 (72.7) [59.0, 83.9]	30	22 (73.3) [54.1, 87.7]	0.992 [0.757, 1.299]	0.970 [0.356, 2.645]	-0.6 [-22.9, 21.7]	1.000	
Other	11	10 (90.9) [58.7, 99.8]	6	6 (100.0) [54.1, 100.0]	0.909 [0.754, 1.096]	0.538 + [0.019, 15.298]	-9.1 [-39.0, 20.8]	1.000	

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_LLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Region								0.510	
Europe	52	43 (82.7) [69.7, 91.8]	24	16 (66.7) [44.7, 84.4]	1.240 [0.911, 1.690]	2.389 [0.786, 7.263]	16.0 [-8.5, 40.6]	0.144	
America	123	97 (78.9) [70.6, 85.7]	50	40 (80.0) [66.3, 90.0]	0.986 [0.835, 1.164]	0.933 [0.412, 2.111]	-1.1 [-15.8, 13.5]	1.000	
Asia/Pacific	51	37 (72.5) [58.3, 84.1]	26	20 (76.9) [56.4, 91.0]	0.943 [0.720, 1.235]	0.793 [0.264, 2.382]	-4.4 [-27.6, 18.8]	0.787	
Rest of the world	70	56 (80.0) [68.7, 88.6]	37	31 (83.8) [68.0, 93.8]	0.955 [0.794, 1.148]	0.774 [0.270, 2.217]	-3.8 [-21.0, 13.4]	0.796	
BMI		N<10 any level						NE	
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	0						
18.5 - < 25.0 kg/m**2	75	55 (73.3) [61.9, 82.9]	39	27 (69.2) [52.4, 83.0]					
25.0 - < 30.0 kg/m**2	102	78 (76.5) [67.0, 84.3]	45	36 (80.0) [65.4, 90.4]					
>= 30.0 kg/m**2	117	99 (84.6) [76.8, 90.6]	53	44 (83.0) [70.2, 91.9]					
Baseline eosinophils - Low								0.488	
< 150 cells/uL	73	55 (75.3) [63.9, 84.7]	36	25 (69.4) [51.9, 83.7]	1.085 [0.842, 1.398]	1.344 [0.554, 3.263]	5.9 [-14.2, 26.0]	0.645	
>= 150 cells/uL	223	178 (79.8) [73.9, 84.9]	101	82 (81.2) [72.2, 88.3]	0.983 [0.877, 1.103]	0.917 [0.505, 1.664]	-1.4 [-11.4, 8.6]	0.880	
Baseline eosinophils - High								0.042	i
< 300 cells/uL	172	134 (77.9) [71.0, 83.9]	81	57 (70.4) [59.2, 80.0]	1.107 [0.941, 1.302]	1.485 [0.817, 2.699]	7.5 [-5.1, 20.2]	0.212	
>= 300 cells/uL	124	99 (79.8) [71.7, 86.5]	56	50 (89.3) [78.1, 96.0]	0.894 [0.788, 1.015]	0.475 [0.183, 1.233]	-9.4 [-21.5, 2.6]	0.140	

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_LLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.410
< 25 ppb	124	92 (74.2) [65.6, 81.6]	60	47 (78.3) [65.8, 87.9]	0.947 [0.800, 1.121]	0.795 [0.382, 1.657]	-4.1 [-18.3, 10.1]	0.587
>= 25 ppb	169	138 (81.7) [75.0, 87.2]	75	59 (78.7) [67.7, 87.3]	1.038 [0.904, 1.191]	1.207 [0.614, 2.373]	3.0 [-8.9, 14.9]	0.600
Baseline specific perennial FEIA status								0.998
All negative	113	94 (83.2) [75.0, 89.6]	52	43 (82.7) [69.7, 91.8]	1.006 [0.866, 1.168]	1.035 [0.433, 2.475]	0.5 [-13.3, 14.3]	1.000
Any positive	182	139 (76.4) [69.5, 82.3]	83	63 (75.9) [65.3, 84.6]	1.006 [0.870, 1.164]	1.026 [0.559, 1.885]	0.5 [-11.5, 12.4]	1.000
Total serum IgE								0.592
Low	92	74 (80.4) [70.9, 88.0]	48	41 (85.4) [72.2, 93.9]	0.942 [0.807, 1.099]	0.702 [0.271, 1.820]	-5.0 [-19.4, 9.5]	0.643
Normal	182	142 (78.0) [71.3, 83.8]	75	56 (74.7) [63.3, 84.0]	1.045 [0.897, 1.217]	1.204 [0.643, 2.256]	3.4 [-9.1, 15.8]	0.625
High	22	17 (77.3) [54.6, 92.2]	14	10 (71.4) [41.9, 91.6]	1.082 [0.724, 1.616]	1.360 [0.295, 6.276]	5.8 [-29.4, 41.1]	0.712
OCS at baseline								0.061
Yes	27	23 (85.2) [66.3, 95.8]	12	12 (100.0) [73.5, 100.0]	0.852 [0.728, 0.997]	0.209 + [0.010, 4.201]	-14.8 [-34.2, 4.6]	0.292
No	269	210 (78.1) [72.6, 82.9]	125	95 (76.0) [67.5, 83.2]	1.027 [0.914, 1.155]	1.124 [0.680, 1.857]	2.1 [-7.5, 11.6]	0.698

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_LLSIK: Incidence of non-disease related TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.252
Yes	80	66 (82.5) [72.4, 90.1]	38	28 (73.7) [56.9, 86.6]	1.120 [0.903, 1.388]	1.684 [0.668, 4.242]	8.8 [-9.4, 27.0]	0.329
No	216	167 (77.3) [71.1, 82.7]	99	79 (79.8) [70.5, 87.2]	0.969 [0.857, 1.095]	0.863 [0.481, 1.549]	-2.5 [-12.9, 7.9]	0.662
Tiotropium use at baseline								0.376
Yes	73	60 (82.2) [71.5, 90.2]	36	27 (75.0) [57.8, 87.9]	1.096 [0.882, 1.361]	1.538 [0.587, 4.033]	7.2 [-11.5, 25.9]	0.449
No	223	173 (77.6) [71.5, 82.9]	101	80 (79.2) [70.0, 86.6]	0.979 [0.867, 1.107]	0.908 [0.511, 1.613]	-1.6 [-12.0, 8.7]	0.774
Montelukast/ Cromoglicic acid use at baseline								0.105
Yes	118	92 (78.0) [69.4, 85.1]	50	43 (86.0) [73.3, 94.2]	0.907 [0.782, 1.050]	0.576 [0.232, 1.431]	-8.0 [-21.6, 5.6]	0.291
No	178	141 (79.2) [72.5, 84.9]	87	64 (73.6) [63.0, 82.4]	1.077 [0.930, 1.247]	1.370 [0.753, 2.491]	5.7 [-6.2, 17.5]	0.349

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AA_LLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.703
Western Europe	57	48 (84.2) [72.1, 92.5]	25	17 (68.0) [46.5, 85.1]	1.238 [0.925, 1.657]	2.510 [0.834, 7.550]	16.2 [-7.3, 39.7]	0.138
North America	61	48 (78.7) [66.3, 88.1]	22	17 (77.3) [54.6, 92.2]	1.018 [0.784, 1.323]	1.086 [0.337, 3.500]	1.4 [-22.0, 24.8]	1.000
South America	62	49 (79.0) [66.8, 88.3]	28	23 (82.1) [63.1, 93.9]	0.962 [0.776, 1.193]	0.819 [0.261, 2.573]	-3.1 [-23.1, 16.9]	1.000
Central/Eastern Europe	19	16 (84.2) [60.4, 96.6]	12	11 (91.7) [61.5, 99.8]	0.919 [0.709, 1.190]	0.485 [0.044, 5.290]	-7.5 [-36.9, 22.0]	1.000
Asia Pacific	46	32 (69.6) [54.2, 82.3]	25	19 (76.0) [54.9, 90.6]	0.915 [0.684, 1.225]	0.722 [0.237, 2.195]	-6.4 [-30.9, 18.0]	0.783
Rest of the world	51	40 (78.4) [64.7, 88.7]	25	20 (80.0) [59.3, 93.2]	0.980 [0.769, 1.250]	0.909 [0.278, 2.975]	-1.6 [-23.9, 20.7]	1.000
Baseline eosinophils (cat. N)								0.195
< 150 cells/uL	73	55 (75.3) [63.9, 84.7]	36	25 (69.4) [51.9, 83.7]	1.085 [0.842, 1.398]	1.344 [0.554, 3.263]	5.9 [-14.2, 26.0]	0.645
150 - < 300 cells/uL	99	79 (79.8) [70.5, 87.2]	45	32 (71.1) [55.7, 83.6]	1.122 [0.909, 1.386]	1.605 [0.714, 3.608]	8.7 [-8.4, 25.7]	0.287
300 - < 450 cells/uL	58	44 (75.9) [62.8, 86.1]	29	26 (89.7) [72.6, 97.8]	0.846 [0.699, 1.024]	0.363 [0.095, 1.382]	-13.8 [-32.0, 4.4]	0.159
>= 450 cells/uL	66	55 (83.3) [72.1, 91.4]	27	24 (88.9) [70.8, 97.6]	0.938 [0.790, 1.113]	0.625 [0.160, 2.444]	-5.6 [-23.0, 11.9]	0.750

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_LLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. Q)								0.689
Q1: < 140 cells/uL	67	49 (73.1) [60.9, 83.2]	33	22 (66.7) [48.2, 82.0]	1.097 [0.828, 1.454]	1.361 [0.552, 3.358]	6.5 [-15.1, 28.0]	0.640
Q2: 140 - < 250 cells/uL	79	62 (78.5) [67.8, 86.9]	38	29 (76.3) [59.8, 88.6]	1.028 [0.832, 1.271]	1.132 [0.451, 2.841]	2.2 [-16.1, 20.4]	0.815
Q3: 250 - < 430 cells/uL	81	65 (80.2) [69.9, 88.3]	36	29 (80.6) [64.0, 91.8]	0.996 [0.821, 1.209]	0.981 [0.364, 2.639]	-0.3 [-17.9, 17.3]	1.000
Q4: >= 430 cells/uL	69	57 (82.6) [71.6, 90.7]	30	27 (90.0) [73.5, 97.9]	0.918 [0.781, 1.078]	0.528 [0.137, 2.027]	-7.4 [-23.8, 9.0]	0.543
Baseline FENO (cat. N)								0.580
< 25 ppb	124	92 (74.2) [65.6, 81.6]	60	47 (78.3) [65.8, 87.9]	0.947 [0.800, 1.121]	0.795 [0.382, 1.657]	-4.1 [-18.3, 10.1]	0.587
25 - < 50 ppb	86	71 (82.6) [72.9, 89.9]	37	28 (75.7) [58.8, 88.2]	1.091 [0.887, 1.342]	1.521 [0.597, 3.875]	6.9 [-11.0, 24.8]	0.458
>= 50 ppb	83	67 (80.7) [70.6, 88.6]	38	31 (81.6) [65.7, 92.3]	0.990 [0.823, 1.189]	0.946 [0.353, 2.532]	-0.9 [-17.7, 16.0]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_LLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.372
Q1: < 16 ppb	71	51 (71.8) [59.9, 81.9]	35	27 (77.1) [59.9, 89.6]	0.931 [0.738, 1.174]	0.756 [0.294, 1.941]	-5.3 [-24.9, 14.2]	0.644
Q2: 16 - < 30 ppb	72	57 (79.2) [68.0, 87.8]	36	25 (69.4) [51.9, 83.7]	1.140 [0.891, 1.459]	1.672 [0.674, 4.150]	9.7 [-10.1, 29.5]	0.340
Q3: 30 - < 56 ppb	79	65 (82.3) [72.1, 90.0]	34	31 (91.2) [76.3, 98.1]	0.902 [0.780, 1.045]	0.449 [0.120, 1.679]	-8.9 [-23.7, 5.9]	0.267
Q4: >= 56 ppb	71	57 (80.3) [69.1, 88.8]	30	23 (76.7) [57.7, 90.1]	1.047 [0.833, 1.316]	1.239 [0.443, 3.465]	3.6 [-16.5, 23.7]	0.789
Total serum IgE (cat. N)								0.639
Q1: < 53.1 IU/ml	74	62 (83.8) [73.4, 91.3]	35	30 (85.7) [69.7, 95.2]	0.977 [0.826, 1.157]	0.861 [0.278, 2.667]	-1.9 [-18.3, 14.5]	1.000
Q2: 53.1 - < 195.6 IU/ml	72	51 (70.8) [58.9, 81.0]	41	32 (78.0) [62.4, 89.4]	0.908 [0.728, 1.131]	0.683 [0.278, 1.675]	-7.2 [-25.6, 11.2]	0.508
Q3: 195.6 - < 572.4 IU/ml	82	66 (80.5) [70.3, 88.4]	29	22 (75.9) [56.5, 89.7]	1.061 [0.842, 1.337]	1.313 [0.478, 3.606]	4.6 [-15.5, 24.7]	0.602
Q4: >= 572.4 IU/ml	68	54 (79.4) [67.9, 88.3]	32	23 (71.9) [53.3, 86.3]	1.105 [0.862, 1.416]	1.509 [0.573, 3.978]	7.5 [-13.1, 28.1]	0.450

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AA_LLSIN: Incidence of non-disease related TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years								0.992
Yes	27	23 (85.2) [66.3, 95.8]	13	11 (84.6) [54.6, 98.1]	1.007 [0.761, 1.332]	1.045 [0.166, 6.604]	0.6 [-28.9, 30.0]	1.000
No	269	210 (78.1) [72.6, 82.9]	124	96 (77.4) [69.0, 84.4]	1.008 [0.900, 1.130]	1.038 [0.623, 1.730]	0.6 [-8.8, 10.1]	0.896

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_LLMI0: Incidence of non-disease related non-severe TEAEs during study period
DSAFNL - LTE - adult

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related non-severe TEAEs during study period	296	229 (77.4) [72.2, 82.0]	137	104 (75.9) [67.9, 82.8]	1.019 [0.911, 1.141]	1.085 [0.673, 1.747]	1.5 [-7.7, 10.6]	0.806

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AAN_LLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Sex								0.016	i
Male	108	85 (78.7) [69.8, 86.0]	50	31 (62.0) [47.2, 75.3]	1.269 [1.000, 1.611]	2.265 [1.088, 4.718]	16.7 [-0.3, 33.7]	0.034	*
Female	188	144 (76.6) [69.9, 82.4]	87	73 (83.9) [74.5, 90.9]	0.913 [0.809, 1.031]	0.628 [0.323, 1.219]	-7.3 [-18.0, 3.3]	0.204	
Age								0.360	
< 65 years	236	184 (78.0) [72.1, 83.1]	115	86 (74.8) [65.8, 82.4]	1.043 [0.919, 1.183]	1.193 [0.708, 2.010]	3.2 [-7.0, 13.4]	0.503	
>= 65 years	60	45 (75.0) [62.1, 85.3]	22	18 (81.8) [59.7, 94.8]	0.917 [0.717, 1.171]	0.667 [0.195, 2.283]	-6.8 [-29.4, 15.8]	0.768	
Exacerbations in the year before study								0.571	
<= 2	166	126 (75.9) [68.7, 82.2]	80	58 (72.5) [61.4, 81.9]	1.047 [0.892, 1.228]	1.195 [0.652, 2.190]	3.4 [-9.3, 16.1]	0.638	
> 2	130	103 (79.2) [71.2, 85.8]	57	46 (80.7) [68.1, 90.0]	0.982 [0.841, 1.146]	0.912 [0.417, 1.995]	-1.5 [-15.1, 12.2]	1.000	
Race								0.857	
White	214	170 (79.4) [73.4, 84.6]	89	68 (76.4) [66.2, 84.8]	1.040 [0.909, 1.189]	1.193 [0.661, 2.155]	3.0 [-8.1, 14.2]	0.543	
Black or African American	16	10 (62.5) [35.4, 84.8]	12	9 (75.0) [42.8, 94.5]	0.833 [0.505, 1.375]	0.556 [0.106, 2.901]	-12.5 [-53.9, 28.9]	0.687	
Asian	55	40 (72.7) [59.0, 83.9]	30	22 (73.3) [54.1, 87.7]	0.992 [0.757, 1.299]	0.970 [0.356, 2.645]	-0.6 [-22.9, 21.7]	1.000	
Other	11	9 (81.8) [48.2, 97.7]	6	5 (83.3) [35.9, 99.6]	0.982 [0.624, 1.545]	0.900 [0.064, 12.583]	-1.5 [-51.9, 48.9]	1.000	

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_LLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.634
Europe	52	42 (80.8) [67.5, 90.4]	24	16 (66.7) [44.7, 84.4]	1.212 [0.886, 1.656]	2.100 [0.704, 6.268]	14.1 [-10.6, 38.8]	0.246
America	123	97 (78.9) [70.6, 85.7]	50	39 (78.0) [64.0, 88.5]	1.011 [0.850, 1.202]	1.052 [0.474, 2.335]	0.9 [-14.1, 15.8]	1.000
Asia/Pacific	51	37 (72.5) [58.3, 84.1]	26	20 (76.9) [56.4, 91.0]	0.943 [0.720, 1.235]	0.793 [0.264, 2.382]	-4.4 [-27.6, 18.8]	0.787
Rest of the world	70	53 (75.7) [64.0, 85.2]	37	29 (78.4) [61.8, 90.2]	0.966 [0.779, 1.198]	0.860 [0.331, 2.234]	-2.7 [-21.4, 16.0]	0.815
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	0					
18.5 - < 25.0 kg/m**2	75	55 (73.3) [61.9, 82.9]	39	27 (69.2) [52.4, 83.0]				
25.0 - < 30.0 kg/m**2	102	75 (73.5) [63.9, 81.8]	45	35 (77.8) [62.9, 88.8]				
>= 30.0 kg/m**2	117	98 (83.8) [75.8, 89.9]	53	42 (79.2) [65.9, 89.2]				
Baseline eosinophils - Low								0.680
< 150 cells/uL	73	54 (74.0) [62.4, 83.5]	36	25 (69.4) [51.9, 83.7]	1.065 [0.825, 1.376]	1.251 [0.518, 3.018]	4.5 [-15.6, 24.7]	0.653
>= 150 cells/uL	223	175 (78.5) [72.5, 83.7]	101	79 (78.2) [68.9, 85.8]	1.003 [0.887, 1.135]	1.015 [0.574, 1.796]	0.3 [-10.2, 10.7]	1.000
Baseline eosinophils - High								0.162
< 300 cells/uL	172	132 (76.7) [69.7, 82.8]	81	57 (70.4) [59.2, 80.0]	1.091 [0.926, 1.284]	1.389 [0.767, 2.516]	6.4 [-6.3, 19.1]	0.282
>= 300 cells/uL	124	97 (78.2) [69.9, 85.1]	56	47 (83.9) [71.7, 92.4]	0.932 [0.804, 1.080]	0.688 [0.300, 1.579]	-5.7 [-19.1, 7.6]	0.426

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_LLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.539
< 25 ppb	124	90 (72.6) [63.8, 80.2]	60	45 (75.0) [62.1, 85.3]	0.968 [0.807, 1.161]	0.882 [0.436, 1.786]	-2.4 [-17.1, 12.3]	0.859
>= 25 ppb	169	136 (80.5) [73.7, 86.2]	75	58 (77.3) [66.2, 86.2]	1.041 [0.902, 1.201]	1.208 [0.624, 2.339]	3.1 [-9.0, 15.3]	0.608
Baseline specific perennial FEIA status								0.857
All negative	113	94 (83.2) [75.0, 89.6]	52	42 (80.8) [67.5, 90.4]	1.030 [0.881, 1.204]	1.178 [0.505, 2.750]	2.4 [-11.7, 16.6]	0.826
Any positive	182	135 (74.2) [67.2, 80.4]	83	61 (73.5) [62.7, 82.6]	1.009 [0.864, 1.179]	1.036 [0.574, 1.868]	0.7 [-11.6, 13.0]	1.000
Total serum IgE								0.718
Low	92	74 (80.4) [70.9, 88.0]	48	40 (83.3) [69.8, 92.5]	0.965 [0.821, 1.135]	0.822 [0.329, 2.058]	-2.9 [-17.8, 12.0]	0.820
Normal	182	138 (75.8) [68.9, 81.9]	75	54 (72.0) [60.4, 81.8]	1.053 [0.894, 1.240]	1.220 [0.664, 2.239]	3.8 [-9.0, 16.7]	0.531
High	22	17 (77.3) [54.6, 92.2]	14	10 (71.4) [41.9, 91.6]	1.082 [0.724, 1.616]	1.360 [0.295, 6.276]	5.8 [-29.4, 41.1]	0.712
OCS at baseline								0.050
Yes	27	23 (85.2) [66.3, 95.8]	12	12 (100.0) [73.5, 100.0]	0.852 [0.728, 0.997]	0.209 + [0.010, 4.201]	-14.8 [-34.2, 4.6]	0.292
No	269	206 (76.6) [71.1, 81.5]	125	92 (73.6) [65.0, 81.1]	1.040 [0.919, 1.178]	1.173 [0.720, 1.910]	3.0 [-6.8, 12.8]	0.530

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_LLSIK: Incidence of non-disease related non-severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

	Teze+Teze		Pbo+Pbo					
Non-disease related non-severe TEAEs during study period	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.401
Yes	80	65 (81.3) [71.0, 89.1]	38	28 (73.7) [56.9, 86.6]	1.103 [0.887, 1.370]	1.548 [0.620, 3.863]	7.6 [-10.8, 25.9]	0.347
No	216	164 (75.9) [69.7, 81.5]	99	76 (76.8) [67.2, 84.7]	0.989 [0.867, 1.128]	0.954 [0.545, 1.673]	-0.8 [-11.7, 10.0]	1.000
Tiotropium use at baseline								0.566
Yes	73	59 (80.8) [69.9, 89.1]	36	27 (75.0) [57.8, 87.9]	1.078 [0.865, 1.342]	1.405 [0.542, 3.644]	5.8 [-13.0, 24.7]	0.618
No	223	170 (76.2) [70.1, 81.7]	101	77 (76.2) [66.7, 84.1]	1.000 [0.877, 1.140]	1.000 [0.575, 1.737]	-0.0 [-10.7, 10.7]	1.000
Montelukast/ Cromoglicic acid use at baseline								0.130
Yes	118	91 (77.1) [68.5, 84.3]	50	42 (84.0) [70.9, 92.8]	0.918 [0.786, 1.073]	0.642 [0.269, 1.532]	-6.9 [-21.0, 7.2]	0.407
No	178	138 (77.5) [70.7, 83.4]	87	62 (71.3) [60.6, 80.5]	1.088 [0.932, 1.270]	1.391 [0.777, 2.491]	6.3 [-5.9, 18.4]	0.289

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAN_LLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.787
Western Europe	57	47 (82.5) [70.1, 91.3]	25	17 (68.0) [46.5, 85.1]	1.213 [0.903, 1.628]	2.212 [0.749, 6.530]	14.5 [-9.2, 38.1]	0.159
North America	61	48 (78.7) [66.3, 88.1]	22	17 (77.3) [54.6, 92.2]	1.018 [0.784, 1.323]	1.086 [0.337, 3.500]	1.4 [-22.0, 24.8]	1.000
South America	62	49 (79.0) [66.8, 88.3]	28	22 (78.6) [59.0, 91.7]	1.006 [0.798, 1.269]	1.028 [0.346, 3.058]	0.5 [-20.4, 21.3]	1.000
Central/Eastern Europe	19	16 (84.2) [60.4, 96.6]	12	11 (91.7) [61.5, 99.8]	0.919 [0.709, 1.190]	0.485 [0.044, 5.290]	-7.5 [-36.9, 22.0]	1.000
Asia Pacific	46	32 (69.6) [54.2, 82.3]	25	19 (76.0) [54.9, 90.6]	0.915 [0.684, 1.225]	0.722 [0.237, 2.195]	-6.4 [-30.9, 18.0]	0.783
Rest of the world	51	37 (72.5) [58.3, 84.1]	25	18 (72.0) [50.6, 87.9]	1.008 [0.749, 1.356]	1.028 [0.353, 2.990]	0.5 [-23.9, 25.0]	1.000
Baseline eosinophils (cat. N)								0.376
< 150 cells/uL	73	54 (74.0) [62.4, 83.5]	36	25 (69.4) [51.9, 83.7]	1.065 [0.825, 1.376]	1.251 [0.518, 3.018]	4.5 [-15.6, 24.7]	0.653
150 - < 300 cells/uL	99	78 (78.8) [69.4, 86.4]	45	32 (71.1) [55.7, 83.6]	1.108 [0.896, 1.370]	1.509 [0.675, 3.374]	7.7 [-9.4, 24.8]	0.397
300 - < 450 cells/uL	58	43 (74.1) [61.0, 84.7]	29	25 (86.2) [68.3, 96.1]	0.860 [0.697, 1.061]	0.459 [0.137, 1.535]	-12.1 [-31.5, 7.4]	0.274
>= 450 cells/uL	66	54 (81.8) [70.4, 90.2]	27	22 (81.5) [61.9, 93.7]	1.004 [0.812, 1.242]	1.023 [0.322, 3.246]	0.3 [-19.6, 20.3]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_LLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. Q)								0.950
Q1: < 140 cells/uL	67	48 (71.6) [59.3, 82.0]	33	22 (66.7) [48.2, 82.0]	1.075 [0.809, 1.428]	1.263 [0.515, 3.100]	5.0 [-16.7, 26.6]	0.647
Q2: 140 - < 250 cells/uL	79	62 (78.5) [67.8, 86.9]	38	29 (76.3) [59.8, 88.6]	1.028 [0.832, 1.271]	1.132 [0.451, 2.841]	2.2 [-16.1, 20.4]	0.815
Q3: 250 - < 430 cells/uL	81	63 (77.8) [67.2, 86.3]	36	28 (77.8) [60.8, 89.9]	1.000 [0.811, 1.233]	1.000 [0.389, 2.571]	0.0 [-18.3, 18.3]	1.000
Q4: >= 430 cells/uL	69	56 (81.2) [69.9, 89.6]	30	25 (83.3) [65.3, 94.4]	0.974 [0.800, 1.185]	0.862 [0.277, 2.678]	-2.2 [-20.8, 16.4]	1.000
Baseline FENO (cat. N)								0.755
< 25 ppb	124	90 (72.6) [63.8, 80.2]	60	45 (75.0) [62.1, 85.3]	0.968 [0.807, 1.161]	0.882 [0.436, 1.786]	-2.4 [-17.1, 12.3]	0.859
25 - < 50 ppb	86	70 (81.4) [71.6, 89.0]	37	28 (75.7) [58.8, 88.2]	1.076 [0.873, 1.325]	1.406 [0.557, 3.553]	5.7 [-12.3, 23.7]	0.473
>= 50 ppb	83	66 (79.5) [69.2, 87.6]	38	30 (78.9) [62.7, 90.4]	1.007 [0.827, 1.227]	1.035 [0.403, 2.663]	0.6 [-16.9, 18.1]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_LLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.241
Q1: < 16 ppb	71	49 (69.0) [56.9, 79.5]	35	27 (77.1) [59.9, 89.6]	0.895 [0.705, 1.135]	0.660 [0.259, 1.682]	-8.1 [-27.8, 11.6]	0.493
Q2: 16 - < 30 ppb	72	57 (79.2) [68.0, 87.8]	36	23 (63.9) [46.2, 79.2]	1.239 [0.943, 1.628]	2.148 [0.885, 5.212]	15.3 [-5.1, 35.6]	0.106
Q3: 30 - < 56 ppb	79	64 (81.0) [70.6, 89.0]	34	30 (88.2) [72.5, 96.7]	0.918 [0.780, 1.080]	0.569 [0.174, 1.861]	-7.2 [-23.2, 8.7]	0.421
Q4: >= 56 ppb	71	56 (78.9) [67.6, 87.7]	30	23 (76.7) [57.7, 90.1]	1.029 [0.816, 1.296]	1.136 [0.410, 3.151]	2.2 [-18.0, 22.4]	0.797
Total serum IgE (cat. N)								0.809
Q1: < 53.1 IU/ml	74	62 (83.8) [73.4, 91.3]	35	29 (82.9) [66.4, 93.4]	1.011 [0.844, 1.212]	1.069 [0.365, 3.131]	0.9 [-16.2, 18.1]	1.000
Q2: 53.1 - < 195.6 IU/ml	72	51 (70.8) [58.9, 81.0]	41	31 (75.6) [59.7, 87.6]	0.937 [0.745, 1.177]	0.783 [0.326, 1.880]	-4.8 [-23.5, 14.0]	0.664
Q3: 195.6 - < 572.4 IU/ml	82	62 (75.6) [64.9, 84.4]	29	21 (72.4) [52.8, 87.3]	1.044 [0.808, 1.349]	1.181 [0.453, 3.077]	3.2 [-17.9, 24.3]	0.805
Q4: >= 572.4 IU/ml	68	54 (79.4) [67.9, 88.3]	32	23 (71.9) [53.3, 86.3]	1.105 [0.862, 1.416]	1.509 [0.573, 3.978]	7.5 [-13.1, 28.1]	0.450

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAN_LLSIN: Incidence of non-disease related non-severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related non-severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years								0.614
Yes	27	23 (85.2) [66.3, 95.8]	13	10 (76.9) [46.2, 95.0]	1.107 [0.791, 1.551]	1.725 [0.324, 9.172]	8.3 [-24.0, 40.5]	0.662
No	269	206 (76.6) [71.1, 81.5]	124	94 (75.8) [67.3, 83.0]	1.010 [0.897, 1.138]	1.044 [0.634, 1.718]	0.8 [-8.9, 10.4]	0.899

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_LLMI0: Incidence of non-disease related severe TEAEs during study period
DSAFNL - LTE - adult

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related severe TEAEs during study period	296	27 (9.1) [6.1, 13.0]	137	12 (8.8) [4.6, 14.8]	1.041 [0.544, 1.993]	1.046 [0.513, 2.132]	0.4 [-5.9, 6.7]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AAC_LLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.758
Male	108	8 (7.4) [3.3, 14.1]	50	3 (6.0) [1.3, 16.5]	1.235 [0.342, 4.457]	1.253 [0.318, 4.939]	1.4 [-8.3, 11.1]	1.000
Female	188	19 (10.1) [6.2, 15.3]	87	9 (10.3) [4.8, 18.7]	0.977 [0.461, 2.071]	0.974 [0.422, 2.251]	-0.2 [-8.8, 8.3]	1.000
Age								0.239
< 65 years	236	21 (8.9) [5.6, 13.3]	115	8 (7.0) [3.1, 13.2]	1.279 [0.584, 2.799]	1.306 [0.560, 3.046]	1.9 [-4.6, 8.5]	0.680
>= 65 years	60	6 (10.0) [3.8, 20.5]	22	4 (18.2) [5.2, 40.3]	0.550 [0.171, 1.767]	0.500 [0.127, 1.974]	-8.2 [-29.1, 12.7]	0.446
Exacerbations in the year before study								0.802
<= 2	166	14 (8.4) [4.7, 13.7]	80	7 (8.8) [3.6, 17.2]	0.964 [0.405, 2.294]	0.961 [0.372, 2.482]	-0.3 [-8.7, 8.1]	1.000
> 2	130	13 (10.0) [5.4, 16.5]	57	5 (8.8) [2.9, 19.3]	1.140 [0.426, 3.047]	1.156 [0.392, 3.409]	1.2 [-9.0, 11.5]	1.000
Race								0.244
White	214	17 (7.9) [4.7, 12.4]	89	11 (12.4) [6.3, 21.0]	0.643 [0.314, 1.316]	0.612 [0.274, 1.365]	-4.4 [-12.9, 4.1]	0.276
Black or African American	16	4 (25.0) [7.3, 52.4]	12	0 (0.0) [0.0, 26.5]	6.882 + [0.406, 116.753]	9.000 + [0.437, 185.364]	25.0 [-3.5, 53.5]	0.113
Asian	55	4 (7.3) [2.0, 17.6]	30	0 (0.0) [0.0, 11.6]	4.982 + [0.277, 89.521]	5.330 + [0.277, 102.435]	7.3 [-2.2, 16.7]	0.292
Other	11	2 (18.2) [2.3, 51.8]	6	1 (16.7) [0.4, 64.1]	1.091 [0.123, 9.696]	1.111 [0.079, 15.534]	1.5 [-48.9, 51.9]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_LLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.321
Europe	52	7 (13.5) [5.6, 25.8]	24	3 (12.5) [2.7, 32.4]	1.077 [0.305, 3.808]	1.089 [0.256, 4.634]	1.0 [-18.2, 20.2]	1.000
America	123	9 (7.3) [3.4, 13.4]	50	7 (14.0) [5.8, 26.7]	0.523 [0.206, 1.327]	0.485 [0.170, 1.383]	-6.7 [-18.8, 5.4]	0.244
Asia/Pacific	51	4 (7.8) [2.2, 18.9]	26	0 (0.0) [0.0, 13.2]	4.673 + [0.261, 83.624]	5.021 + [0.260, 96.909]	7.8 [-2.4, 18.1]	0.294
Rest of the world	70	7 (10.0) [4.1, 19.5]	37	2 (5.4) [0.7, 18.2]	1.850 [0.405, 8.460]	1.944 [0.383, 9.874]	4.6 [-7.6, 16.8]	0.493
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	0 (0.0) [0.0, 84.2]	0					
18.5 - < 25.0 kg/m**2	75	2 (2.7) [0.3, 9.3]	39	2 (5.1) [0.6, 17.3]				
25.0 - < 30.0 kg/m**2	102	10 (9.8) [4.8, 17.3]	45	4 (8.9) [2.5, 21.2]				
>= 30.0 kg/m**2	117	15 (12.8) [7.4, 20.3]	53	6 (11.3) [4.3, 23.0]				
Baseline eosinophils - Low								0.377
< 150 cells/uL	73	10 (13.7) [6.8, 23.8]	36	3 (8.3) [1.8, 22.5]	1.644 [0.482, 5.607]	1.746 [0.449, 6.784]	5.4 [-8.7, 19.4]	0.539
>= 150 cells/uL	223	17 (7.6) [4.5, 11.9]	101	9 (8.9) [4.2, 16.2]	0.856 [0.395, 1.853]	0.844 [0.363, 1.963]	-1.3 [-8.6, 6.0]	0.665
Baseline eosinophils - High								0.953
< 300 cells/uL	172	18 (10.5) [6.3, 16.0]	81	8 (9.9) [4.4, 18.5]	1.060 [0.481, 2.334]	1.067 [0.443, 2.567]	0.6 [-8.3, 9.4]	1.000
>= 300 cells/uL	124	9 (7.3) [3.4, 13.3]	56	4 (7.1) [2.0, 17.3]	1.016 [0.327, 3.161]	1.017 [0.300, 3.455]	0.1 [-9.3, 9.6]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_LLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.985
< 25 ppb	124	13 (10.5) [5.7, 17.3]	60	6 (10.0) [3.8, 20.5]	1.048 [0.419, 2.623]	1.054 [0.380, 2.925]	0.5 [-10.1, 11.0]	1.000
>= 25 ppb	169	14 (8.3) [4.6, 13.5]	75	6 (8.0) [3.0, 16.6]	1.036 [0.414, 2.590]	1.039 [0.383, 2.817]	0.3 [-8.1, 8.7]	1.000
Baseline specific perennial FEIA status								0.410
All negative	113	12 (10.6) [5.6, 17.8]	52	7 (13.5) [5.6, 25.8]	0.789 [0.330, 1.887]	0.764 [0.282, 2.068]	-2.8 [-15.1, 9.4]	0.606
Any positive	182	15 (8.2) [4.7, 13.2]	83	5 (6.0) [2.0, 13.5]	1.368 [0.514, 3.639]	1.401 [0.492, 3.993]	2.2 [-5.2, 9.6]	0.623
Total serum IgE								0.953
Low	92	11 (12.0) [6.1, 20.4]	48	6 (12.5) [4.7, 25.2]	0.957 [0.377, 2.428]	0.951 [0.329, 2.750]	-0.5 [-13.6, 12.5]	1.000
Normal	182	16 (8.8) [5.1, 13.9]	75	6 (8.0) [3.0, 16.6]	1.099 [0.447, 2.700]	1.108 [0.416, 2.951]	0.8 [-7.5, 9.1]	1.000
High	22	0 (0.0) [0.0, 15.4]	14	0 (0.0) [0.0, 23.2]	0.652 + [0.014, 31.129]	0.644 + [0.012, 34.320]	-1.2 + [-17.5, 15.2]	NE
OCS at baseline								0.589
Yes	27	4 (14.8) [4.2, 33.7]	12	1 (8.3) [0.2, 38.5]	1.778 [0.221, 14.275]	1.913 [0.191, 19.198]	6.5 [-20.1, 33.1]	1.000
No	269	23 (8.6) [5.5, 12.6]	125	11 (8.8) [4.5, 15.2]	0.972 [0.489, 1.930]	0.969 [0.457, 2.055]	-0.2 [-6.8, 6.3]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_LLSIK: Incidence of non-disease related severe TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
LAMA use at baseline								0.129
Yes	80	11 (13.8) [7.1, 23.3]	38	2 (5.3) [0.6, 17.7]	2.613 [0.609, 11.208]	2.870 [0.603, 13.650]	8.5 [-3.8, 20.8]	0.219
No	216	16 (7.4) [4.3, 11.8]	99	10 (10.1) [5.0, 17.8]	0.733 [0.345, 1.558]	0.712 [0.311, 1.631]	-2.7 [-10.3, 4.9]	0.508
Tiotropium use at baseline								0.165
Yes	73	10 (13.7) [6.8, 23.8]	36	2 (5.6) [0.7, 18.7]	2.466 [0.570, 10.668]	2.698 [0.559, 13.028]	8.1 [-4.8, 21.1]	0.330
No	223	17 (7.6) [4.5, 11.9]	101	10 (9.9) [4.9, 17.5]	0.770 [0.366, 1.622]	0.751 [0.331, 1.704]	-2.3 [-9.8, 5.2]	0.518
Montelukast/ Cromoglicic acid use at baseline								0.787
Yes	118	11 (9.3) [4.7, 16.1]	50	5 (10.0) [3.3, 21.8]	0.932 [0.342, 2.544]	0.925 [0.304, 2.816]	-0.7 [-11.9, 10.6]	1.000
No	178	16 (9.0) [5.2, 14.2]	87	7 (8.0) [3.3, 15.9]	1.117 [0.477, 2.615]	1.129 [0.446, 2.854]	0.9 [-7.0, 8.9]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAC_LLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.536
Western Europe	57	7 (12.3) [5.1, 23.7]	25	3 (12.0) [2.5, 31.2]	1.023 [0.288, 3.637]	1.027 [0.243, 4.344]	0.3 [-17.9, 18.5]	1.000
North America	61	4 (6.6) [1.8, 15.9]	22	4 (18.2) [5.2, 40.3]	0.361 [0.099, 1.320]	0.316 [0.072, 1.392]	-11.6 [-32.0, 8.7]	0.199
South America	62	5 (8.1) [2.7, 17.8]	28	3 (10.7) [2.3, 28.2]	0.753 [0.193, 2.933]	0.731 [0.162, 3.298]	-2.6 [-18.6, 13.3]	0.700
Central/Eastern Europe	19	0 (0.0) [0.0, 17.6]	12	0 (0.0) [0.0, 26.5]	0.650 + [0.014, 30.767]	0.641 + [0.012, 34.434]	-1.3 + [-20.2, 17.5]	NE
Asia Pacific	46	4 (8.7) [2.4, 20.8]	25	0 (0.0) [0.0, 13.7]	4.979 + [0.279, 88.888]	5.400 + [0.279, 104.491]	8.7 [-2.5, 19.9]	0.290
Rest of the world	51	7 (13.7) [5.7, 26.3]	25	2 (8.0) [1.0, 26.0]	1.716 [0.384, 7.665]	1.830 [0.351, 9.530]	5.7 [-11.5, 22.9]	0.709
Baseline eosinophils (cat. N)								0.806
< 150 cells/uL	73	10 (13.7) [6.8, 23.8]	36	3 (8.3) [1.8, 22.5]	1.644 [0.482, 5.607]	1.746 [0.449, 6.784]	5.4 [-8.7, 19.4]	0.539
150 - < 300 cells/uL	99	8 (8.1) [3.6, 15.3]	45	5 (11.1) [3.7, 24.1]	0.727 [0.252, 2.100]	0.703 [0.217, 2.283]	-3.0 [-15.3, 9.2]	0.545
300 - < 450 cells/uL	58	2 (3.4) [0.4, 11.9]	29	1 (3.4) [0.1, 17.8]	1.000 [0.095, 10.577]	1.000 [0.087, 11.507]	0.0 [-10.7, 10.7]	1.000
>= 450 cells/uL	66	7 (10.6) [4.4, 20.6]	27	3 (11.1) [2.4, 29.2]	0.955 [0.266, 3.420]	0.949 [0.226, 3.979]	-0.5 [-17.1, 16.1]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_LLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
Baseline eosinophils (cat. Q)								0.105	
Q1: < 140 cells/uL	67	10 (14.9) [7.4, 25.7]	33	2 (6.1) [0.7, 20.2]	2.463 [0.572, 10.603]	2.719 [0.560, 13.201]	8.9 [-5.2, 22.9]	0.327	
Q2: 140 - < 250 cells/uL	79	2 (2.5) [0.3, 8.8]	38	5 (13.2) [4.4, 28.1]	0.192 [0.039, 0.947]	0.171 [0.032, 0.929]	-10.6 [-23.9, 2.6]	0.036	*
Q3: 250 - < 430 cells/uL	81	8 (9.9) [4.4, 18.5]	36	2 (5.6) [0.7, 18.7]	1.778 [0.397, 7.959]	1.863 [0.375, 9.246]	4.3 [-7.6, 16.2]	0.722	
Q4: >= 430 cells/uL	69	7 (10.1) [4.2, 19.8]	30	3 (10.0) [2.1, 26.5]	1.014 [0.281, 3.659]	1.016 [0.244, 4.229]	0.1 [-15.1, 15.4]	1.000	
Baseline FENO (cat. N)								0.998	
< 25 ppb	124	13 (10.5) [5.7, 17.3]	60	6 (10.0) [3.8, 20.5]	1.048 [0.419, 2.623]	1.054 [0.380, 2.925]	0.5 [-10.1, 11.0]	1.000	
25 - < 50 ppb	86	7 (8.1) [3.3, 16.1]	37	3 (8.1) [1.7, 21.9]	1.004 [0.275, 3.670]	1.004 [0.245, 4.117]	0.0 [-12.4, 12.5]	1.000	
>= 50 ppb	83	7 (8.4) [3.5, 16.6]	38	3 (7.9) [1.7, 21.4]	1.068 [0.292, 3.908]	1.075 [0.262, 4.404]	0.5 [-11.8, 12.9]	1.000	

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_LLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.714
Q1: < 16 ppb	71	6 (8.5) [3.2, 17.5]	35	4 (11.4) [3.2, 26.7]	0.739 [0.223, 2.452]	0.715 [0.188, 2.720]	-3.0 [-17.5, 11.5]	0.727
Q2: 16 - < 30 ppb	72	8 (11.1) [4.9, 20.7]	36	4 (11.1) [3.1, 26.1]	1.000 [0.323, 3.101]	1.000 [0.280, 3.572]	0.0 [-14.7, 14.7]	1.000
Q3: 30 - < 56 ppb	79	6 (7.6) [2.8, 15.8]	34	3 (8.8) [1.9, 23.7]	0.861 [0.228, 3.243]	0.849 [0.200, 3.614]	-1.2 [-14.5, 12.1]	1.000
Q4: >= 56 ppb	71	7 (9.9) [4.1, 19.3]	30	1 (3.3) [0.1, 17.2]	2.958 [0.380, 23.007]	3.172 [0.373, 26.979]	6.5 [-5.3, 18.3]	0.430
Total serum IgE (cat. N)								0.807
Q1: < 53.1 IU/ml	74	7 (9.5) [3.9, 18.5]	35	4 (11.4) [3.2, 26.7]	0.828 [0.259, 2.642]	0.810 [0.221, 2.971]	-2.0 [-16.5, 12.6]	0.743
Q2: 53.1 - < 195.6 IU/ml	72	9 (12.5) [5.9, 22.4]	41	5 (12.2) [4.1, 26.2]	1.025 [0.368, 2.853]	1.029 [0.320, 3.305]	0.3 [-14.2, 14.8]	1.000
Q3: 195.6 - < 572.4 IU/ml	82	10 (12.2) [6.0, 21.3]	29	2 (6.9) [0.8, 22.8]	1.768 [0.412, 7.598]	1.875 [0.386, 9.115]	5.3 [-8.7, 19.3]	0.728
Q4: >= 572.4 IU/ml	68	1 (1.5) [0.0, 7.9]	32	1 (3.1) [0.1, 16.2]	0.471 [0.030, 7.286]	0.463 [0.028, 7.642]	-1.7 [-10.6, 7.3]	0.540

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAC_LLSIN: Incidence of non-disease related severe TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related severe TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years								0.755
Yes	27	3 (11.1) [2.4, 29.2]	13	1 (7.7) [0.2, 36.0]	1.444 [0.166, 12.579]	1.500 [0.141, 15.996]	3.4 [-21.0, 27.8]	1.000
No	269	24 (8.9) [5.8, 13.0]	124	11 (8.9) [4.5, 15.3]	1.006 [0.509, 1.988]	1.006 [0.476, 2.125]	0.1 [-6.6, 6.7]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_LLMI0: Incidence of non-disease related serious TEAEs during study period
DSAFNL - LTE - adult

	Teze+Teze		Pbo+Pbo					
	N	n (%) [95 % CI]	N	n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Non-disease related serious TEAEs during study period	296	43 (14.5) [10.7, 19.1]	137	16 (11.7) [6.8, 18.3]	1.244 [0.727, 2.128]	1.285 [0.696, 2.374]	2.8 [-4.4, 10.1]	0.455

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with events.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = exact test of Fisher. * = significant treatment effect. + = adding of + 0.5 to each cell.
TEAE = treatment emergent adverse event. RR = relative risk. OR = odds ratio. RD = risk difference.
Source Data: aae, created on: 15JUL2022

Table DT1AAS_LLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Sex								0.621
Male	108	19 (17.6) [10.9, 26.1]	50	6 (12.0) [4.5, 24.3]	1.466 [0.624, 3.445]	1.566 [0.584, 4.198]	5.6 [-7.4, 18.6]	0.484
Female	188	24 (12.8) [8.4, 18.4]	87	10 (11.5) [5.7, 20.1]	1.111 [0.556, 2.220]	1.127 [0.514, 2.473]	1.3 [-7.8, 10.3]	0.846
Age								0.825
< 65 years	236	31 (13.1) [9.1, 18.1]	115	12 (10.4) [5.5, 17.5]	1.259 [0.672, 2.359]	1.298 [0.640, 2.633]	2.7 [-5.0, 10.4]	0.603
>= 65 years	60	12 (20.0) [10.8, 32.3]	22	4 (18.2) [5.2, 40.3]	1.100 [0.396, 3.053]	1.125 [0.321, 3.945]	1.8 [-20.3, 24.0]	1.000
Exacerbations in the year before study								0.712
<= 2	166	21 (12.7) [8.0, 18.7]	80	9 (11.3) [5.3, 20.3]	1.124 [0.540, 2.343]	1.143 [0.498, 2.622]	1.4 [-8.1, 10.9]	0.837
> 2	130	22 (16.9) [10.9, 24.5]	57	7 (12.3) [5.1, 23.7]	1.378 [0.624, 3.041]	1.455 [0.583, 3.630]	4.6 [-7.3, 16.6]	0.514
Race								0.619
White	214	27 (12.6) [8.5, 17.8]	89	11 (12.4) [6.3, 21.0]	1.021 [0.530, 1.967]	1.024 [0.484, 2.166]	0.3 [-8.7, 9.2]	1.000
Black or African American	16	4 (25.0) [7.3, 52.4]	12	0 (0.0) [0.0, 26.5]	6.882 + [0.406, 116.753]	9.000 + [0.437, 185.364]	25.0 [-3.5, 53.5]	0.113
Asian	55	9 (16.4) [7.8, 28.8]	30	4 (13.3) [3.8, 30.7]	1.227 [0.412, 3.652]	1.272 [0.356, 4.538]	3.0 [-15.2, 21.2]	1.000
Other	11	3 (27.3) [6.0, 61.0]	6	1 (16.7) [0.4, 64.1]	1.636 [0.214, 12.495]	1.875 [0.150, 23.396]	10.6 [-42.0, 63.3]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_LLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region								0.395
Europe	52	12 (23.1) [12.5, 36.8]	24	2 (8.3) [1.0, 27.0]	2.769 [0.672, 11.418]	3.300 [0.676, 16.098]	14.7 [-4.2, 33.7]	0.203
America	123	10 (8.1) [4.0, 14.4]	50	6 (12.0) [4.5, 24.3]	0.678 [0.260, 1.765]	0.649 [0.223, 1.893]	-3.9 [-15.5, 7.8]	0.403
Asia/Pacific	51	9 (17.6) [8.4, 30.9]	26	4 (15.4) [4.4, 34.9]	1.147 [0.390, 3.374]	1.179 [0.326, 4.264]	2.3 [-18.0, 22.5]	1.000
Rest of the world	70	12 (17.1) [9.2, 28.0]	37	4 (10.8) [3.0, 25.4]	1.586 [0.550, 4.573]	1.707 [0.509, 5.722]	6.3 [-9.1, 21.7]	0.570
BMI		N<10 any level						NE
< 18.5 kg/m**2	2	1 (50.0) [1.3, 98.7]	0					
18.5 - < 25.0 kg/m**2	75	7 (9.3) [3.8, 18.3]	39	5 (12.8) [4.3, 27.4]				
25.0 - < 30.0 kg/m**2	102	14 (13.7) [7.7, 22.0]	45	5 (11.1) [3.7, 24.1]				
>= 30.0 kg/m**2	117	21 (17.9) [11.5, 26.1]	53	6 (11.3) [4.3, 23.0]				
Baseline eosinophils - Low								0.484
< 150 cells/uL	73	11 (15.1) [7.8, 25.4]	36	3 (8.3) [1.8, 22.5]	1.808 [0.538, 6.080]	1.952 [0.509, 7.488]	6.7 [-7.5, 21.0]	0.380
>= 150 cells/uL	223	32 (14.3) [10.0, 19.6]	101	13 (12.9) [7.0, 21.0]	1.115 [0.612, 2.032]	1.134 [0.568, 2.266]	1.5 [-7.2, 10.2]	0.863
Baseline eosinophils - High								0.573
< 300 cells/uL	172	27 (15.7) [10.6, 22.0]	81	9 (11.1) [5.2, 20.0]	1.413 [0.697, 2.864]	1.490 [0.666, 3.334]	4.6 [-5.1, 14.2]	0.441
>= 300 cells/uL	124	16 (12.9) [7.6, 20.1]	56	7 (12.5) [5.2, 24.1]	1.032 [0.450, 2.368]	1.037 [0.401, 2.682]	0.4 [-11.4, 12.2]	1.000

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_LLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO								0.667
< 25 ppb	124	16 (12.9) [7.6, 20.1]	60	5 (8.3) [2.8, 18.4]	1.548 [0.595, 4.027]	1.630 [0.567, 4.682]	4.6 [-5.8, 15.0]	0.462
>= 25 ppb	169	27 (16.0) [10.8, 22.4]	75	10 (13.3) [6.6, 23.2]	1.198 [0.612, 2.348]	1.236 [0.565, 2.703]	2.6 [-7.8, 13.1]	0.700
Baseline specific perennial FEIA status								0.987
All negative	113	24 (21.2) [14.1, 29.9]	52	9 (17.3) [8.2, 30.3]	1.227 [0.614, 2.452]	1.288 [0.552, 3.009]	3.9 [-10.2, 18.1]	0.677
Any positive	182	19 (10.4) [6.4, 15.8]	83	7 (8.4) [3.5, 16.6]	1.238 [0.541, 2.830]	1.266 [0.510, 3.139]	2.0 [-6.3, 10.3]	0.664
Total serum IgE								0.548
Low	92	18 (19.6) [12.0, 29.1]	48	6 (12.5) [4.7, 25.2]	1.565 [0.665, 3.682]	1.703 [0.627, 4.622]	7.1 [-6.9, 21.0]	0.351
Normal	182	21 (11.5) [7.3, 17.1]	75	9 (12.0) [5.6, 21.6]	0.962 [0.462, 2.001]	0.957 [0.416, 2.197]	-0.5 [-10.1, 9.2]	1.000
High	22	4 (18.2) [5.2, 40.3]	14	1 (7.1) [0.2, 33.9]	2.545 [0.316, 20.505]	2.889 [0.288, 28.944]	11.0 [-15.8, 37.9]	0.628
OCS at baseline								0.255
Yes	27	8 (29.6) [13.8, 50.2]	12	1 (8.3) [0.2, 38.5]	3.556 [0.499, 25.356]	4.632 [0.509, 42.115]	21.3 [-8.0, 50.6]	0.228
No	269	35 (13.0) [9.2, 17.6]	125	15 (12.0) [6.9, 19.0]	1.084 [0.615, 1.910]	1.097 [0.575, 2.093]	1.0 [-6.5, 8.6]	0.871

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_LLSIK: Incidence of non-disease related serious TEAEs during study period by key subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value	
LAMA use at baseline								0.063	
Yes	80	16 (20.0) [11.9, 30.4]	38	2 (5.3) [0.6, 17.7]	3.800 [0.920, 15.695]	4.500 [0.979, 20.691]	14.7 [1.5, 28.0]	0.053	
No	216	27 (12.5) [8.4, 17.7]	99	14 (14.1) [8.0, 22.6]	0.884 [0.485, 1.611]	0.867 [0.433, 1.737]	-1.6 [-10.5, 7.3]	0.720	
Tiotropium use at baseline								0.031	i
Yes	73	16 (21.9) [13.1, 33.1]	36	1 (2.8) [0.1, 14.5]	7.890 [1.089, 57.174]	9.825 [1.248, 77.366]	19.1 [6.2, 32.1]	0.010	*
No	223	27 (12.1) [8.1, 17.1]	101	15 (14.9) [8.6, 23.3]	0.815 [0.454, 1.464]	0.790 [0.400, 1.559]	-2.7 [-11.6, 6.1]	0.481	
Montelukast/ Cromoglicic acid use at baseline								0.605	
Yes	118	20 (16.9) [10.7, 25.0]	50	8 (16.0) [7.2, 29.1]	1.059 [0.500, 2.243]	1.071 [0.437, 2.625]	0.9 [-12.7, 14.6]	1.000	
No	178	23 (12.9) [8.4, 18.8]	87	8 (9.2) [4.1, 17.3]	1.405 [0.655, 3.012]	1.465 [0.627, 3.425]	3.7 [-4.9, 12.4]	0.423	

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. OCS = oral corticosteroids. TEAE = treatment emergent adverse events. LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 11JUL2022

Table DT1AAS_LLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Region (cat. N)								0.629
Western Europe	57	12 (21.1) [11.4, 33.9]	25	2 (8.0) [1.0, 26.0]	2.632 [0.635, 10.900]	3.067 [0.632, 14.874]	13.1 [-4.8, 30.9]	0.208
North America	61	5 (8.2) [2.7, 18.1]	22	3 (13.6) [2.9, 34.9]	0.601 [0.156, 2.309]	0.565 [0.123, 2.593]	-5.4 [-24.4, 13.6]	0.431
South America	62	5 (8.1) [2.7, 17.8]	28	3 (10.7) [2.3, 28.2]	0.753 [0.193, 2.933]	0.731 [0.162, 3.298]	-2.6 [-18.6, 13.3]	0.700
Central/Eastern Europe	19	3 (15.8) [3.4, 39.6]	12	0 (0.0) [0.0, 26.5]	4.550 + [0.255, 81.034]	5.303 + [0.250, 112.308]	15.8 [-7.4, 39.0]	0.265
Asia Pacific	46	9 (19.6) [9.4, 33.9]	25	4 (16.0) [4.5, 36.1]	1.223 [0.418, 3.574]	1.277 [0.350, 4.657]	3.6 [-17.9, 25.0]	1.000
Rest of the world	51	9 (17.6) [8.4, 30.9]	25	4 (16.0) [4.5, 36.1]	1.103 [0.376, 3.235]	1.125 [0.310, 4.083]	1.6 [-19.1, 22.4]	1.000
Baseline eosinophils (cat. N)								0.774
< 150 cells/uL	73	11 (15.1) [7.8, 25.4]	36	3 (8.3) [1.8, 22.5]	1.808 [0.538, 6.080]	1.952 [0.509, 7.488]	6.7 [-7.5, 21.0]	0.380
150 - < 300 cells/uL	99	16 (16.2) [9.5, 24.9]	45	6 (13.3) [5.1, 26.8]	1.212 [0.508, 2.892]	1.253 [0.455, 3.449]	2.8 [-11.1, 16.7]	0.805
300 - < 450 cells/uL	58	6 (10.3) [3.9, 21.2]	29	2 (6.9) [0.8, 22.8]	1.500 [0.323, 6.976]	1.558 [0.294, 8.246]	3.4 [-11.2, 18.1]	0.713
>= 450 cells/uL	66	10 (15.2) [7.5, 26.1]	27	5 (18.5) [6.3, 38.1]	0.818 [0.308, 2.171]	0.786 [0.241, 2.561]	-3.4 [-23.0, 16.3]	0.759

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_LLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline eosinophils (cat. Q)								0.579
Q1: < 140 cells/uL	67	10 (14.9) [7.4, 25.7]	33	2 (6.1) [0.7, 20.2]	2.463 [0.572, 10.603]	2.719 [0.560, 13.201]	8.9 [-5.2, 22.9]	0.327
Q2: 140 - < 250 cells/uL	79	9 (11.4) [5.3, 20.5]	38	5 (13.2) [4.4, 28.1]	0.866 [0.311, 2.407]	0.849 [0.264, 2.731]	-1.8 [-16.5, 13.0]	0.769
Q3: 250 - < 430 cells/uL	81	14 (17.3) [9.8, 27.3]	36	4 (11.1) [3.1, 26.1]	1.556 [0.550, 4.399]	1.672 [0.509, 5.486]	6.2 [-9.0, 21.3]	0.580
Q4: >= 430 cells/uL	69	10 (14.5) [7.2, 25.0]	30	5 (16.7) [5.6, 34.7]	0.870 [0.325, 2.327]	0.847 [0.263, 2.733]	-2.2 [-20.3, 15.9]	0.768
Baseline FENO (cat. N)								0.546
< 25 ppb	124	16 (12.9) [7.6, 20.1]	60	5 (8.3) [2.8, 18.4]	1.548 [0.595, 4.027]	1.630 [0.567, 4.682]	4.6 [-5.8, 15.0]	0.462
25 - < 50 ppb	86	12 (14.0) [7.4, 23.1]	37	6 (16.2) [6.2, 32.0]	0.860 [0.349, 2.119]	0.838 [0.289, 2.433]	-2.3 [-18.1, 13.6]	0.784
>= 50 ppb	83	15 (18.1) [10.5, 28.0]	38	4 (10.5) [2.9, 24.8]	1.717 [0.611, 4.828]	1.875 [0.578, 6.085]	7.5 [-7.2, 22.3]	0.421

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_LLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Baseline FENO (cat. Q)								0.487
Q1: < 16 ppb	71	6 (8.5) [3.2, 17.5]	35	2 (5.7) [0.7, 19.2]	1.479 [0.314, 6.956]	1.523 [0.291, 7.964]	2.7 [-9.4, 14.9]	1.000
Q2: 16 - < 30 ppb	72	12 (16.7) [8.9, 27.3]	36	5 (13.9) [4.7, 29.5]	1.200 [0.458, 3.145]	1.240 [0.401, 3.838]	2.8 [-13.5, 19.1]	0.786
Q3: 30 - < 56 ppb	79	11 (13.9) [7.2, 23.5]	34	6 (17.6) [6.8, 34.5]	0.789 [0.318, 1.960]	0.755 [0.254, 2.240]	-3.7 [-20.7, 13.3]	0.581
Q4: >= 56 ppb	71	14 (19.7) [11.2, 30.9]	30	2 (6.7) [0.8, 22.1]	2.958 [0.716, 12.222]	3.439 [0.730, 16.186]	13.1 [-2.2, 28.3]	0.139
Total serum IgE (cat. N)								0.606
Q1: < 53.1 IU/ml	74	13 (17.6) [9.7, 28.2]	35	3 (8.6) [1.8, 23.1]	2.050 [0.624, 6.732]	2.273 [0.603, 8.563]	9.0 [-5.8, 23.8]	0.260
Q2: 53.1 - < 195.6 IU/ml	72	12 (16.7) [8.9, 27.3]	41	7 (17.1) [7.2, 32.1]	0.976 [0.417, 2.283]	0.971 [0.349, 2.701]	-0.4 [-16.7, 15.9]	1.000
Q3: 195.6 - < 572.4 IU/ml	82	11 (13.4) [6.9, 22.7]	29	2 (6.9) [0.8, 22.8]	1.945 [0.458, 8.258]	2.092 [0.435, 10.058]	6.5 [-7.6, 20.7]	0.508
Q4: >= 572.4 IU/ml	68	7 (10.3) [4.2, 20.1]	32	4 (12.5) [3.5, 29.0]	0.824 [0.260, 2.612]	0.803 [0.217, 2.969]	-2.2 [-18.0, 13.6]	0.741

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022

Table DT1AAS_LLSIN: Incidence of non-disease related serious TEAEs during study period by study specific subgroups
DSAFNL - LTE - adult

Non-disease related serious TEAEs during study period	Teze+Teze N	Teze+Teze n (%) [95 % CI]	Pbo+Pbo N	Pbo+Pbo n (%) [95 % CI]	RR [95 % CI]	OR [95 % CI]	RD [95 % CI]	p-value
Nasal polyps last 2 years								0.654
Yes	27	7 (25.9) [11.1, 46.3]	13	2 (15.4) [1.9, 45.4]	1.685 [0.405, 7.009]	1.925 [0.340, 10.915]	10.5 [-20.8, 41.9]	0.690
No	269	36 (13.4) [9.6, 18.0]	124	14 (11.3) [6.3, 18.2]	1.185 [0.664, 2.116]	1.214 [0.629, 2.343]	2.1 [-5.4, 9.6]	0.628

Note: DSAFNL - LTE - adult = Dossier Label Safety Set - predecessor NAVIGATOR - Long term extension - adults.
N = total number of patients in analysis set. n = number of patients with response. TEAE = treatment emergent adverse events.
LTE = long term extension.
95% CI = 95% confidence interval (percentages: Clopper-Pearson, RR/OR: Wald, RD: Newcombe method).
p-value = Cochran Q test for heterogeneity / exact test of Fisher. * = significant treatment effect. i = significant Cochran Q.
RR = relative risk. OR = odds ratio. RD = risk difference. + = adding of 0.5 to each cell. NE = not evaluable. Cochran Q test and risk measures are only calculated if there are at least 10 patients with events in a subgroup.
Source Data: aae, created on: 02AUG2022