

Supplemental appendix

Tezepelumab can Restore Normal Lung Function in Patients with Severe, Uncontrolled Asthma: Pooled Results from the PATHWAY and NAVIGATOR Studies

Ian D. Pavord · Christopher E. Brightling · Stephanie Korn · Nicole L. Martin · Sandhya S. Ponnarambil · Nestor A. Molfino · Jane R. Parnes · Christopher S. Ambrose

I. D. Pavord (ORCID iD: 0000-0002-4288-5973)

Respiratory Medicine, National Institute for Health and Care Research Oxford Biomedical Research Centre, Nuffield Department of Medicine, University of Oxford, Oxford, UK

C. E. Brightling (ORCID iD: 0000-0002-9345-4903)

Institute for Lung Health, National Institute for Health and Care Research Leicester Biomedical Research Centre, University of Leicester, Leicester, UK

S. Korn

IKF Pneumologie Mainz, Mainz, Germany, and Thoraxklinik Heidelberg, Heidelberg, Germany

N. L. Martin

Biometrics, Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Waltham, MA, USA, and Cytel Inc., Waltham, MA, USA

S. S. Ponnarambil (ORCID iD: 0009-0008-8310-6041)

Late-stage Development, Respiratory and Immunology, BioPharmaceuticals R&D, AstraZeneca, Cambridge, UK

N. A. Molfino

Global Development, Amgen, Thousand Oaks, CA, USA

J. R. Parnes

Early Development, Amgen, Thousand Oaks, CA, USA

C. S. Ambrose (ORCID iD: 0000-0003-4175-7336)

Respiratory and Immunology, BioPharmaceuticals Medical, AstraZeneca,
Gaithersburg, MD, USA

Corresponding author:

Ian D Pavord

ian.pavord@ndm.ox.ac.uk

Table S1 Baseline demographics and clinical characteristics of patients with abnormal lung function at baseline who did and did not achieve normal lung function at week 52, and of the overall pooled population

Baseline demographic/ characteristic	Abnormal lung function at baseline and normal lung function at week 52			Abnormal lung function at baseline and at week 52			Overall pooled population <i>N</i> = 1334
	Tezepelumab 210 mg Q4W <i>n</i> = 102	Placebo <i>n</i> = 58	Overall <i>n</i> = 160	Tezepelumab 210 mg Q4W <i>n</i> = 406	Placebo <i>n</i> = 438	Overall <i>n</i> = 844	
Age, years, mean (SD)	48.4 (17.1)	42.7 (16.2)	46.3 (17.0)	53.5 (12.6)	52.2 (12.6)	52.8 (12.6)	50.1 (15.4)
Female, <i>n</i> (%)	67 (65.7)	40 (69.0)	107 (66.9)	256 (63.1)	281 (64.2)	537 (63.6)	853 (63.9)
Male, <i>n</i> (%)	35 (34.3)	18 (31.0)	53 (33.1)	150 (36.9)	157 (35.8)	307 (36.4)	481 (36.1)
Race, <i>n</i> (%)							
White	68 (66.7)	36 (62.1)	104 (65.0)	289 (71.2)	294 (67.1)	583 (69.1)	910 (68.2)
Black or African American	3 (2.9)	5 (8.6)	8 (5.0)	19 (4.7)	23 (5.3)	42 (5.0)	70 (5.2)
Asian	28 (27.5)	13 (22.4)	41 (25.6)	84 (20.7)	106 (24.2)	190 (22.5)	306 (22.9)
Other ^a	3 (2.9)	4 (6.9)	7 (4.4)	14 (3.4)	15 (3.4)	29 (3.4)	48 (3.6)
Ethnicity, <i>n</i> (%)							
Hispanic or Latino	13 (12.7)	11 (19.0)	24 (15.0)	44 (10.8)	45 (10.3)	89 (10.5)	166 (12.4)
BMI, kg/m ² , mean (SD)	28.3 (5.2)	27.0 (7.1)	27.8 (6.0)	29.2 (7.0)	28.9 (6.7)	29.1 (6.8)	28.5 (6.7)

ICS dose group, <i>n</i> (%) ^b							
Medium	28 (27.5)	18 (31.0)	46 (28.8)	117 (28.8)	145 (33.1)	262 (31.0)	406 (30.4)
High	74 (72.5)	40 (69.0)	114 (71.3)	289 (71.2)	292 (66.7)	581 (68.8)	927 (69.5)
Maintenance OCS use, <i>n</i> (%)	8 (7.8)	5 (8.6)	13 (8.1)	33 (8.1)	35 (8.0)	68 (8.1)	122 (9.1)
Number of exacerbations in the previous 12 months, mean (SD)	3.0 (1.5)	2.5 (0.8)	2.8 (1.3)	2.7 (1.5)	2.7 (1.3)	2.7 (1.4)	2.7 (1.4)
Pre-BD FEV ₁ , L, mean (SD)	1.9 (0.6)	2.1 (0.5)	2.0 (0.6)	1.6 (0.6)	1.7 (0.6)	1.6 (0.6)	1.8 (0.7)
Percent predicted pre-BD FEV ₁ , mean (SD)	65.6 (10.2)	68.7 (8.5)	66.7 (9.7)	55.5 (13.5)	56.5 (13.0)	56.0 (13.3)	62.1 (17.1)
Percent FEV ₁ reversibility, mean (SD)	19.8 (16.6)	20.9 (16.6)	20.2 (16.6)	17.2 (16.5)	18.0 (17.1)	17.6 (16.8)	16.4 (16.4)
Serum total IgE level, IU/mL, median (min, max)	187.4 (1.5, 3664.7)	282.5 (4.7, 7406.3)	197.6 (1.5, 7406.3)	165.0 (1.5, 12 823.2)	160.3 (1.5, 11 859.6)	162.3 (1.5, 12 823.2)	179.4 (1.5, 12 823.2)
BEC, cells/μL, median (min, max)	335 (20, 3180)	255 (40, 8170)	325 (20, 8170)	245 (0, 1680)	260(0, 4640)	250 (0, 4640)	260 (0, 8170)
BEC subgroup, <i>n</i> (%)							
< 300 cells/μL	42 (41.2)	33 (56.9)	75 (46.9)	245 (60.3)	249 (56.8)	494 (58.5)	761 (57.0)

≥ 300 cells/μL	60 (58.8)	25 (43.1)	85 (53.1)	161 (39.7)	189 (43.2)	350 (41.5)	573 (43.0)
FeNO level, ppb, median (min, max)	35.0 (5.0, 213.0)	34.0 (3.5, 258.0)	35.0 (3.5, 258.0)	25.0 (4.0, 198.0)	28.0 (5.0, 276.3)	26.0 (4.0, 276.3)	28.0 (4.0, 276.0)
FeNO level subgroup, <i>n</i> (%)							
< 25 ppb	36 (35.3)	25 (43.1)	61 (38.1)	199 (49.0)	196 (44.7)	395 (46.8)	585 (43.9)
≥ 25 to < 50 ppb	32 (31.4)	11 (19.0)	43 (26.9)	117 (28.8)	122 (27.9)	239 (28.3)	372 (27.9)
≥ 50 ppb	34 (33.3)	22 (37.9)	56 (35.0)	84 (20.7)	117 (26.7)	201 (23.8)	364 (27.3)
Time since asthma diagnosis, years, median (min, max)							
	11 (1, 66)	20 (1, 49)	13 (1, 66)	20 (1, 69)	18 (1, 65)	19 (1, 69)	17 (1, 69)
FEIA positive for any perennial aeroallergen, <i>n</i> (%) ^c							
	53 (52.0)	39 (67.2)	92 (57.5)	251 (61.8)	259 (59.1)	510 (60.4)	815 (61.1)

BD bronchodilator, *BEC* blood eosinophil count, *BMI* body mass index, *FEIA* fluorescence enzyme immunoassay, *FeNO* fractional exhaled nitric oxide, *FEV1* forced expiratory volume in 1 second, *ICS* inhaled corticosteroid, *IgE* immunoglobulin E, *OCS* oral corticosteroid, *Q4W* every 4 weeks, *SD* standard deviation.

Abnormal lung function: percent predicted pre-BD FEV₁ < 80%; normal lung function: percent predicted pre-BD FEV₁ ≥ 80%.

^aOther includes Native Hawaiian or Other Pacific Islander, and American Indian or Alaska Native categories.

^bMedium-dose ICS: fluticasone propionate 250–500 μg/day or equivalent; high-dose ICS: fluticasone propionate > 500 μg/day or equivalent; there was one patient in the placebo group in the overall pooled population (originally from NAVIGATOR) who received fluticasone propionate < 500 μg/day or equivalent.

^cPositive for at least one common perennial aeroallergen (animal [cat dander, dog dander], cockroach, dust mite [*Dermatophagoides farina* or *D. pteronyssinus*] or moulds).