PCR200

Characteristics at Baseline of Patients With Asthma and Prior Systemic Corticosteroid Use Initiating Dupilumab Enrolled in the Real-World Study RAPID

DUPILUMAB

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Background

- Oral corticosteroid (OCS) use is a common therapeutic option for management of acute asthma exacerbations as well as chronic maintenance therapy for patients with severe disease[1]
- Dupilumab, a fully human monoclonal antibody,[2,3] blocks the shared receptor component for interleukin (IL)-4 and IL-13, which are key and central drivers of type 2 inflammation in multiple diseases[4,5]
- In previous dupilumab asthma studies (Phase 2b, QUEST, VENTURE, TRAVERSE), dupilumab significantly reduced the risk of severe asthma exacerbation, improved lung function, and reduced OCS use in the overall population of patients with uncontrolled, moderate-to-severe asthma[6–9]
- The Registry of Asthma Patients Initiating DUPIXENT® (RAPID; NCT04287621) is the first global, prospective, observational cohort of adolescent and adult patients with asthma initiating dupilumab treatment in a real-world setting

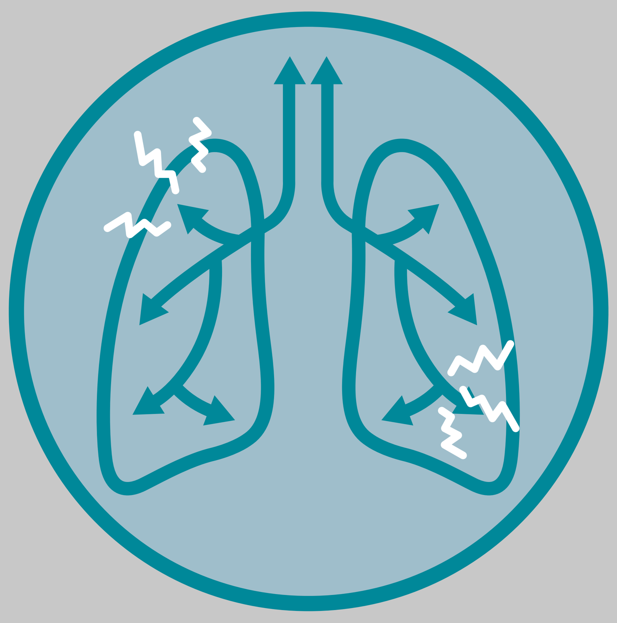
Methods

Study design

- RAPID enrolled patients aged ≥12 years with moderate-to-severe asthma initiating dupilumab treatment for a primary indication of asthma
- Eligible patients initiated dupilumab treatment for asthma according to country-specific prescribing information, per physician discretion, as part of routine care and will be followed prospectively for up to 3 years after treatment initiation
- This initial analysis of RAPID includes 205 patients who were enrolled between March 2020 and October 2021

Population

- Analysis population (N = 205)
- Patients with OCS use within 3 months prior to enrollment (n = 52)
- Patients without OCS use within 3 months prior to enrollment (n = 153)



Objective

- To report baseline characteristics with focus on OCS use in patients enrolled in RAPID

Conclusion

- In this initial presentation of baseline characteristics of patients from RAPID initiating dupilumab for moderate-to-severe asthma, we show that 25.4% of patients were currently or had recently received OCS, indicating a high unmet need for optimized treatment in this population

Results

Table 1. Baseline demographics of patients in the analysis population and in patients with and without a history of previous OCS use in the 3 months prior to enrollment in RAPID.

	Analysis population (N = 205)	Patients with previous OCS use (n = 52)	Patients without previous OCS use (n = 153)
Age, mean (SD), years	50.1 (17.4)	48.8 (16.8)	50.5 (17.7)
Female gender, n (%)	134 (65.4)	34 (65.4)	100 (65.4)
Race, n (%)			
White	152 (74.1)	35 (67.3)	117 (76.5)
Black or African American	27 (13.2)	8 (15.4)	19 (12.4)
Asian	2 (1.0)	0	2 (1.3)
Multiple	2 (1.0)	1 (1.9)	1 (0.7)
Other	6 (2.9)	3 (5.8)	3 (2.0)
Not reported	15 (7.3)	4 (7.7)	11 (7.2)
Missing	1 (0.5)	1 (1.9)	0
Ethnicity, n (%)			
Not Hispanic or Latino	162 (79.0)	41 (78.8)	121 (79.1)
Hispanic or Latino	35 (17.1)	9 (17.3)	26 (17.0)
Not reported	6 (2.9)	2 (3.8)	4 (2.6)
Unknown	2 (1.0)	0	2 (1.3)
Age at diagnosis of asthma, mean (SD), years	31.1 (21.9)	26.8 (21.8)	32.6 (21.8)
BMI, mean (SD), kg/m^2	30.67 (8.0)	31.65 (8.8)	30.33 (7.7)

BMI, body mass index; SD, standard deviation.

Table 2. Baseline disease characteristics and patient-related outcome scores of patients in the analysis population and in patients with and without a history of previous OCS use in the 3 months prior to enrollment in RAPID.

	Analysis population (N = 205)	Patients with previous OCS use (n = 52)	Patients without previous OCS use (n = 153)
Spirometry			
Pre-BD FEV_1, mean (SD), L	2.29 (1.1)	2.27 (1.5)	2.31 (0.9)
Pre-BD $ppFEV_1$, mean (SD), %	70.34 (20.3)	66.61 (21.4)	72.44 (19.5)
Pre-BD $ppFEF_{25–75\%}$, mean (SD), %	56.70 (29.2)	45.30 (26.7)	62.60 (29.0)
Pre-BD FVC, mean (SD), L	3.09 (1.1)	2.86 (1.1)	3.21 (1.1)
Pre-BD ppFVC, mean (SD), %	80.24 (19.0)	80.70 (20.3)	80.00 (18.5)
Pre-BD PEF, mean (SD), (L/min)	356.88 (169.8)	367.91 (203.6)	354.27 (162.9)
Eosinophils and FeNO			
Blood eosinophil count (Giga/L)			
Median (Q1–Q3)	0.305 (0.200–0.695)	0.252 (0.200–0.960)	0.310 (0.200–0.600)
Blood eosinophil count category, n/N1 (%)			
<150 cells/µL	10/64 (15.6)	3/15 (20.0)	7/49 (14.3)
≥150 to <300 cells/µL	15/64 (23.4)	5/15 (33.3)	10/49 (20.4)
≥300 cells/µL	39/64 (60.9)	7/15 (46.7)	32/49 (65.3)
FeNO, mean (SD), ppb	42.2 (34.8)	50.6 (34.8)	37.5 (34.4)
FeNO category, n/N1 (%)			
<25 ppb	22/61 (36.1)	5/22 (22.7)	17/39 (43.6)
≥25 ppb	39/61 (63.9)	17/22 (77.3)	22/39 (56.4)
PRO Scores			
ACQ-6, mean (SD)	2.36 (1.2)	2.77 (1.4)	2.21 (1.1)

ACQ-6, 6-item Asthma Control questionnaire; BD, bronchodilator; FEF, forced expiratory flow; $FEF_{25–75\%}$, forced expiratory flow at 25–75% of pulmonary volume; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; L, liter; PEF, peak expiratory flow; pp, percent predicted; ppb, parts per billion; PRO, patient-related outcome; Q, quartile; SD, standard deviation.

Table 3. Baseline ICS asthma controller medications used by patients in the analysis population and in patients with and without a history of previous OCS use in the 3 months prior to enrollment in RAPID.

	Analysis population (N = 205)	Patients with previous OCS use (n = 52)	Patients without previous OCS use (n = 153)
ICS asthma controller medications, n (%)			
ICS	17 (8.3)	13 (25.0)	10 (6.5)
ICS + LABA	112 (54.6)	30 (57.7)	99 (64.7)
ICS + LABA + LAMA	23 (11.2)	10 (19.2)	16 (10.5)

ICS, inhaled corticosteroids; LABA, long-acting beta agonist; LAMA, long-acting muscarinic antagonist.

Table 4. Previous OCS medications used by patients with a history of previous OCS use in the 3 months prior to enrollment in RAPID.

	Patients with previous OCS use (n = 52)
Any previous OCS medications, n1 (%)	52 (100.0)
Ongoing[a], n/n1 (%)	21/52 (40.4)
Prednisone, n1 (%)	46 (88.5)
Ongoing, n/n1 (%)	19/46 (41.3)
Methylprednisolone, n1 (%)	2 (3.8)
Ongoing, n/n1 (%)	1/2 (50.0)
Methylprednisolone sodium succinate, n1 (%)	0 (0)
Ongoing, n/n1 (%)	0/0 (0)
Prednisolone, n1 (%)	3 (5.8)
Ongoing, n/n1 (%)	0/3 (0)
Dexamethasone, n1 (%)	1 (1.9)
Ongoing, n/n1 (%)	1/1 (100.0)
Betamethasone sodium phosphate, n1 (%)	0 (0)
Ongoing, n/n1 (%)	0/0 (0)
Hydrocortisone, n1 (%)	0 (0)
Ongoing, n/n1 (%)	0/0 (0)
Uncoded: methylprednisolone, n1 (%)	1 (1.9)
Ongoing, n/n1 (%)	0/1 (0)
Uncoded: prednisone, n1 (%)	0 (0)
Ongoing, n/n1 (%)	0/0 (0)

[a]Ongoing refers to medications used by patients enrolled in RAPID during a 6-month period.

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