CHEST®

Characteristics, treatment patterns and outcomes of patients with pulmonary arterial hypertension by race: real-world data from the combined OPUS/OrPHeUS studies

Vallerie V. McLaughlin[1], Richard Channick[2], Lana Melendres-Groves[3], Kelly M. Chin[4], Gwen MacDonald[5], Nicolas Martin[6], Rose Ong[7], Marinella Sandros[8], Nick H. Kim[9]

[1]University of Michigan, Ann Arbor, MI, USA. [2]David Geffen School of Medicine at UCLA, Los Angeles, CA, USA. [3]University of New Mexico, Albuquerque, NM, USA. [4]UT Southwestern Medical Center, Dallas, TX, USA. [5]Actelion Pharmaceuticals Ltd, a Johnson & Johnson Company, Global Medical Affairs, Allschwil, Switzerland. [6]Actelion Pharmaceuticals Ltd, a Johnson & Johnson Company, Statistics & Decision Sciences, Allschwil, Switzerland. [7]Actelion Pharmaceuticals Ltd, a Johnson & Johnson Company, Global Epidemiology, Allschwil, Switzerland. [8]Actelion Pharmaceuticals US, Inc., a Johnson & Johnson Company, US Medical Affairs, Titusville, NJ, USA. [9]University of California San Diego, La Jolla, CA, USA.

This material is distributed for scientific purposes only by Janssen Science, and is not for promotional use

Financial Disclosure

- I have served as a Scientific Committee member for Johnson & Johnson; received research grants from Aerovate, Altavant, Gossamer Bio, Johnson & Johnson, Merck, and SoniVie; and received consultant fees from Aerami, Aerovate, Altavant, Bayer, Caremark, Corvista, Gossamer Bio, Johnson & Johnson, L.L.C, Merck and United Therapeutics.

This material is distributed for scientific purposes of Janssen Science, and is not for promotional use

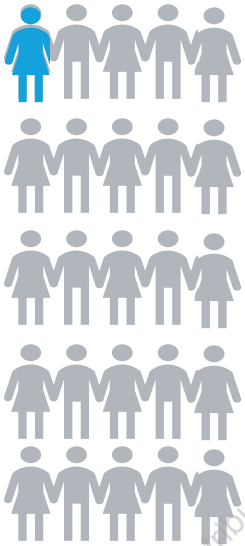
Background

Racial minorities are under-represented in most PAH clinical studies

Data from the 2020 Census[1] records 12.4% of the US population identified as Black/African American

PAH RCTs[2-5]

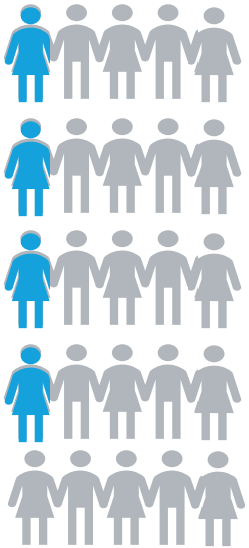
4%
Black/African American



Enrolled patients worldwide (2000 – 2022)

OPUS & OrPHeUS[6]

16%
Black/African American



Studies enrolled **patients newly initiating macitentan** in US centers (2013 – 2020)

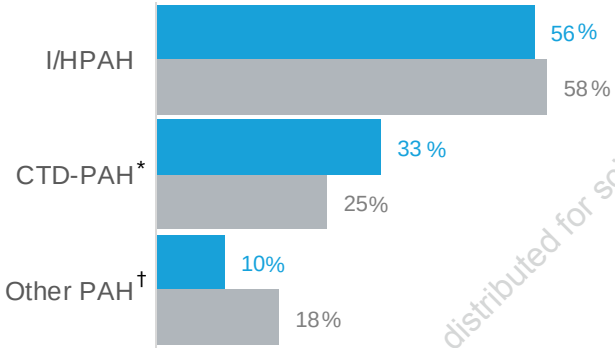
Poster material is distributed for scientific purposes on Janssen Science, and is not for promotional use

OPUS was a prospective registry (NCT02126943); OrPHeUS was a retrospective chart review (NCT03197688). PAH: pulmonary arterial hypertension; RCT: randomized controlled trial. 1. Jones N, *et al*. 2021 Source: https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html accessed 03.09.2024; 2. Contreras J, *et al. J Clin Med* 2024; 13:285; 3. Chin KM, *et al. JACC* 2021; 78:1393-403; 4. Grünig E, *et al. JACC* 2024; 83:473-84; 5. Hoeper MM, *et al. N Engl J Med* 2023; 388:1478-90; 6. McLaughlin VV, *et al. Pulm Circ* 2022; 12:e12150.

OPUS/OrPHeUS patient population: demographics

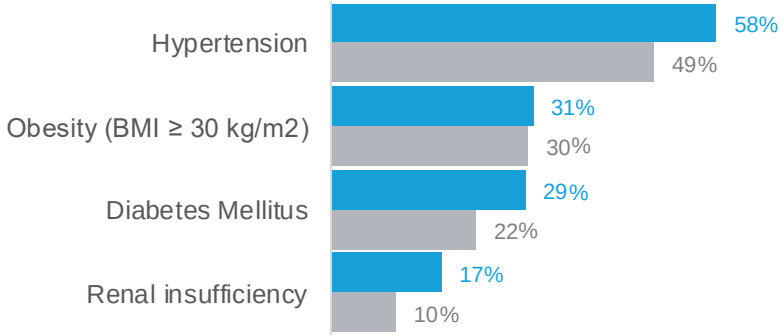
	Median age at diagnosis	Proportion female	Median time from diagnosis to macitentan initiation	Proportion with baseline PAH-specific therapy
Black/African American (N=752)	**57 years** (Q1=47, Q3=66)	**82%**	**8.4 months** (Q1=1.5, Q3=36.3)	**62.5%**
White (N=3484)	**61 years** (Q1=48, Q3=71)	**74%**	**7.4 months** (Q1=1.3, Q3=40.3)	**62.5%**

PAH etiology



Relevant medical history

at or before macitentan initiation



*CTD-PAH subtype breakdown for Black/African American and White patients respectively: systemic sclerosis/scleroderma: 13%, 17%; systemic lupus erythematosus: 7%, 2%; Mixed CTD: 6%, 2%; Other: 7%, 4%. †In Black/African American and White patients respectively, includes: 3% and 6% congenital heart disease associated-PAH; 3% and 6% drug/toxin-induced-PAH; 2% and 5% portopulmonary hypertension; 2% and 0.5% patients with HIV-PAH; 0.3% and 0.4% "Other PAH etiology". Percentages may not add up to 100% due to rounding. BMI: body mass index; CTD-PAH: PAH associated with connective tissue disease; I/HPAH: idiopathic/heritable PAH; PAH: pulmonary arterial hypertension; Q1,Q3: interquartile range.

This material is distributed for scientific purposes on Janssen Science, and is not for promotional use

OPUS/OrPHeUS patient population: baseline disease characteristics

Black/African American (N=752) White (N=3484)

Functional Parameters

Patients with available data

Median 6MWD

256 m (Q1=165, Q3=335) — 32%

300 m (Q1=198, Q3=382) — 37%

WHO FC

	I	II	III	IV
56%	6%	22%	64%	7%
55%	8%	30%	55%	7%

NT-proBNP risk category*

	Low	Intermediate	High
39%	26%	35%	39%
37%	27%	40%	34%

Hemodynamics (median values)

Patients with available data

PVR	7.1 WU (Q1=4.8, Q3=10.3)	41%
	7.0 WU (Q1=4.7, Q3=10.8)	41%
mPAP	44 mmHg (Q1=37, Q3=51)	49%
	45 mmHg (Q1=35, Q3=54)	49%
PAWP	11 mmHg (Q1=8, Q3=15)	47%
	12 mmHg (Q1=8, Q3=15)	47%
CI	2.3 L/min/m^2 (Q1=1.8, Q3=2.9)	46%
	2.4 L/min/m^2 (Q1=1.9, Q3=3.0)	46%

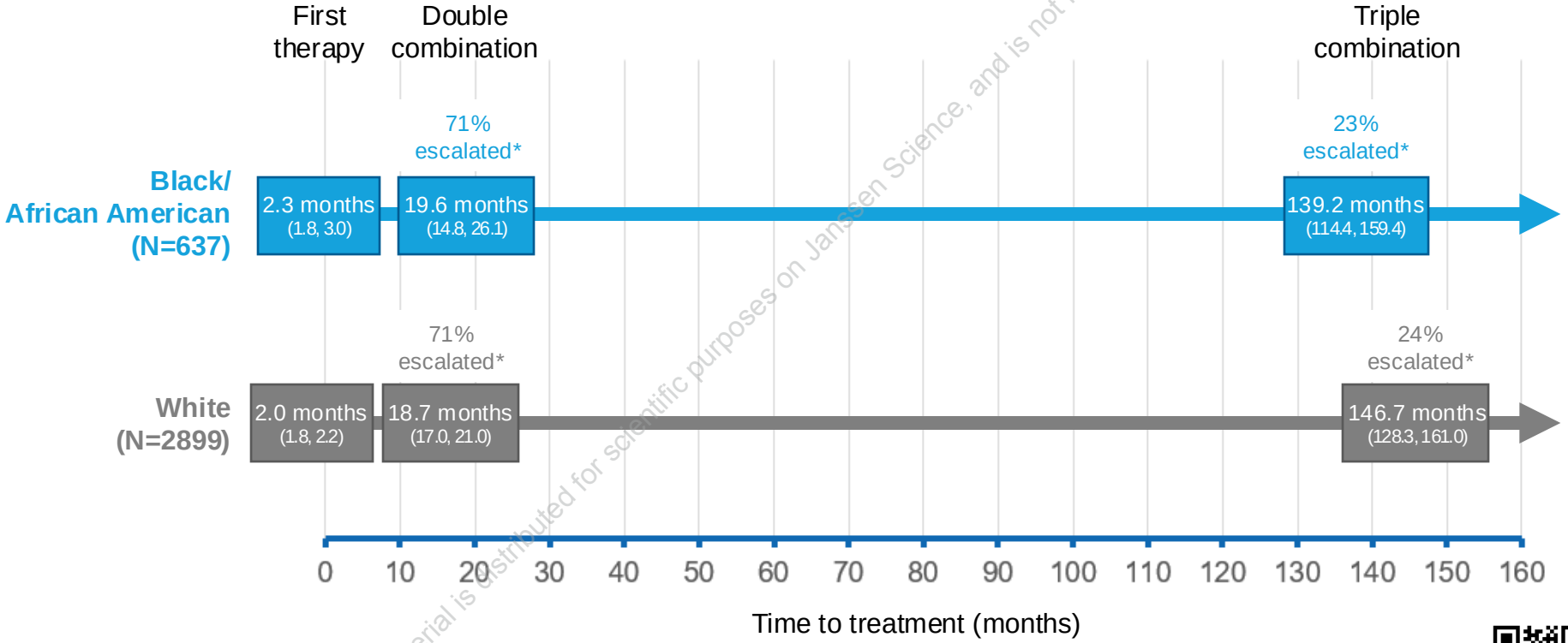
Material is distributed for scientific purposes on Janssen Science and not for promotional use

*Low: BNP <50 ng/L, NT-proBNP <300 ng/L; Intermediate: BNP 50-300 ng/L, NT-proBNP 300-1400 ng/L; High: BNP >300 ng/L, NT-proBNP >1400 ng/L[1,2]. 6MWD: 6-minute walk distance; BNP: brain natriuretic peptide; CI: cardiac index; mPAP; mean pulmonary arterial pressure; NT-proBNP: N-terminal pro-brain natriuretic peptide; PAWP: pulmonary arterial wedge pressure; PVR: pulmonary vascular resistance; WHO FC: World Health Organization functional class; WU: Wood units.

1. Galiè N, *et al. Eur Heart J* 2016; 37:67-119; 2. Galiè N, *et al. Eur Respir J* 2015; 46:903-75.

Treatment patterns

Time from diagnosis to PAH-specific therapy – Kaplan-Meier estimates, median (95% CL)



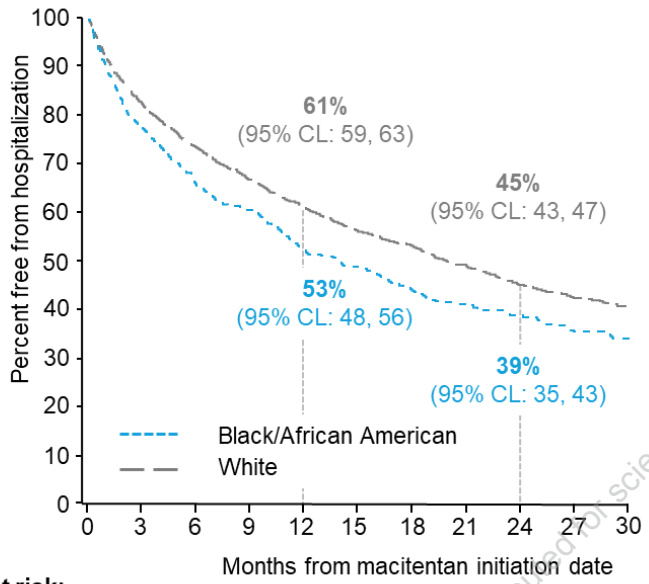
This material is distributed for scientific purposes on Janssen Science, and is not for promotional use

Patients with an incomplete date of diagnosis, or a diagnosis date after the date of initiation of first PAH therapy were excluded from these analyses. *Calculated as number of patients with event over entire observation period / total number of patients. CL: confidence limit.

Hospitalization and survival

Kaplan-Meier estimates (95% CL) from macitentan initiation

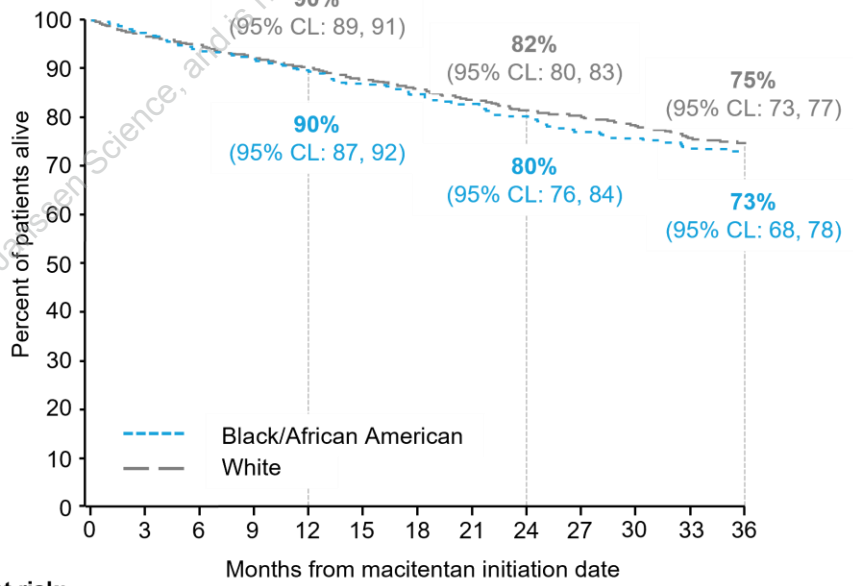
First all-cause hospitalization



Patients at risk:

751	528	396	330	248	202	164	135	106	87	72	
3481	2490	1995	1632	1361	1127	965	817	667	564	468	

Survival



Patients at risk:

752	652	552	484	414	361	309	268	219	185	158	127	107	
3484	2902	2537	2228	1969	1719	1516	1331	1155	995	845	698	551	

All analyses are descriptive and unadjusted. For first all-cause hospitalization, patients with missing hospitalization date were excluded from the analyses for Black/African American n=1 and White n=3 groups, respectively. Curves are cut at the point where <10% of patients remain at risk.

This material is distributed for scientific purposes on Janssen Science, and is not for promotional use

Safety

	Black/African American N=752	White N=3484
Median exposure to macitentan – months	**13.9** (Q1=5.4, Q3=26.8)	**14.6** (Q1=5.2, Q3=29.6)
Patients discontinuing macitentan – %		
Due to an adverse event	16.8%	18.1%
Other reason*	16.8%	17.8%
Missing reason	7.4%	7.2%
Adverse events (OPUS only)	**N=355**	**N=1748**
Patients with ≥1 adverse event – %	**81.7%**	**80.3%**
Most common (>10%) adverse events by Preferred Term – %		
Dyspnea	27.9%	22.8%
Headache	12.4%	12.3%
Peripheral edema	11.8%	10.2%
Nausea	11.0%	10.1%
Dizziness	10.4%	8.1%
Cough	10.1%	7.2%

*Includes withdrawal of consent, patient lost to follow up, patient moved or was no longer under site care, and non-safety related treatment interruptions of >14 days (e.g., due to changing health insurance providers).

This material is distributed for scientific purposes on Janssen Science, and is not for promotional use

Conclusions

- Black/African American patients tended to be younger, were more often female, with a higher incidence of CTD-PAH and a greater comorbidity burden than White patients.
- For those with data, Black/African American patients had more functional impairment at macitentan initiation than White patients; hemodynamics were similar.
- Overall treatment patterns, safety, tolerability and survival outcomes with macitentan treatment were similar; however, all-cause hospitalization was higher for Black/African American patients.

Clinical Implications

- Data on the use of PAH-specific drugs in Black/African American patients can inform treatment decisions and may help to close racial health equity gaps

This material is distributed for scientific purposes by Janssen Science, and is not for promotional use