Baseline characteristics of patients enrolled in the ASCENT study: Evaluating safety and tolerability of YUTREPIA™, a dry-powder inhaled treprostinil in pulmonary hypertension associated with interstitial lung disease (PH-ILD)

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Background

Pulmonary hypertension (PH) is a frequent complication of interstitial lung disease (ILD) and is associated with substantially increased morbidity and mortality. LIQ861 (YUTREPIA™) is an investigational dry-powder inhaled (DPI) formulation of treprostinil.

The ASCENT study is an open-label, multicenter trial assessing the safety and tolerability of YUTREPIA in prostacyclin-naïve WHO group 3 PH-ILD, including CPFE.

The objective of this poster is to report the baseline characteristics of the first 7 patients enrolled in ASCENT.

Key inclusion criteria

- mPAP ≥30 mmHg and PVR ≥3 WU
- mPAP ≥21 mmHg and PVR ≥3 WU*
- Baseline 6MWD ≥125m
- CT chest imaging consistent with ILD or CPFE
- FEV1/FVC ≥70%

Methods

We analyzed the baseline demographic, hemodynamic, exercise capacity (6MWD), and pulmonary function data of patients enrolled between December 2023 and March 2024. Descriptive statistics were used to summarize the characteristics of this initial cohort of 7 patients.

Results

Baseline patient characteristics

Patient	Age, y	Gender	PVR, WU	mPAP, mmHg	FEV1/FVC, %	FVC,%	DLco,%	ILD type	6MWD, m
1	68	M	5.0	30	83	52	59	iNSIP	207
2	75	F	5.0	34	98	26	15	IPF	147
3	68	F	5.2	23	78	117	47	SSc-ILD	457
4	76	M	3.3	34	88	64	38	IPF	420
5	53	F	5.3	32	76	72	65	Unclassifiable	324
6	76	M	11.9	57	71	87	51	CPFE	183
7	72	M	11.0	45	72	81	20	CPFE	180

Demographics

- 43% female, 57% male
- Mean age: 70 years

Pulmonary function

- Mean FVC: 71%
- Mean FEV1/FVC ratio: 81%
- Mean DLco: 42%

6MWD

- Mean 6MWD: 274 m

Hemodynamics

- Mean PVR: 7 WU
- Mean mPAP: 36 mmHg

Treatment (dose titration)

Over the initial 12 weeks of treatment, the highest dose achieved by any patient was 238.5 µg treprostinil, equivalent to ≥27 breaths of nebulized treprostinil

Adverse events

Over the initial 12 weeks of treatment, 5 of 7 patients have experienced mild AEs:

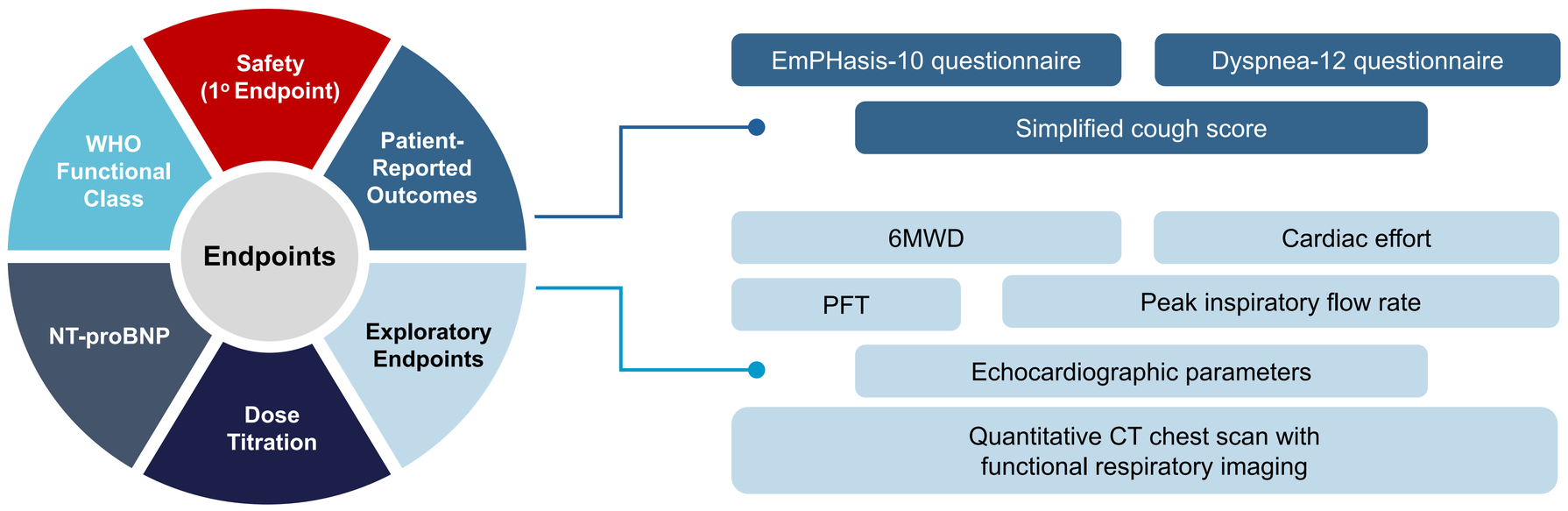
- Cough, headache, stomach flu, n=1
- Chest discomfort, n=1
- Nausea and dry cough, n=1
- Insomnia, n=1
- Dry throat, n=1

Conclusions

The present study reports the baseline demographics and clinical characteristics of the first 7 patients enrolled in the ASCENT study.

This study will enroll approximately 60 subjects with prostacyclin-naïve WHO group 3 PH-ILD to be treated with LIQ861 for up to 52 weeks.

The ASCENT study endpoints, including additional exploratory endpoints, are represented in the chart to the right.



References and Disclosures

*Additional limited exploratory subset of patients with mPAP ≥21 mmHg and PVR ≥3 WU.

6MWD = 6-minute walk distance; AE = adverse event; CPFE = combined pulmonary fibrosis and emphysema; CT = computed tomography; DLco = diffusion capacity for carbon monoxide; FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity; |IPF = idiopathic pulmonary fibrosis; iNSIP = Idiopathic nonspecific interstitial pneumonia; mPAP = mean pulmonary arterial pressure; NT-proBNP = N-terminal pro–brain natriuretic peptide; PFT = pulmonary function test; PVR = pulmonary vascular resistance; SSc = systemic sclerosis; WHO = World Health Organization; WU = Wood units.

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Conflict of Interest disclosures: **N. Habib** receives consulting fees for Janssen Pharmaceuticals, United Therapeutics Corporation (UTC), Aerovate Therapeutics, and Liquidia Corporation, along with speaking for Janssen, UTC, and Liquidia Corporation. **A. Ravichandran** receives consulting fees for Abbot Laboratorie, and reports payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from UTC and Johnson & Johnson. **J. Feldman** receives consulting fees from Liquidia Corporation. **S. Patel**, **A.L. Galloway**, **G. Gwyn**, and **R. Saggar** are salaried employees and shareholders of Liquidia Corporation.