Hearing from Patients: Self-Reported Cough Outcomes During Treatment with YUTREPIA® (treprostinil) in the ASCENT Trial

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ASCENT CLINICAL TRIAL

Background

- Cough is a common and burdensome symptom for patients living with interstitial lung disease (ILD) that impacts daily activities and quality of life[1]
- In patients with pulmonary hypertension associated with ILD (PH-ILD), there may be concern that dry powder inhaler (DPI) therapies could worsen cough
- Traditional clinical trial adverse event (AE) reporting may not fully capture the patient experience or day-to-day impact of cough[2]
- In Cohort A of the ASCENT trial of YUTREPIA® (treprostinil) inhalation powder delivered via DPI in patients with PH-ILD, patient-reported cough assessments were collected alongside traditional AE reporting to better understand the patient experience with cough[3,4]

Methods[3,4]

- ASCENT (NCT06129240) is an open-label, prospective, multicenter study evaluating the safety and tolerability of YUTREPIA® inhalation powder via DPI in patients with PH-ILD
  - Patients receive open-label YUTREPIA® with dose titration based on tolerability and clinical response
  - Patient cough during treatment was assessed by investigator-reported treatment-emergent adverse events (TEAEs), treatment discontinuations due to cough, and patient-reported daytime cough using a Simplified Cough Score[5,6] (**Table 1**)
  - Mean patient-reported cough scores were evaluated at baseline, Week 8, Week 16, and Week 24 as YUTREPIA® doses increased (**Figure 1**)
- Safety and tolerability, including cough scores, will be further evaluated at the end of the 52-week study. Presented findings are preliminary and are subject to change upon completion of the trial

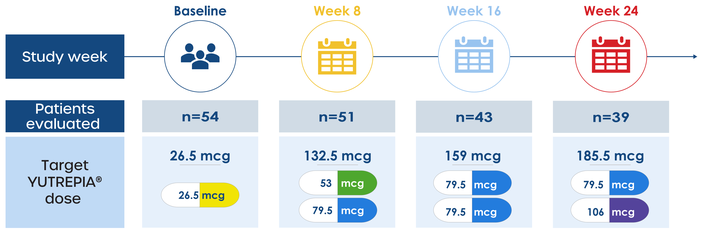
Table 1. Simplified Cough Score[5,6]

Score	Daytime Cough
0	No cough
1	**Transient cough** occasionally during the daytime
2	**Frequent cough** mildly affecting daily life
3	**Frequent cough** severely affecting daily life

Instructions: The patient should circle the score that best describes their cough over the past 2 weeks

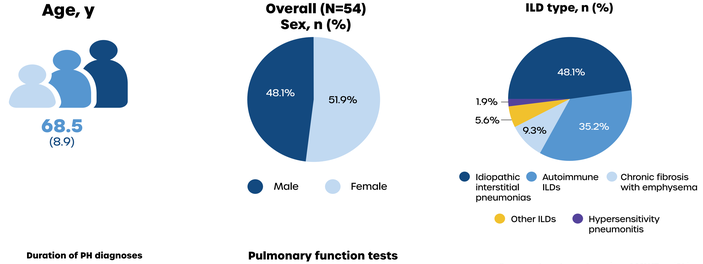
Methods[3,4] (Cont.)

Figure 1. ASCENT Cohort A: Patient Assessment and Dose Titration



Results[4]

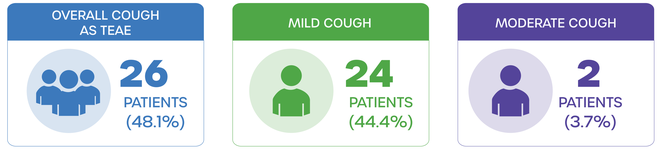
Figure 2. Select Baseline Demographics and Clinical Characteristics



Data are mean (SD) unless otherwise noted.
6MWT, 6-minute walk test; DLCO, diffusing capacity of the lung for carbon monoxide; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; ILD, interstitial lung disease; mPAP, mean pulmonary arterial pressure; PCWP, pulmonary capillary wedge pressure; PH, pulmonary hypertension; PVR, pulmonary vascular resistance.

Results (Cont.)

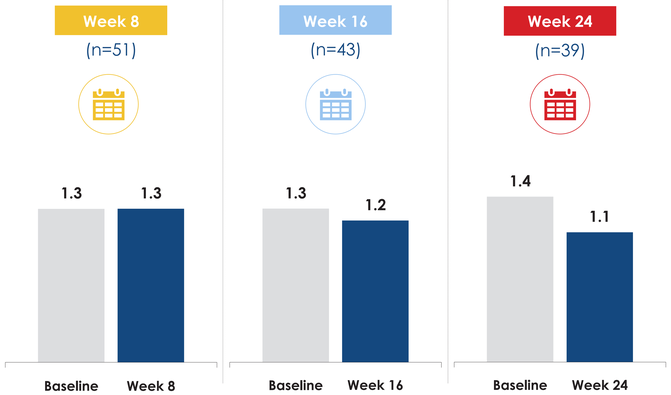
At week 24, of 54* patients:



*Two patients had protocol violations and were excluded.

- No treatment-related serious adverse events occurred, and no patients discontinued treatment due to cough at Week 24
- When patients reported on their own cough experience, mean daytime cough scores were relatively unchanged to slightly improved (**Figure 3**)
- From the patient perspective, cough burden did not appear to worsen, and showed a trend toward non-worsening through 24 weeks

Figure 3. Patient-Reported Simplified Mean Cough Score



Conclusions

- Over 24 weeks of treatment with YUTREPIA® inhalation powder delivered via DPI, patients with PH-ILD reported stable daytime cough severity, without worsening as doses increased during titration
- Patient-reported cough findings complement investigator-reported safety data and may help address concerns about cough worsening with DPI therapy in patients with underlying ILD
- No patients discontinued treatment due to cough, supporting the tolerability of YUTREPIA®
- These preliminary findings highlight the importance of including patient-reported experiences alongside traditional clinical trial safety assessments

References

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2. Mackay EC, et al. *J Thorac Dis.* 2024;16(10):7165-7181.
3. An Open-Label ProSpective MultiCENTer Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in PH (ASCENT). ClinicalTrials.gov identifier: NCT06129240. Updated February 9, 2026. Accessed May 20, 2026. https://clinicaltrials.gov/study/NCT06129240
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Disclosures

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