Characteristics and treatment patterns of patients initiated on or transitioned to OPSYNVI® (macitentan/tadalafil single tablet combination therapy) for treatment of pulmonary arterial hypertension

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Background

- Early initiation of dual ERA+PDE-5i therapy improves outcomes of patients with PAH; however, real-world use of dual therapy is influenced by several factors such as patient demographics, tolerability, HCP preference and treatment compliance.
- The treatment approach for initial ERA+PDE-5i therapy remains ambiguous for patients with comorbidities.
- OPSYNVI® is the first once-daily, single-tablet ERA+PDE5i combination therapy. Since its approval in March 2024, real-world experience is still emerging as physicians begin to adopt it into clinical practice.

Objective

To characterize real-world patient profiles, treatment patterns, and short-term outcomes with OPSYNVI®.

Methods

- In this IRB approved study, HCPs reviewed charts of adult PAH patients in the US treated with OPSYNVI.
- HCPs were recruited from a large PAH research panel.
- No patient identifying data was reviewed by the interviewer/ research team.

50 HCPs participated; HCPs were predominantly physicians (84%, vs. 10% Nurse Practitioners and 6% Physician Assistants) with specialty in Pulmonology (58%, vs. 38% Cardiology, 4% Rheumatology) and affiliation with PH Care Center (56%).

144 charts of adult patients (aged 18 or older) diagnosed with Group 1 PAH and treated with OPSYNVI for at least 3 months were summarized by HCPs.

3 timepoints were collected per patient: baseline (≤90 days pre-initiation), follow-up (≥90 days post-initiation), and most recent visit (occurring at least 30 days after follow-up).

Data collected related to primary outcomes included

Patient demographics | PAH clinical status | PAH treatment history | OPSYNVI initiation rationale

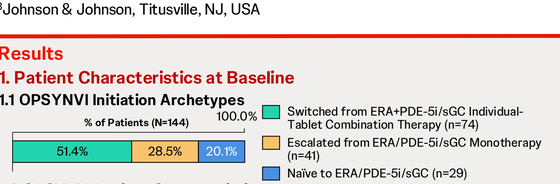
Data collected related to exploratory outcomes included

Change in outcomes (6MWD, BNP, hospitalization) from baseline to first follow-up.

Results

1. Patient Characteristics at Baseline

1.1 OPSYNVI Initiation Archetypes



1.2 OPSYNVI Patient Characteristics

50.7% of OPSYNVI patients were diagnosed with IPAH; this was the most common etiology across archetypes, especially for patients escalated from ERA/PDE-5i/sGC monotherapy (61.0% had IPAH)

34.5% of OPSYNVI patients naïve to ERA/PDE-5i/sGC were diagnosed with CTD-PAH

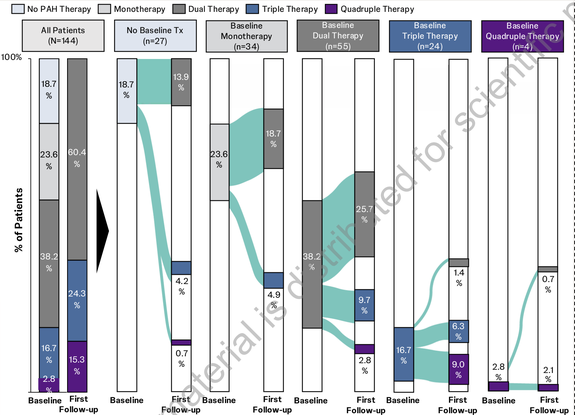
13.8% of OPSYNVI patients naïve to ERA/PDE-5i/sGC were diagnosed with drug- and toxin-induced PAH

88.9% of patients were FCII or FCIII at the time of OPSYNVI initiation

83.3% of patients had 1 or more comorbidities of interest* at the time of OPSYNVI initiation

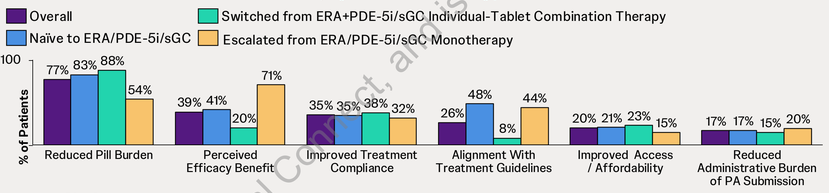
Note: *HCPs provided all patient comorbidities during interview, selected ones of interest included: ILD/pneumonitis, DM, obesity, HTN, GI disease/perforations, neuropathy, hepatic insufficiency, CKD, CAD, COPD, HLD, and OSA. n=4 patients were switched from ERA+sGC combinations at baseline.

2. OPSYNVI Treatment Patterns



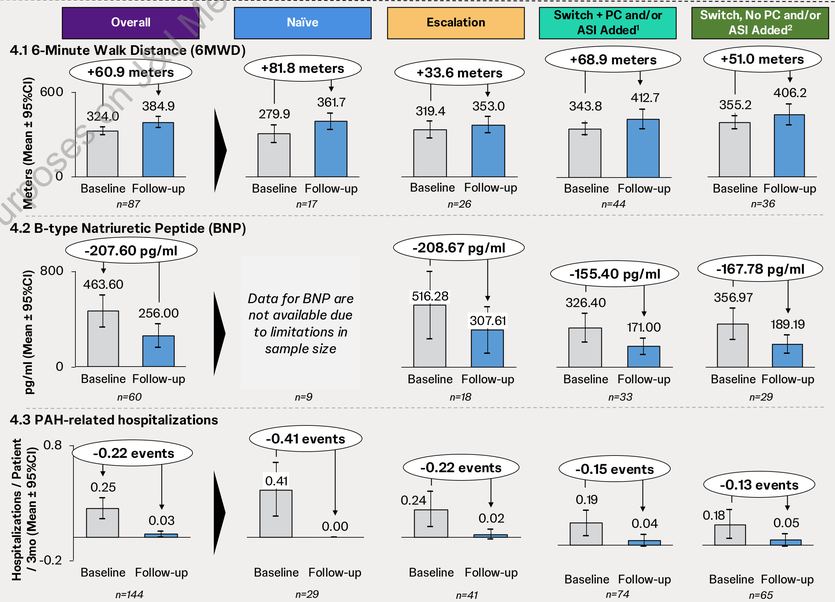
At baseline, 38.2% (n=55) patients were on dual therapy; the majority (81.8%, n=45) of these patients received ERA + PDE-5i combination.

3. HCP Rationale for OPSYNVI Initiation, by Initiation Archetype



Notes: N=50 HCPs; N=144 patient charts. HCPs could select multiple rationales per patient. Two additional reasons not shown include "patient preference" (18% Overall; 21% Naïve; 15% Escalation; 19% Switch) and "perceived tolerability benefit" (11% Overall; 19% Naïve; 12% Escalation; 8% Switch).

4. Exploratory Patient Outcomes on OPSYNVI



Improved outcomes were observed, including for patients switched from individual tablet combinations to OPSYNVI without the addition of PC and/or ASI.

Note: [1]This group includes all switch patients, which is why naïve, escalation, and this group sums to 87 (17+26+44); [2]Subset of the overall switch group

Abbreviations 6MWD=6-Minute Walk Distance; ASI=Activin Signaling Inhibitor; BNP=B-type Natriuretic Peptide; CAD=Coronary Artery Disease; CKD=chronic kidney disease/renal impairment; COPD=Chronic Obstructive Pulmonary Disease; CTD-PAH=Connective Tissue Disease PAH; DM=Diabetes Mellitus; ERA=Endothelin Receptor Antagonist; ERS=European Respiratory Society; ESC=European Society of Cardiology; GI=GastrointestinalDisease; HCP=Healthcare Provider; HI=Hepatic Impairment; HLD=Hypercholesterolemia; HTN=Hypertension; ILD=Interstitial Lung Disease; IPAH=Idiopathic PAH; OSA=Obstructive Sleep Apnea; PAH=Pulmonary Arterial Hypertension; PC=Prostacyclin; PDE-5i=Phosphodiesterase Type 5 Inhibitor; sGC stimulator=Soluble Guanylate Cyclase Stimulator; WHO FC=World Health Organization Functional Class.

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Key Takeaways and Implications

This study provides insights on real-world patient characteristics, treatment patterns and outcomes associated with the use of OPSYNVI at first follow-up in the management of PAH.

OPSYNVI is Adopted Across a Diverse Patient Subset
- n=144 patients remained on OPSYNVI for at least 6 months.
- In real world settings, OPSYNVI is utilized across a broad spectrum of patients with PAH, including those with multiple comorbidities (83.3% had ≥1 comorbidities).

The Majority of OPSYNVI Initiations Are in Patients Switched From Dual ERA+PDE-5i Regimens
- 60.8% (n=45) patients switched from individual-tablet combination therapy were on dual ERA + PDE-5i therapy.
- 22.2% (n=32) patients initiated on OPSYNVI were escalated from ERA/PDE-5i monotherapy; 20.1% (n=29) patients initiated on OPSYNVI were naïve to ERA/PDE-5i.
- Pill burden was the most cited reason for initiation (77.1%).

OPSYNVI Suited Across PAH Etiologies
- A higher proportion of patients naïve to ERA/PDE-5i/sGC were diagnosed with CTD-PAH (34.5%) or drug- and toxin-induced PAH (13.8%) compared to other initiation groups.

OPSYNVI Associated With Improved Outcomes
- Clinical benefits were observed across all patient groups following OPSYNVI initiation.
- Patients on baseline individual-tablet combination therapy (ERA + PDE-5i/sGC) switched to OPSYNVI demonstrated numerical improvement in 6MWD, reduction in BNP and PAH-related hospitalization after 3 months of initiation.

Harmonization of Guidelines With Real World Practice
- Findings highlight the need for guideline harmonization with US context and reinforce OPSYNVI's role in facilitating dual therapy.

Limitations

Study limitations were inherent to its **retrospective and observational design**, which include:
- **Selection bias** (patients were randomly selected by HCPs)
- **Variable data availability** (clinical assessments were non-standardized)
- **Associational findings** (results do not demonstrate causality)

Despite these limitations, this study provides important data on how OPSYNVI is being adopted in clinical practice in the US.

Disclosures

Research supported by Johnson & Johnson. MK has affiliations with Johnson & Johnson, including service on the Speakers Bureau, Scientific Advisory Board, and as a consultant. MK also serves on the Speakers Bureau for Liquidia and serves as a consultant and Advisory Board member for United Therapeutics and NorthGauge HealthCare Advisors. NK has received consultancy fees from Johnson & Johnson, Merck, Liquidia, United Therapeutics, Gossamer, and Bayer. JR has received research funding from Merck, Bayer, Janssen PH, and Kiniksa, and consultancy fees from Merck, Liquidia, Janssen PH, United Therapeutics, and Kiniksa. AS is an employee of Putnam Associates and consultant for Johnson & Johnson. MS, NG, AA, and DL are employees of Johnson & Johnson.

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