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SURWEY Study of Solriamfetol: Initiation, Titration, Safety, Efficacy, and Follow-Up Experience for Patients with OSA in Germany

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Introduction

- Excessive daytime sleepiness (EDS) is a common symptom of obstructive sleep apnea (OSA) that can persist in patients despite positive airway pressure (PAP) therapy, and may pose challenges to clinical management of symptoms[1-4]
- Solriamfetol (Sunosi®) is a dopamine and norepinephrine reuptake inhibitor approved for use in adults in the European Union and United States (US) for the treatment of EDS associated with OSA (37.5–150 mg/day)[5,6]
  - Solriamfetol has been shown to activate trace amine-associated receptor 1 (TAAR1), a potential target to improve cognitive functions[7,8]
- There is limited real-world evidence on how physicians initiate solriamfetol and subsequent treatment outcomes in patients with OSA and associated EDS[9]; such data may help clinicians optimize patient care

Objective

- This real-world study characterizes dosing and titration strategies among European physicians initiating solriamfetol, as well as treatment outcomes following initiation in patients with EDS and OSA

Methods

- **SU**nosi **R**eal **W**orld **E**xperience Stud**Y** (SURWEY) was a retrospective chart review among physicians in Germany who have prescribed solriamfetol to patients with EDS associated with narcolepsy or OSA
- The present analysis focuses on data from 83 patients with OSA from Germany
  - Eligible patients were ≥18 years of age, had a diagnosis of EDS due to OSA, had reached a stable maintenance dose of solriamfetol, and completed ≥6 weeks of treatment; patients who received solriamfetol during a clinical trial or early access program were excluded
- Solriamfetol initiation strategies: **changeover** (switched/switching from existing EDS medication[s]), **add-on** (added/adding to current EDS medication[s]), and **new-to-therapy** (no current/previous EDS medication)
- Data related to solriamfetol dosing/titration, comorbidities, Epworth Sleepiness Scale (ESS) scores, patient- and physician-reported improvement in EDS, duration of solriamfetol effects, and adverse events were summarized descriptively

Results

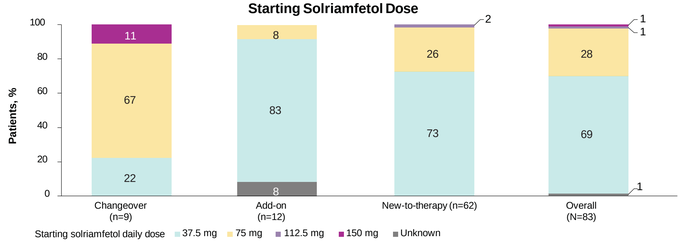
Table 1. Baseline Demographic and Clinical Characteristics

	Changeover (n=9)	Add-on (n=12)	New-to-therapy (n=62)	Overall (N=83)
Age, mean (SD), years	44 (10)	40 (12)	51 (14)	49 (14)
Sex (female), n (%)	2 (22)	5 (42)	22 (36)	29 (35)
BMI, mean (SD), kg/m^2	33.5 (4.0)	30.7 (5.8)	32.3 (6.2)	32.2 (6.0)
ESS score, mean (SD)	16.6 (2.0)	16.3 (3.8)	15.9 (3.2)	16.0 (3.2)
Any comorbidities, n (%)	9 (100)	11 (92)	56 (90)	76 (92)
Obesity	7 (78)	6 (55)	31 (55)	44 (58)
Hypertension	4 (44)	4 (36)	29 (52)	37 (49)
Anxiety/depression	2 (22)	4 (36)	17 (30)	23 (30)
Diabetes type 2	3 (33)	2 (18)	15 (27)	20 (26)
Hyperlipidemia	5 (56)	3 (27)	10 (18)	18 (24)
Migraine headache	1 (11)	2 (18)	9 (16)	12 (16)
Congestive heart failure	0	0	8 (14)	8 (11)
Coronary artery disease	1 (11)	1 (9)	5 (9)	7 (9)
Arrhythmia	0	0	6 (11)	6 (8)
Fibromyalgia	0	1 (9)	4 (7)	5 (7)
ADHD	2 (22)	0	0	2 (3)
Other	3 (33)	5 (46)	28 (50)	36 (47)

ADHD, attention deficit hyperactivity disorder; BMI, body mass index; ESS, Epworth Sleepiness Scale; SD, standard deviation.

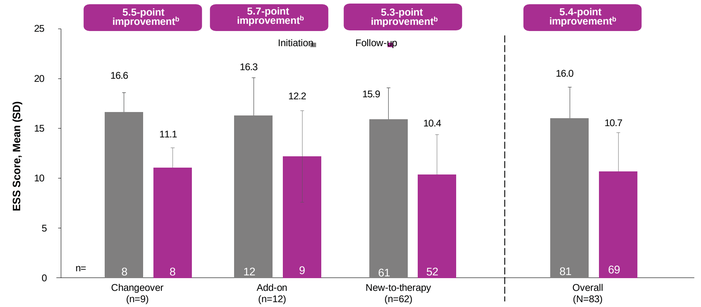
- New-to-therapy was the most common initiation strategy (75%), followed by add-on (14%) and changeover (11%)
- Obesity (58%) was the most common comorbidity
- Overall, 73 (88%) patients used PAP therapy; 60 (72%) patients used PAP for ≥4 hours/night and 66 (80%) patients used PAP on ≥4 nights/week
- The most commonly used concomitant medication for EDS was pitolisant

Figure 1. The Most Common Starting Dose of Solriamfetol Was 37.5 mg/day



- All 9 (100%) patients in the changeover group switched to solriamfetol due to lack of efficacy of other EDS medications
- Solriamfetol was titrated in 53 (64%) patients, most of whom (57%) completed titration within 2 weeks

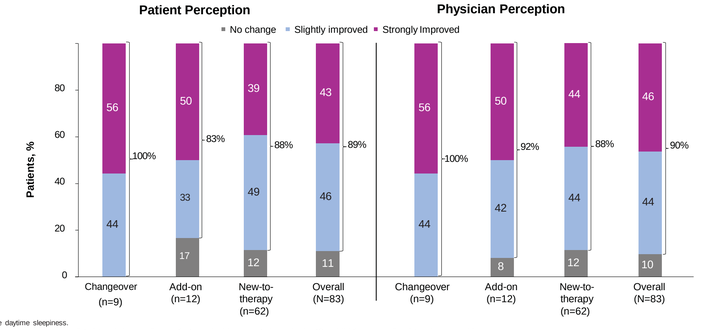
Figure 2. Mean Decrease in ESS Scores[a] With Solriamfetol Was ≥5 Points, Indicating Clinically Meaningful Improvement in EDS



ESS, Epworth Sleepiness Scale; SD, standard deviation.
[a]Scale range, 0–24; ESS scores >10 indicate EDS.[10] [b]Mean change from baseline.

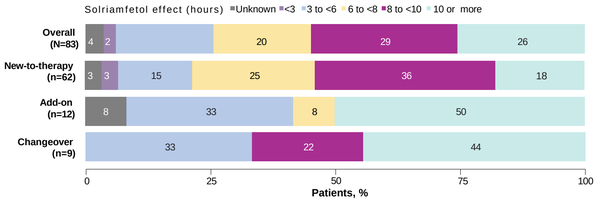
- Mean improvements in ESS in changeover, add-on, and new-to-therapy groups were substantially greater than the minimum clinically important difference of 2–3 points[11]

Figure 3. Patients and Physicians Perceived Improvements in Symptoms in Approximately 90% of Patients



EDS, excessive daytime sleepiness.
[a]Scale ranged from "strongly worsened" to "strongly improved"; no patients or physicians reported perceived EDS as "slightly worsened" or "strongly worsened."

Figure 4. Most Patients Reported That the Effects of Solriamfetol Lasted ≥8 Hours



- Overall, 75 (91%) patients reported no change in nighttime sleep quality with solriamfetol

Table 2. Treatment-Emergent Adverse Events[a]

n (%)	Changeover (n=9)	Add-on (n=12)	New-to-therapy (n=62)	Overall (N=83)
Any TEAE	2 (22)	7 (58)	18 (29)	27 (33)
Headache	1 (11)	1 (8)	5 (8)	7 (8)
Decreased appetite	1 (11)	1 (8)	4 (6)	6 (7)
Insomnia	0	0	5 (8)	5 (6)
Feeling jittery	0	2 (17)	2 (3)	4 (5)
Irritability	0	1 (8)	3 (5)	4 (5)
Dizziness	0	2 (17)	1 (2)	3 (4)
Abdominal pain	0	0	2 (3)	2 (2)
Other	0	1 (8)	2 (3)	3 (4)

TEAE, treatment-emergent adverse event.
[a]Reported by ≥2 participants.

- Adverse events were consistent with those previously reported in clinical trials of solriamfetol in participants with OSA[12,13]

Conclusions

- In the SURWEY study of solriamfetol in patients with OSA, solriamfetol was typically initiated at 37.5 mg/day and most patients were new-to-therapy; titration was common
- Overall, mean ESS scores improved by 5.4 points, and mean improvement in all groups was substantially greater than the minimum clinically important difference of 2–3 points[11]
  - This is consistent with improvements in sleepiness reported in clinical trials for solriamfetol[12,13]
  - Both patients and physicians perceived improvement in EDS for the vast majority of patients, regardless of initiation strategies
  - The majority of patients reported the effects of solriamfetol lasted at least 8 hours
- Common adverse events were consistent with those previously reported for solriamfetol[12,13]

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