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Solriamfetol Real World Experience Study (SURWEY): Safety, Effectiveness, and Experience During Follow-Up for Patients with Narcolepsy from Germany

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Introduction

- Excessive daytime sleepiness (EDS) is a core symptom of narcolepsy type 1 and type 2 that has historically been managed with wake-promoting agents, sodium oxybate, or traditional stimulants[1-3]
- Solriamfetol (Sunosi™) is a dopamine/norepinephrine reuptake inhibitor approved in the EU and the US to treat EDS associated with narcolepsy (75–150 mg/day) and obstructive sleep apnoea (OSA) (37.5–150 mg/day)[4,5]
- With the clinical availability of solriamfetol, data describing real- world physician dosing and titration strategies may help health providers optimise patient care

Objective

- To characterise real-world outcomes following initiation of solriamfetol treatment for patients with narcolepsy in Germany

Methods

- SURWEY is an ongoing retrospective chart review study among physicians in Germany, France, and Italy prescribing solriamfetol for patients with EDS associated with narcolepsy or OSA
- The current analysis focuses on data from patients with narcolepsy from Germany
- Physicians currently prescribing solriamfetol to ≥10 patients with EDS associated with narcolepsy provided data from the patients' medical records
  - Eligible patients were ≥18 years old, had been diagnosed with EDS due to narcolepsy, achieved a stable dose of solriamfetol, and completed ≥6 weeks of solriamfetol treatment
- Solriamfetol initiation strategies were characterised as:
  - Changeover: switched/switching from existing EDS medications onto solriamfetol
  - Add-on: adding solriamfetol to current EDS medication
  - New-to-therapy: no current EDS medication prior to solriamfetol

Table 1. Patient demographics and baseline characteristics

	Changeover (n=43)	Add-on (n=19)	New-to-therapy (n=8)	Overall (N=70)
Age, years				
Mean (SD)	38.0 (15.2)	36.2 (11.4)	32.6 (12.0)	36.9 (13.9)
Median (min, max)	36.0 (18, 76)	34.0 (18, 56)	28.0 (21, 53)	33.5 (18, 76)
Gender, n (%)				
Female	25 (58)	11 (58)	3 (38)	39 (56)
BMI, kg/m², mean (SD)	26.5 (5.4)[a]	27.7 (5.5)[b]	24.7 (3.4)[c]	26.7 (5.2)[d]
Patients with cataplexy, n (%)	23 (53)	15 (79)	2 (25)	40 (57)
Baseline ESS score, mean (SD)	17.1 (3.6)	18.5 (2.2)	17.6 (2.7)	17.6 (3.1)

BMI, body mass index; ESS, Epworth Sleepiness Scale; SD, standard deviation.
[a]n=36. [b]n=18. [c]n=7. [d]n=61.

- Most patients (84%) were treated in specialty sleep centres
- Overall, the most commonly reported comorbidities were anxiety and depression
- Changeover was the most common initiation strategy (n=43), followed by add-on (n=19) and new-to-therapy (n=8)
- Across all patients, solriamfetol was typically started at 75 mg/day (69%), although some patients started at doses of 150 mg/day (20%) or 37.5 mg/day (10%)
- For additional details on initiation strategies, considerations, and prior medications, please see poster 133
- Mean (SD) time to final follow-up visit was 15.3 (7.6), 17.1 (6.3), and 16.0 (5.7) weeks after solriamfetol initiation for the changeover, add-on, and new-to-therapy groups, respectively

Table 2. Adverse events[a]

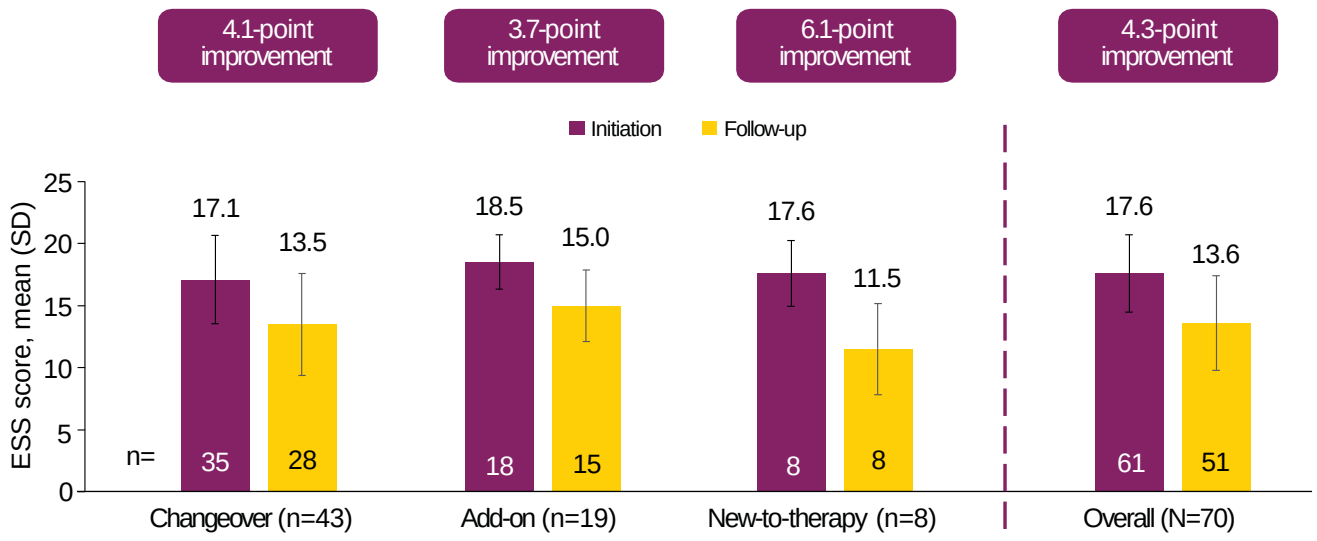
	Changeover (n=43)	Add-on (n=19)	New-to-therapy (n=8)	Overall (N=70)
Any side effect, n (%)	17 (40)	4 (21)	0	21 (30)
Headache	4 (9)	2 (11)	0	6 (9)
Decreased appetite	4 (9)	0	0	4 (6)
Insomnia	3 (7)	1 (5)	0	4 (6)
Anxiety	3 (7)	0	0	3 (4)
Irritability	3 (7)	0	0	3 (4)
Weight decreased	2 (5)	0	0	2 (3)
Dizziness	1 (2)	1 (5)	0	2 (3)
Dry mouth	1 (2)	1 (5)	0	2 (3)
Nausea	1 (2)	1 (5)	0	2 (3)

[a]Reported by ≥2 patients.

- Adverse events were consistent with those reported in clinical trials of solriamfetol in participants with narcolepsy[7]
- The most common adverse events were headache, decreased appetite, and insomnia
- No cardiovascular events were reported

Results

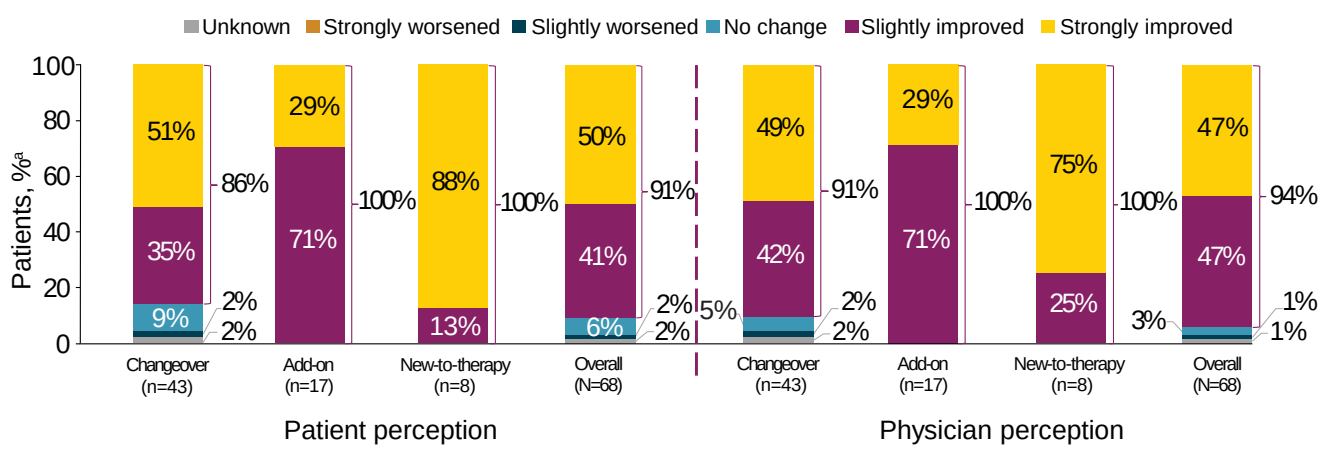
Figure 1. ESS scores[a] decreased following initiation of solriamfetol, indicating improvement of EDS



EDS, excessive daytime sleepiness; ESS, Epworth Sleepiness Scale; SD, standard deviation.
[a]Scale range: 0–24; ESS scores >10 indicate EDS.[5,6]

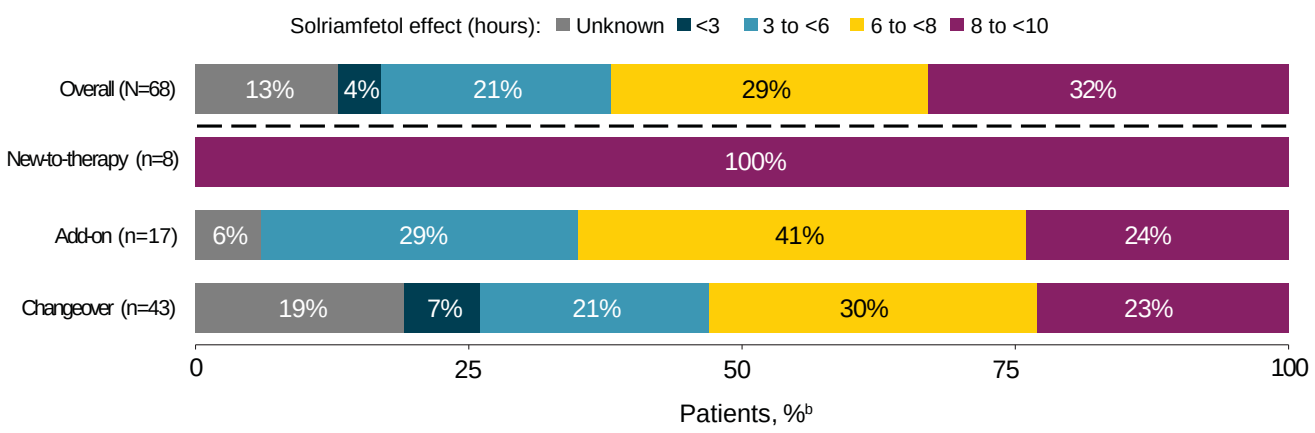
- Improvements in ESS scores were seen regardless of solriamfetol initiation strategy and were most pronounced in the new-to-therapy group

Figure 2. Overall, more than 90% of patients and physicians perceived improvement of EDS after initiating solriamfetol



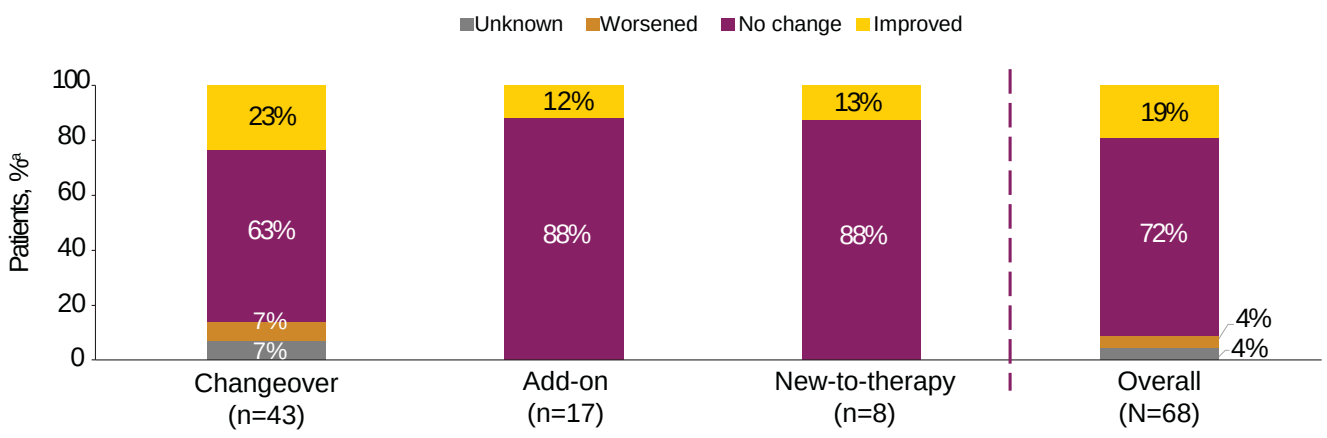
EDS, excessive daytime sleepiness.
[a]Percent totals may not equal 100% due to rounding.

Figure 3. Most patients reported a duration of effect of solriamfetol of 6 to <10 hours[a]



[a]No patients indicated a duration of effect ≥10 hours. [b]Percent totals may not equal 100% due to rounding.

Figure 4. Most patients reported no change in their perceived nighttime sleep quality



[a]Percent totals may not equal 100% due to rounding.

Conclusions

- This study provides the first multicentre real-world data regarding patient outcomes following initiation of solriamfetol in a cohort of German patients with narcolepsy
- Following solriamfetol initiation, improvements in EDS were observed across all subgroups (changeover, add-on, and new-to-therapy)
- ESS scores improved (average improvement, 4.3 points)
- Over 90% of patients and physicians perceived improvement in EDS
- Common adverse events were consistent with those reported in the clinical trial setting

References: 1. Thorpy MJ. *CNS Drugs*. 2020;34(1):9-27. 2. Thorpy MJ, Dauvilliers Y. *Sleep Med*. 2015; 16(1):9-18. **3.** Sunosi™ (solriamfetol) tablets Summary of Product Characteristics. Dublin, Ireland: Jazz Pharmaceuticals Ireland Ltd; 2020. **4.** Sunosi™ (solriamfetol) tablets Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc; 2021. **5.** Johns MW. *Sleep.* 1991;14(6):540-545. **6.** Johns M, Hocking B. *Sleep.* 1997;20(10):844-849. **7.** Thorpy MJ, et al. *Ann Neurol.* 2019;85(3):359-370.

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