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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 types 1 and 2, which historically have been managed through treatment with sodium oxybate, wake-promoting agents, or traditional stimulants[1,2]
- Solriamfetol (Sunosi™) is a dopamine/norepinephrine reuptake inhibitor approved in the EU and US to treat EDS associated with narcolepsy (75–150 mg/day) or obstructive sleep apnoea (OSA) (37.5–150 mg/day)[3,4]
- 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 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 in 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 on solriamfetol, and completed ≥6 weeks of solriamfetol treatment
- Solriamfetol initiation strategies were characterised as:
  - Changeover: switched/switching from existing EDS medications to solriamfetol
  - Add-on: adding solriamfetol to current EDS medication
  - New-to-therapy: no current EDS medication prior to solriamfetol
- Changes in Epworth Sleepiness Scale (ESS) scores, physician and patient impression of effectiveness, and adverse events are summarised descriptively; missing or partially missing data were not imputed

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/m^2, 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

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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Disclosures: U Kallweit is on the advisory board at AOP Orphan Pharmaceuticals, Bioprojet Pharma, Jazz Pharmaceuticals, Harmony Biosciences, Takeda Pharma, and UCB Pharma. He is also a consultant to AOP Orphan Pharmaceuticals, Bioprojet Pharma, Jazz Pharmaceuticals, Harmony Biosciences, and Takeda Pharma, and has accepted grants/research support from Bioprojet Pharma, Jazz Pharmaceuticals, and Harmony Biosciences. **Y Winter** has received honoraria for educational presentations and consultations from Arvelle Therapeutics, Angelini Pharma, Bayer, BIAL, Bioprojet Pharma, Bristol Myers Squibb, Eisai, Ethypharm, GW Pharmaceuticals, Jazz Pharmaceuticals, LivaNova, Neuraxpharm, Novartis, and UCB Pharma not related to the current study. **S Kotterba** received honoraria for educational presentations and consultations from Bioprojet Pharma and Jazz Pharmaceuticals. **H Benes** and **L Burghaus** have nothing to disclose. **A Koch**, **D Girfoglio**, and **M Setanoians** are employees of Jazz Pharmaceuticals who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. **G Mayer** is on the advisory board for Janssen Pharma in Germany and for NLS Pharma in Basel, Switzerland.

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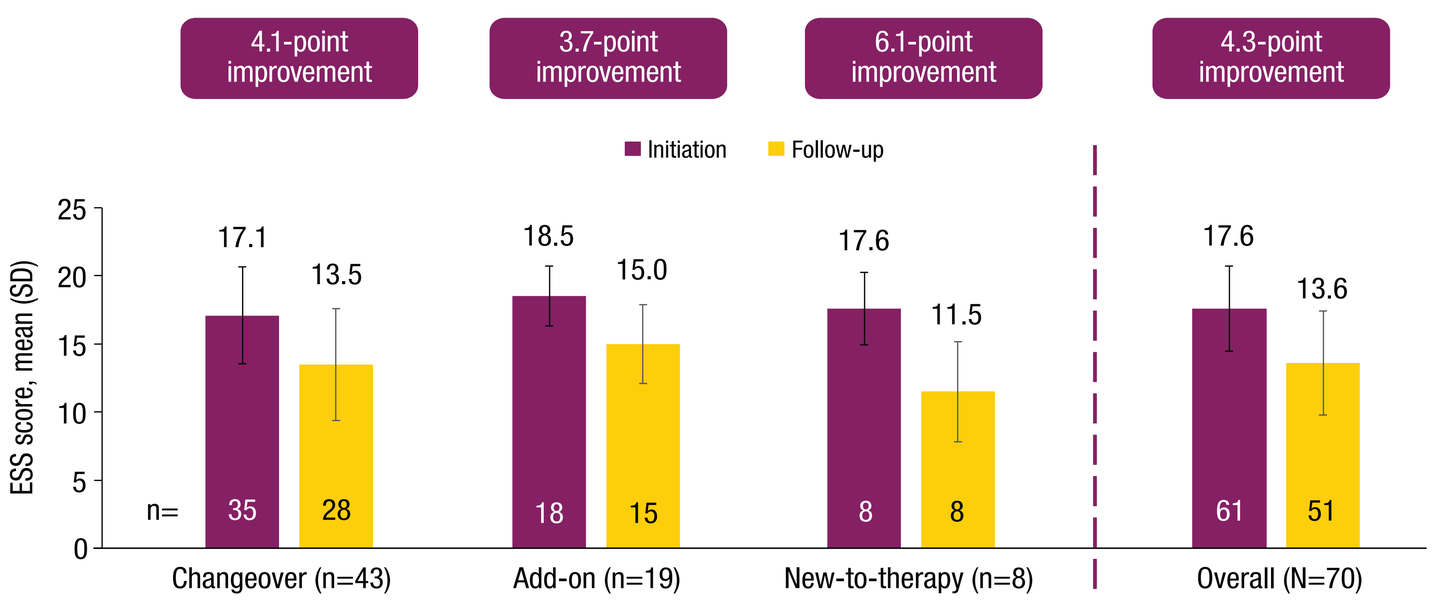
Results

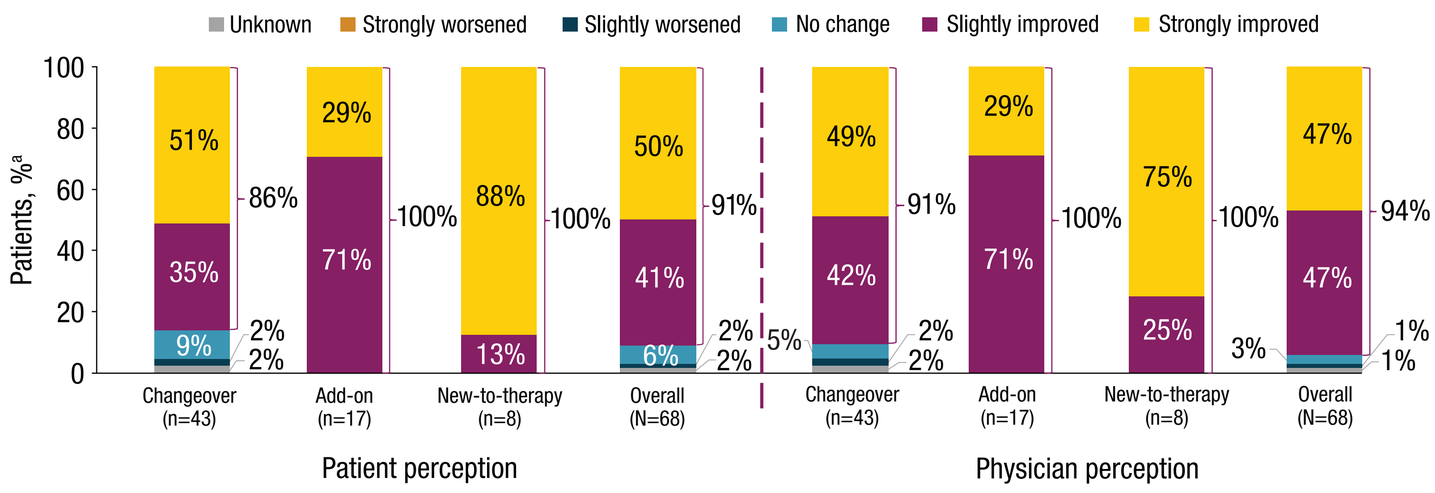
Figure 1. ESS scores[a] decreased following initiation of solriamfetol, indicating improvement of EDS



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

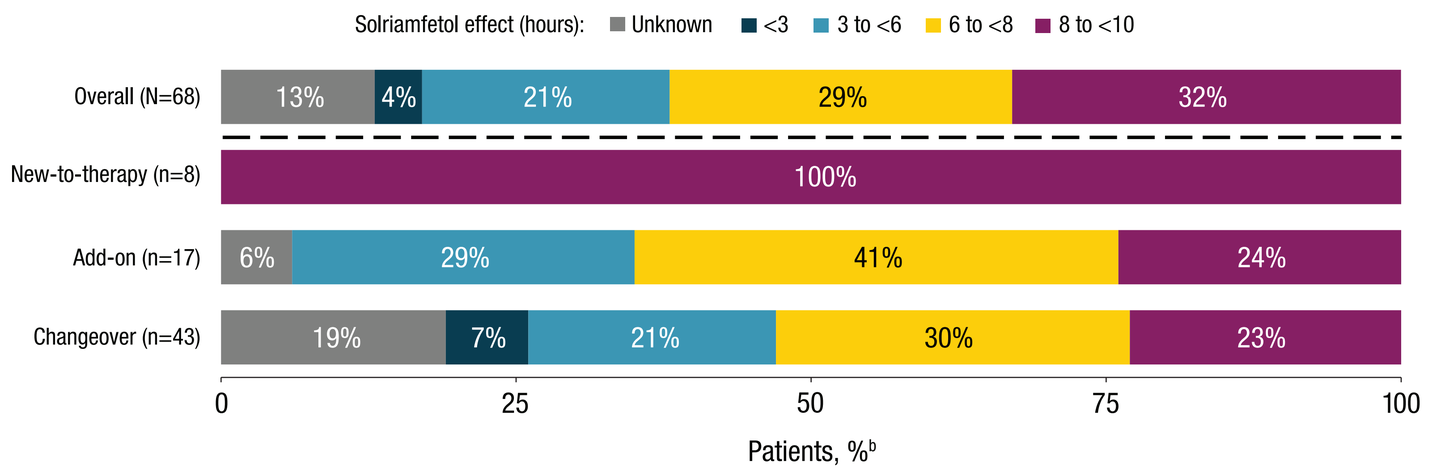
- Improvements in ESS scores were seen regardless of solriamfetol initiation strategy and were most pronounced in the new-to-therapy group

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



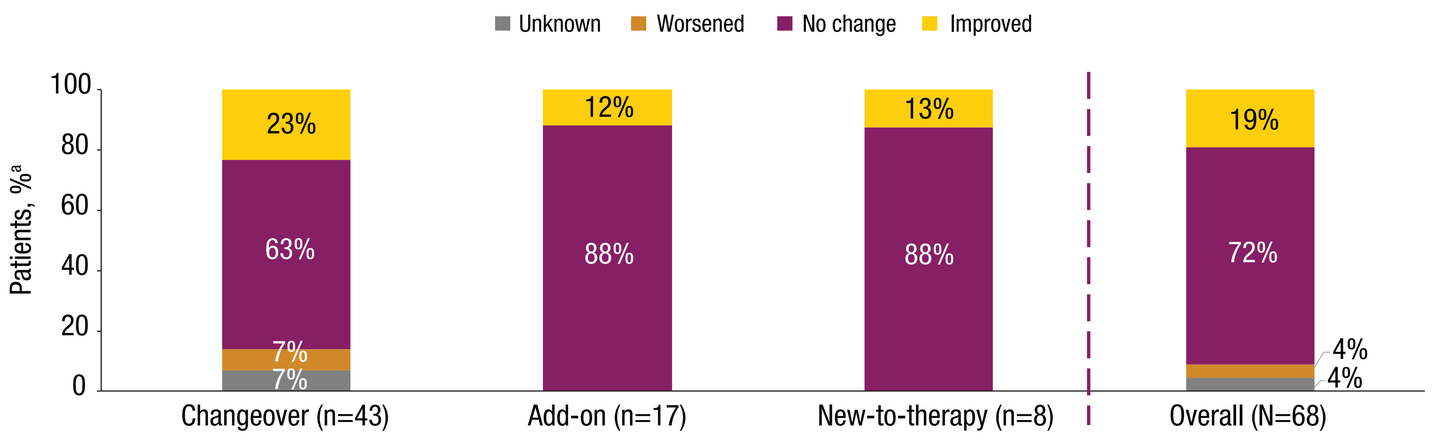
EDS, excessive daytime sleepiness.
[a]Percent totals may not equal 100% due to rounding.

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

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