ProDiGyA - Interim Analysis of a Real-world, Prospective, Non-interventional Study Evaluating Daridorexant in Patients with Insomnia Disorder

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Introduction

- **Chronic insomnia** affects ~6% of adults in Germany[1]
- **Daridorexant** is a dual orexin receptor antagonist, effective on both sleep and daytime functioning as demonstrated in large clinical trials in adults with chronic insomnia[2]
- **Real-world data** for daridorexant remain **limited**
- **ProDiGyA** evaluates effectiveness and safety in routine practice

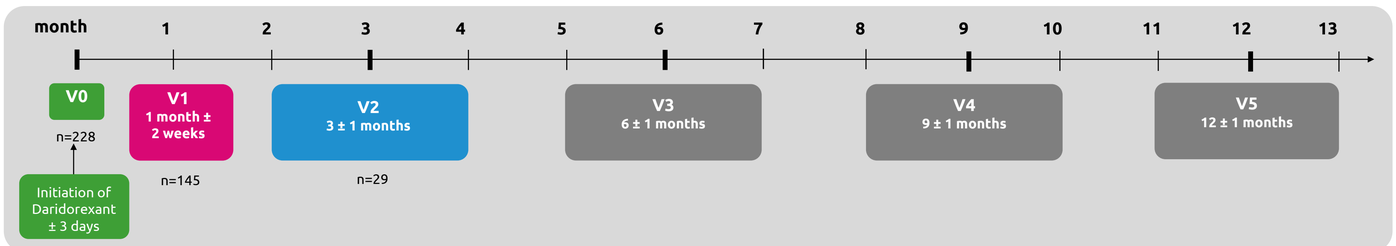
Study objective

To generate real-world evidence on the patient characteristics, treatment patterns, effectiveness and safety associated with daridorexant use in adults with chronic insomnia in Germany and Austria. The primary endpoint of this study is the maximum change in ISI score from baseline during the observation period of up to 12 months.

Methods

Interim analysis includes 228 patients with data available up to month 3

- Prospective, non-interventional, multicenter study in Germany and Austria
- Visit schedule:



- Daridorexant-naïve adults with chronic insomnia according to label[3]
- Interim analysis includes baseline (n=228), month 1 (n=145) and month 3 data (n=29).
- Data cut-off: 6 March 2026; only German sites included (28 sites).
- In total 800 patients to be enrolled, last-patient-out planned November 2027

Results

Table 1. Chronic insomnia rarely comes alone and often remains untreated

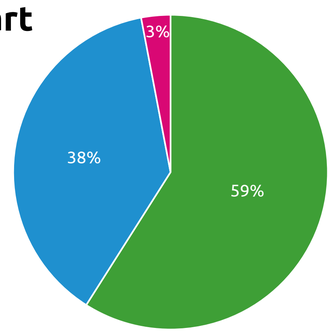
Characteristic	
Female, n(%)	126 (55%)
Mean age (SD)	54.0 (15.6)
Insomnia duration ≥ 1 year, n(%)	190 (83%)
Most common insomnia symptom*: difficulty staying asleep, n(%)	203 (89%)
≥ 1 comorbidity, n (%)	193 (85%)
Prior insomnia pharmacotherapy, n (%)	113 (50%)

Patients: n=228; sites: n=28; *Multiple answers possible

85% had ≥ 1 comorbidity: 45% depression, 20% RLS and 20% OSA

83% had chronic insomnia ≥ 1 year: 51% 1-4 year, 20% 5-10 years, 13% > 10 years

Figure 1. Pre-treated patients were switched to Daridorexant mainly via stop & start



n= 69 documented switch schemes

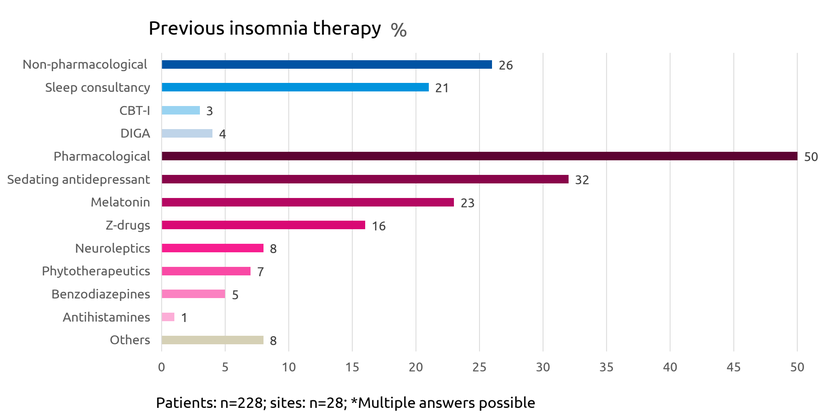
Table 2. No new safety issues were observed in this interim analysis

- Safety profile consistent with previous evidence
- No new safety issues were observed
- Low number of serious adverse events and AESIs were reported

Safety outcome	Patients, n(%)
Patients with ≥TEAE	38 (16.6)
Patients with ≥TEADR	26 (11.4)
Patients with ≥TESAE	2 (0.9)
Patients with ≥TEAESI	2 (0.9)

TAESI: Treatment-emergent adverse event of special interest; TE(S)AE: Treatment-emergent (serious) adverse event; TEADR: Treatment-emergent adverse drug reaction

Figure 2. Daridorexant is often used as first-line pharmaco-therapy



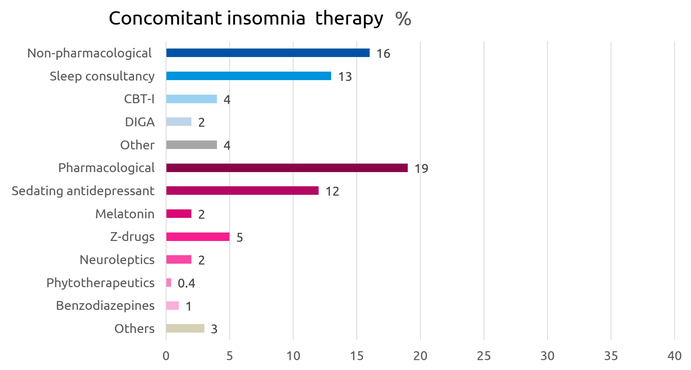
Patients: n=228; sites: n=28; *Multiple answers possible

50% were pharmacotherapy naïve

Dominant previous pharmacological therapy were sedating antidepressants

Only 3% had prior CBT-I

Figure 3. Daridorexant was mainly used as 50 mg monotherapy with high adherence



Patients: n=228; sites: n=28; *Multiple answers possible

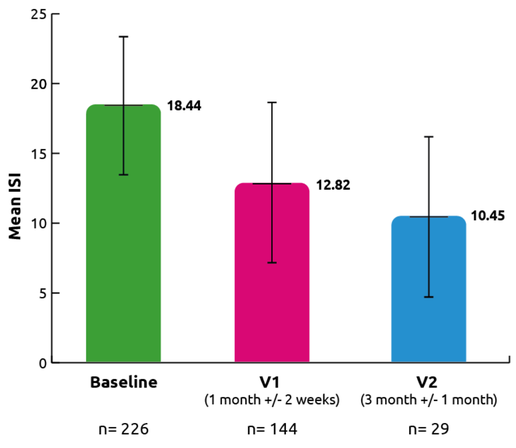
78% started with 50 mg Daridorexant

80% received Daridorexant monotherapy

Daily intake was reported by 87% at V1

10% discontinued treatment

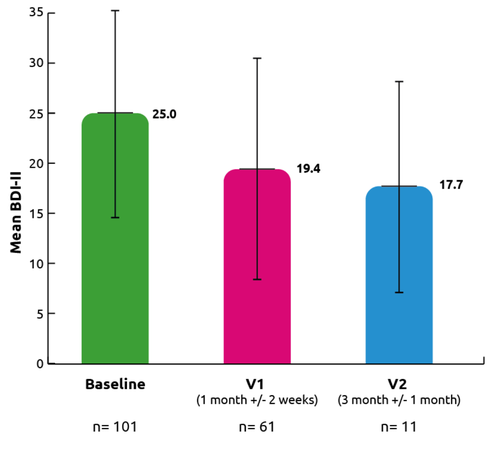
Figure 4. Insomnia severity improved early and continued to improve over time



Data are shown as mean with standard deviation

Primary endpoint (interim analysis): Maximum mean change from baseline in ISI: -6.35 points (SD 5.66)

Figure 5. Reductions in depressive symptom scores were observed over time in patients with comorbid depression



Data are shown for the subgroup with comorbid depression only.
Data are shown as mean with standard deviation

Conclusions

Patient population
Chronic insomnia rarely comes alone and often remains untreated

Treatment use
Daridorexant was mainly used as 50 mg monotherapy with high adherence

Effectiveness
Clinically meaningful improvements in insomnia severity were observed

Safety
No new safety issues were observed in this interim analysis

These interim data support the effectiveness of daridorexant in a broad real-world population treated in routine clinical practice with no new safety issues.

References

1. Schlack, R. et al. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2013;56(5-6):740-8.
2. Mignot et al. *Lancet Neurol.* 2022 Feb;21(2):125-139
3. SmPC Daridorexant, current version

Disclosures

The study was funded by Idorsia Pharmaceuticals Germany GmbH.
Conflict of interest (relevant for this poster): YW, JK, GH, SR, CF, MS, LB are investigators of the study and received speaker/consultant fees from Idorsia; EK, JKS are employees of Idorsia

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