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Idorsia highlights very low real-world abuse potential of DORA class for insomnia treatment at WSC 2025

- Analysis of the FAERS database shows that the real-world abuse potential of the DORA class is very low and markedly less than those seen for other scheduled and non-scheduled insomnia therapies

Allschwil, Switzerland – September 8, 2025

Idorsia Ltd (SIX: IDIA) presented real-world data from the FDA Adverse Event Reporting System (FAERS) at the World Sleep 2025, evaluating abuse-related adverse events for dual orexin receptor antagonists (DORAs) in comparison to other insomnia therapies. [View the poster.](#)

Insomnia disorder is a chronic medical condition that is estimated to affect approximately 12% of adults in the US. Many people with insomnia disorder rely on medication for long-term management. Yet concerns around the abuse potential of certain hypnotics can limit access to effective treatments for this chronic disorder.

The study, conducted in collaboration with the Medical College of Georgia and Johns Hopkins University, examined the real-world abuse potential of approved and off-label medications used for the treatment of insomnia, employing data from the FAERS database. In this study, the percentages represent the proportion of all reported adverse events in FAERS related to cases of abuse, dependence, and withdrawal. These rates were highest for benzodiazepines approved for any indication (27.7%), followed by benzodiazepines approved for insomnia (23.0%), trazodone – not indicated or recommended for insomnia but the most prescribed insomnia medication in the US – (22.7%), doxepin (22.3%), Z-drugs (15.3%), ramelteon (8.0%), and DORAs (2.6%). DORAs were associated with a low reporting odds ratio (ROR) value relative to Z-drugs (ROR = 0.150; 95% CI [0.131, 0.171]), and to trazodone (ROR = 0.092; 95% CI [0.081, 0.105]). Similar results were obtained using the proportional reporting ratios (PRR) to measure disproportionality. These findings reinforce the favorable safety profile of DORAs such as daridorexant, supporting their role as a modern treatment option with minimal abuse potential.

Professor William V. McCall, MD, Professor Emeritus of the Department of Psychiatry and Health Behavior, Medical College of Georgia, commented: “Abuse potential has long shaped the regulation of insomnia medications, with benzodiazepines and z-drugs carrying well-known risks. This study identified a very low rate of reported cases of abuse, misuse, overdose, dependence and withdrawal for the DORA class. This rate was much lower compared with other drugs for insomnia treatment. This observation included schedule IV drugs, but also and surprisingly non-scheduled drugs.”

Professor David Neubauer, MD, Associate Professor of Psychiatry at the Johns Hopkins University School of Medicine and senior faculty of the Johns Hopkins Sleep Disorders Center, added: “The DORA class had significantly lower odds of reporting for adverse events denoting drug abuse when compared with the scheduled drug zolpidem and the non-scheduled drug trazodone, both used as a reference. This suggests that categorization of DORAs as Schedule IV drugs may overstate their abuse potential.”

About the study

Data from 1 January 2014 to 31 March 2024 were retrieved from the FAERS database. The occurrence of unsolicited reported drug abuse events defined via Standardized Medical Dictionary for Regulatory Activities (MedDRA) Queries (SMQ) were compared. Drugs of interest included Schedule IV drugs (benzodiazepines, Z-drugs, dual orexin receptor antagonists [DORAs]) and non-scheduled drugs (trazodone, doxepin, ramelteon). Trazodone was selected for comparison as it is one of the most widely prescribed medications for insomnia in the US, despite it not being approved for this condition. Relevant reported adverse events denoting drug abuse were identified if they contained an event with any preferred terms (PTs) from the SMQ categories: drug abuse, dependence, and withdrawal (MedDRA v26.1), with a modified SMQ applied to exclude cases with PTs associated with overdose or suicidal behaviors. Only PT's with a frequency threshold > 1% in any drug group were reported. Trazodone and zolpidem were used as reference drugs for disproportionality as they are the most widely prescribed drugs for insomnia in the US. Reporting odds ratios (ROR) and proportional reporting ratios (PRR) were used as disproportionality measures.

About World Sleep 2025

World Sleep 2025 will be the 18th World Sleep Congress. The congress facilitates an international discussion forum and collaboration among sleep societies and sleep professionals. Sleep clinicians, technologists, trainees, educators, and scientists from around the world will meet to advance knowledge on sleep science, sleep in public health, sleep health and the sleep-wake disorders, their diagnosis and treatments.

World Sleep Society seeks to maximize learning both from formal presentations by the leading experts in their fields and from informal discussion groups emphasizing opportunities for networking and member participation.

Notes to the editor

About Dr. McCall

Dr. McCall is Professor Emeritus and also an active Professor of the Department of Psychiatry and Health Behavior at the Medical College of Georgia. He completed his medical degree and post-graduate psychiatric training at Duke University. He completed a Masters degree in Epidemiology from Wake Forest University. He is board certified in general psychiatry, geriatric psychiatry, and sleep disorders medicine. His research interests include depression, electroconvulsive therapy, quality of life, insomnia, and suicide. His research has received continuous federal support by the USA National Institute of Mental Health or similar federal institutes in Australia since 1995. He is the author of more than 500 publications, including more than 280 peer-reviewed journal articles. He is on the Editorial Boards of Sleep and the Journal of Clinical Sleep Medicine. Dr McCall serves as a consultant to Idorsia.

About Dr. Neubauer

Dr. Neubauer is Associate Professor of Psychiatry at the Johns Hopkins University School of Medicine and senior faculty of the Johns Hopkins Sleep Disorders Center. He is a Fellow of the American Academy of Sleep Medicine and Life Fellow of the American Psychiatric Association, as well as a member of the Sleep Research Society, European Sleep Research Society, and the World Sleep Society, where he serves on the International Scientific Committee. He has served on the Board of Directors and Executive Committee of the National Sleep Foundation. He is the author of the Understanding Sleeplessness: Perspective on Insomnia published by the Johns Hopkins University Press. He has written numerous journal articles and book chapters on sleep related topics. He coauthored the 2017 American Academy of Sleep Medicine "Clinical Practice Guidelines for the Pharmacologic Treatment of Chronic Insomnia in Adults" and the current Wolters Kluwer UpToDate section on Pharmacotherapy for Insomnia in Adults." Dr. Neubauer was appointed by the American Psychiatric Association as liaison to the National Sleep Foundation Sleep Time Recommendations project. Whenever possible he champions the importance of healthy sleep as a key component in the pursuit of wellness. Dr Neubauer serves as a consultant to Idorsia.



About Idorsia

The purpose of Idorsia is to challenge accepted medical paradigms, answering the questions that matter most. To achieve this, we will discover, develop, and commercialize transformative medicines – either with in-house capabilities or together with partners – and evolve Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech hub – Idorsia has a highly experienced team of dedicated professionals, covering all disciplines from bench to bedside; QUVIVIQ™ (daridorexant), a different kind of insomnia treatment with the potential to revolutionize this mounting public health concern; strong partners to maximize the value of our portfolio; a promising in-house development pipeline; and a specialized drug discovery engine focused on small-molecule drugs that can change the treatment paradigm for many patients. Idorsia is listed on the SIX Swiss Exchange (ticker symbol: IDIA).

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