



Media Release

September 22, 2025

Global expansion of Idorsia's QUVIVIQ continues as Simcere launches in China

Allschwil, Switzerland – September 22, 2025

Idorsia Ltd. (SIX: IDIA) announces that Simcere Pharmaceuticals Group Ltd (2096.HK, "Simcere") has launched **QUVIVIQ® (daridorexant)** in China. QUVIVIQ, Idorsia's dual orexin receptor antagonist, is indicated for the treatment of adult patients with insomnia characterized by difficulty falling asleep and/or maintaining sleep. Notably, QUVIVIQ has been approved without psychotropic drug control labeling, underscoring its differentiated clinical profile.

Insomnia is a major public health challenge in China. Existing treatment options such as benzodiazepines and non-benzodiazepines are often associated with next-day drowsiness, risk of dependence, withdrawal symptoms, and rebound insomnia upon discontinuation – leaving a significant unmet need for safer and effective alternatives.

Daridorexant, discovered by Idorsia, selectively blocks the binding of orexin neuropeptides to their receptors and regulates overactive wake signaling in insomnia disorder, in contrast to traditional hypnotics that broadly suppress brain activity. Through its targeted mechanism of action its equipotent antagonism of both orexin receptors and optimal pharmacokinetics (approximately 80% is eliminated within the first 8 hours of dosing), daridorexant promotes restorative sleep, throughout the entire night, reducing morning sleepiness and improving daytime functioning.

Srishti Gupta, MD, Chief Executive Officer of Idorsia, commented:

"Today marks an important milestone in making QUVIVIQ a truly global brand. Thanks to the close collaboration between Simcere and Idorsia, Chinese patients now have access to a novel therapy that addresses the root cause of insomnia without the limitations associated with older classes of treatments. This launch brings us one step closer to our vision of transforming sleep medicine worldwide."

Ren Jinsheng, Chairman and Chief Executive Officer of Simcere, commented:

"We are proud to introduce QUVIVIQ to patients in China. The positive results from both global and local clinical trials, coupled with its status as a regular prescription medication that is not subject to psychotropic drug control, position QUVIVIQ as a meaningful advancement in the treatment of chronic insomnia. Simcere is committed to ensuring rapid and broad access to this innovative therapy for the many patients in need."

As reported by Mignot E, et al. in the February 2022 issue of *The Lancet Neurology*, the global registration program demonstrated that 25mg and 50mg doses of daridorexant significantly improved sleep onset, sleep maintenance and self-reported total sleep time at months 1 and 3 compared to placebo. A major focus of the trials was to evaluate the impact of daridorexant on daytime functioning in patients with insomnia, as assessed by the IDSIQ. The sleepiness domain score of the IDSIQ was evaluated as a key secondary endpoint in both pivotal studies, and comparisons to placebo included control for multiplicity. Daridorexant 50 mg demonstrated a highly significant improvement in daytime functioning, as measured by the sleepiness domain at month 1 and month 3.

About the collaboration

In 2022, Idorsia and Simcere entered into an exclusive licensing agreement for QUVIVIQ in Greater China (Mainland China, Hong Kong, and Macau). Under the agreement, Simcere has the exclusive right to develop and commercialize QUVIVIQ in Greater China; Idorsia has to date received \$80M in milestone payments from Simcere, and remains eligible for additional commercial milestone payments, as well as tiered royalties ranging from low to high single digits on future net sales of QUVIVIQ.

About availability of daridorexant

Daridorexant is commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, UK, Canada, Austria, France, Sweden, Japan, Finland, Hong Kong, and China, and is approved throughout the EU.

Notes to the editor

About insomnia

Insomnia is defined as a combination of dissatisfaction with sleep and a significant negative impact on daytime functioning. Dissatisfaction with sleep refers to the difficulty to initiate and/or maintain sleep on at least three nights per week for at least three months, despite adequate opportunity to sleep.

Insomnia is a condition of overactive wake signaling and studies have shown that areas of the brain associated with wakefulness remain more active during sleep in patients with insomnia.

Insomnia as a disorder is quite different from a brief period of poor sleep, and it can take its toll on both physical and mental health. It is a persistent condition with a negative impact on daytime functioning. Idorsia's research has shown that poor-quality sleep can affect many aspects of daily life, including the ability to concentrate, mood, and energy levels.

The goals of managing insomnia are to improve sleep quality and quantity, as well as daytime functioning. Current recommended treatment of insomnia includes sleep hygiene recommendations, cognitive behavioral therapy and pharmacotherapy.

About Simcere

Simcere Pharmaceutical Group Limited is a pharmaceutical company driven by innovation and focusing on four therapeutic areas including Neuroscience, Oncology, Autoimmune Diseases and Anti-infection. We proactively explore areas with significant unmet needs, and our mission is Providing Today's Patients with Medicines of the Future. Our industry-leading capabilities and commitment to synergistic innovation have enabled various global strategic collaborations and we are seen as the partner of choice by industry peers, medical institutes, and research organizations across the globe. Simcere is listed on the Hong Kong Stock Exchange (ticker symbol: 02096)

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).

For further information, please contact:

Investor & Media Relations
Idorsia Pharmaceuticals Ltd, Hegenheimerweg 91, CH-4123 Allschwil
+41 58 844 10 10
investor.relations@idorsia.com - media.relations@idorsia.com - www.idorsia.com

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strategy, plans or intentions. Such statements include descriptions of the company's investment and research and development programs, business development activities and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company's existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.