Media Release
June 23, 2025

Ad hoc announcement pursuant to Art. 53 LR

Idorsia's QUVIVIQ expands into China as Simcere receives NDA approval – Idorsia and Simcere update their licensing agreement

- Idorsia to receive USD 50 million (an additional USD 30 million) approval milestone payment in return for a reduction in Simcere potential sales milestones and tiered royalty payments.

Allschwil, Switzerland – June 23, 2025
Idorsia Ltd. (SIX: IDIA) today announced that Simcere Pharmaceuticals Group Ltd (2096.HK, "Simcere") has received approval for QUVIVIQ® (daridorexant) from the Chinese National Medical Products Administration for the treatment of adult patients with insomnia characterized by difficulty falling asleep and/or maintaining sleep, with no psychotropic drug control labeling.

In addition, Idorsia has reached an agreement with Simcere to update the terms of the licensing agreement for QUVIVIQ in China.

André C. Muller, Chief Executive Officer of Idorsia, commented:
"I want to congratulate everyone at Simcere and the team that supported them from Idorsia. Together they have been able to take our drug from pre-IND, through to local Phase 1 and Phase 3, and then filing, resulting in this approval at an incredible pace of 2.5 years since the signing of the license agreement. I'm very happy as QUVIVIQ becomes a truly global brand, now available to millions of patients in North America, Europe, Japan and China, and we aim to continue this expansion to new territories."

Ren Jinsheng, Chairman and Chief Executive Officer of Simcere, commented:
"I echo the congratulations to both teams that have worked diligently together to get this approval. Importantly, the clinical results achieved in both the global and local trials have enabled QUVIVIQ to be approved with no psychotropic drug control labeling in China. We are committed to make QUVIVIQ available to a great number of patients suffering with chronic insomnia."

Under the updated terms of the agreement, Idorsia will receive an approval milestone payment of USD 50 million, commercial milestone payments of up to USD 93 million, and low- to high-single-digit tiered royalties on future net sales.

Arno Groenewoud, Chief Financial Officer of Idorsia, commented:
"The updated agreement with Simcere allows both companies to streamline the collaboration. The increased milestone payment of USD 50 million in 2025 underscores Simcere's commitment and confidence in the potential of QUVIVIQ, following its significant investment in sealing this approval for Chinese patients and the corresponding launch preparations."

In 2022, Idorsia and Simcere entered into an exclusive licensing agreement for Idorsia's QUVIVIQ in China. Under the agreement, Simcere has an exclusive right to develop and commercialize QUVIVIQ in the Greater China region (Mainland China, Hong Kong, and Macau).

Notes to the editor

About Idorsia

Idorsia Ltd is reaching out for more – we have more passion for science, we see more opportunities, and we want to help more patients.

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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