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Simcere Pharmaceutical Group Limited

先聲藥業集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 2096)

**DISCLOSEABLE TRANSACTION
AMENDMENT TO THE LICENSE AGREEMENT WITH IDORSIA**

AMENDMENT TO THE LICENSE AGREEMENT

Reference is made to the voluntary announcement of the Company dated November 16, 2022 in relation to, among others, the License Agreement entered into between Hainan Simcere (an indirectly wholly-owned subsidiary of the Company) as the Licensee and Idorsia as the Licensor.

Pursuant to the License Agreement, (i) the Licensee has been granted (a) an exclusive license for the research, development, manufacture and commercialization of the Licensed Products in the Field in the Territory, as well as for the supply of the Licensed Products to the Licensor in the Retained Territory, and (b) a non-exclusive license for the supply of the Licensed Compound to the Licensor in the Retained Territory, with no right to commercialize the Licensed Compound within or outside of the Territory; and (ii) Idorsia is entitled to receive an upfront payment and a regulatory milestone payment upon approval by the NMPA, as well as sales milestone payments and royalties based upon future commercial sales.

On June 22, 2025, Hainan Simcere entered into the Amendment Agreement with Idorsia to amend certain terms of the License Agreement, which include, among other things, (i) revised payment and royalty structures featuring higher regulatory milestone payment but reduced ongoing commercial milestone payments and royalty rates, and removal of margin adjustment provision; and (ii) additional independent manufacturing rights providing operational flexibility for the Licensee, with effect from June 22, 2025.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio in respect of the transaction contemplated under the License Agreement (as amended by the Amendment Agreement) exceeds 5% but is less than 25%, the transaction contemplated under the License Agreement (as amended by the Amendment Agreement) constitutes a discloseable transaction of the Company and is therefore subject to the reporting and announcement requirements but is exempt from the Shareholders' approval requirement under Chapter 14 of the Listing Rules.

INTRODUCTION

Reference is made to the voluntary announcement of the Company dated November 16, 2022 in relation to, among others, the License Agreement entered into between Hainan Simcere (an indirectly wholly-owned subsidiary of the Company) as the Licensee and Idorsia as the Licensor.

Pursuant to the License Agreement, (i) the Licensee has been granted (a) an exclusive license for the research, development, manufacture and commercialization of the Licensed Products in the Field in the Territory, as well as for the supply of the Licensed Products to the Licensor in the Retained Territory, and (b) a non-exclusive license for the supply of the Licensed Compound to the Licensor in the Retained Territory, with no right to commercialize the Licensed Compound within or outside of the Territory; and (ii) Idorsia is entitled to receive an upfront payment and a regulatory milestone payment upon approval by the NMPA, as well as sales milestone payments and royalties based upon future commercial sales.

The Board hereby announces that, on June 22, 2025, Hainan Simcere entered into the Amendment Agreement with Idorsia to amend certain terms of the License Agreement, which include, among other things, (i) revised payment and royalty structures featuring higher regulatory milestone payment but reduced ongoing commercial milestone payments and royalty rates, and removal of margin adjustment provision; and (ii) additional independent manufacturing rights providing operational flexibility for the Licensee, with effect from June 22, 2025.

PRINCIPAL TERMS OF THE LICENSE AGREEMENT (AS AMENDED BY THE AMENDMENT AGREEMENT)

The principal terms of the License Agreement (as amended by the Amendment Agreement) are set out as follows:

Date of Amendment Agreement

June 22, 2025

Parties

- (i) Hainan Simcere as the Licensee; and
- (ii) Idorsia as the Licensor

To the best of the Directors' knowledge, information and belief, having made all reasonable enquiries, as at the date of this announcement, the Licensor and its ultimate beneficial owners are third parties independent of, and not connected with, the Company and its connected persons (as defined in the Listing Rules).

Term

Unless earlier terminated pursuant to the terms of the License Agreement, the License Agreement shall commence on November 15, 2022 and expire on a Licensed Product-by-Licensed Product, indication-by-indication, and Region-by-Region basis upon expiry of the Royalty Term for a particular Licensed Product for a particular indication in a particular Region within the Territory.

Grant of license

Pursuant to the License Agreement (as amended by the Amendment Agreement), the Licensee has been granted (i) an exclusive license for the research, development, manufacture and commercialization of the Licensed Products in the Field in the Territory, as well as for the supply of the Licensed Products to the Licensors in the Retained Territory; and (ii) a non-exclusive license for the supply of the Licensed Compound to the Licensors in the Retained Territory, with no right to commercialize the Licensed Compound within or outside of the Territory.

Independent manufacturing right

Pursuant to the Amendment Agreement, the Licensee shall have the right to independently develop and manufacture Licensed Compounds using its own technology, facilities, and processes. If the Licensors request technology transfer of manufacturing improvements or proprietary processes developed by the Licensee, the Licensee shall provide such transfer, and the parties will negotiate in good faith to establish payment terms covering the Licensee's actual costs for the technology transfer.

Consideration

Pursuant to the License Agreement (as amended by the Amendment Agreement), the Licensee shall pay to the Licensors (with the amendments underlined below):

- (i) an upfront payment of US\$30 million within thirty (30) business days after full execution of the License Agreement and the Licensee's receipt of an invoice issued by the Licensors for such payment. The aforementioned upfront payment has been fully settled in 2022;
- (ii) an additional amendment execution payment of US\$10 million within thirty (30) business days after full execution of the Amendment Agreement and upon the Licensee's receipt of an invoice issued by the Licensors for such payment;

- (iii) a regulatory milestone payment upon approval by the NMPA of the first Licensed Product to be marketed in the Field in the Territory and within forty-five (45) business days of the Licensee's receipt of an invoice issued by the Licensor for such payment, the amount of which has been increased from US\$20 million to US\$40 million;
- (iv) sales milestone payments on a Licensed Product-by-Licensed Product basis, each due and payable upon occurrence of certain sales milestone events (i.e. Net Sales of the Licensed Product in all indications reaching or exceeding certain amount for the first time in any one calendar year) and within forty-five (45) business days of the Licensee's receipt of an invoice issued by the Licensor for such payment, the amount of which has been reduced from up to US\$215 million to up to US\$93 million;
- (v) royalties during the Royalty Term on a Licensed Product-by-Licensed Product basis, calculated based on the applicable tiered royalty rates applied to the Net Sales of each Licensed Product in a calendar year. The royalty rates were originally set at the range from 11% to 17%. Pursuant to the Amendment Agreement, the royalty structure has been revised into two phases and the royalty rates are also reduced to the revised range of 1%-8%; and
- (vi) escalating per-tablet payments ranging from CHF0.050 to CHF0.080 based on cumulative number of tablets supplied by the Licensee, which has been removed in its entirety in the Amendment Agreement.

The payments under the License Agreement (as amended by the Amendment Agreement) will be settled by the Company through internal resources.

Basis of determination of the payments under the License Agreement (as amended by the Amendment Agreement)

The payments under the License Agreement (as amended by the Amendment Agreement) was determined after arms' length negotiations between the Licensor and the Licensee with reference to various factors, including but not limited to: (i) the development status of QUVIVIQ®; (ii) market prospects in Greater China including addressable patient population, unmet medical needs, and probability of commercial success; and (iii) comparable licensing transactions for similar pharmaceutical assets.

REASONS FOR AND BENEFITS OF ENTERING INTO THE LICENSE AGREEMENT (AS AMENDED BY THE AMENDMENT AGREEMENT)

The Company believes that the research, development, manufacture and/or commercialization of the Licensed Products and Licensed Compound in the Field in the Territory will broaden the portfolio of the Group's proprietary products, strengthen its research and development capabilities and deepen its strategic cooperation with pharmaceutical companies, and is expected to bring additional revenue stream to the Group in the future and contribute to the long-term growth and success of the Group.

In addition, the Company recognizes that QUVIVIQ® represents a groundbreaking innovation in global sleep medicine, with immense market potential in China. As such, Hainan Simcere and Idorsia have entered into the Amendment Agreement to adjust the existing collaboration terms. The Company believes that the amendments to the License Agreement will effectively advance the commercialization of QUVIVIQ® and enhance patient access to this innovative insomnia treatment.

In view of the above, the Directors (including the independent non-executive Directors) are of the view that the terms of the License Agreement (as amended by the Amendment Agreement) are fair and reasonable and the transactions contemplated thereunder are in the interests of the Company and its Shareholders as a whole.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio in respect of the transaction contemplated under the License Agreement (as amended by the Amendment Agreement) exceeds 5% but is less than 25%, the transaction contemplated under the License Agreement (as amended by the Amendment Agreement) constitutes a discloseable transaction of the Company and is therefore subject to the reporting and announcement requirements but is exempt from the Shareholders' approval requirement under Chapter 14 of the Listing Rules.

GENERAL INFORMATION ON THE PARTIES

Information on the Company

The Company is an innovation and R&D-driven pharmaceutical company and has established a “State Key Laboratory of Neurology and Oncology Drug Development”. The Company focuses on the therapeutic areas of neuroscience, anti-oncology, autoimmune and anti-infection, with forward-looking layout of disease areas that may have significant clinical needs in the future, aiming to achieve the mission of “for patients, for life”. Driven by its in-house R&D efforts and synergistic innovation, the Company has established strategic cooperation partnerships with many innovative companies and research institutes.

Information on Hainan Simcere

Hainan Simcere is a limited liability company established in the PRC on April 28, 1993 and is principally engaged in manufacturing and sales of pharmaceutical products. As at the date of this announcement, Hainan Simcere is an indirectly wholly-owned subsidiary of the Company.

Information on Idorsia

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a 25-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, and commercial operations in Europe and North America – the ideal constellation for bringing innovative medicines to patients. Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 750 highly qualified specialists dedicated to realizing its ambitious targets.

INFORMATION ON QUVIVIQ®

QUVIVIQ® is a dual orexin receptor antagonist (“**DORA**”). Unlike traditional sedative-hypnotic drugs that promote sleep by sedating the brain, QUVIVIQ® works by blocking the binding of wake-promoting orexin neuropeptides (orexin A and orexin B) to their receptors. As a result, QUVIVIQ® reduces wake drive and facilitates the onset of sleep, decreases wake time after sleep onset, and extends total sleep duration, without altering sleep architecture. Clinical study results have shown that QUVIVIQ® has a favorable safety and tolerability profile, with no evidence of rebound insomnia, withdrawal symptoms, or drug abuse. In addition to improving nighttime sleep in adults with insomnia disorder, QUVIVIQ® also enhances daytime functioning. It is the only DORA insomnia medication approved by the European Medicines Agency for improving daytime functioning. The Guidelines for the Diagnosis and Treatment of Insomnia Disorders in the PRC (2nd Edition), published in 2025, strongly recommend QUVIVIQ® with Grade A evidence. Previously, QUVIVIQ® has been approved for marketing in 11 countries including the United States, the United Kingdom, Switzerland, Japan and Canada, as well as in the Hong Kong.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions have the following meanings:

“Additional Indications”	any indications other than the Initial Indication for the diagnosis, treatment, prevention, or palliation of sleep disorder in humans, including but not limited to insomnia in pediatric patient, insomnia associated with nocturia, insomnia associated with substance use disorder, and obstructive sleep apnea, each as separately agreed by the Licensor in writing in advance during the term of the License Agreement
“Amendment Agreement”	the amendment agreement to the License Agreement entered into between Hainan Simcere as the Licensee and Idorsia as the Licensor on June 22, 2025

“Board”	the board of Directors
“CHF”	Swiss Franc, the lawfully currency of the Swiss
“Company”	Simcere Pharmaceutical Group Limited (先聲藥業集團有限公司) (Stock Code: 2096), a company incorporated under the laws of Hong Kong with limited liability, the shares of which are listed on the Main Board of the Stock Exchange
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Director(s)”	the director(s) of the Company
“Field”	the Initial Indication and any Additional Indications
“First Commercial Sale”	on a Licensed Product-by-Licensed Product and indication-by-indication basis, the first sale or other disposition for the value of a Licensed Product by the Licensee or any of its affiliates or sublicensees to an independent or unaffiliated third party which is not a sublicensee after regulatory approval for such Licensed Product has been obtained in the Field in the Territory
“Group”	the Company and its subsidiaries
“Hainan Sale”	any sale(s) related to any imported Licensed Product that has not obtained a marketing authorization in Mainland China and that is urgently needed for clinical use or related to any Licensed Product associated with any other similar special treatment provision(s) according to the applicable laws in the Hainan Boao Lecheng International Medical Tourism Pilot Zone

“Hainan Simcere” or “Licensee”	Hainan Simcere Pharmaceutical Co., Ltd. (海南先聲藥業有限公司) (formerly known as Sanya Haifu Pharmaceutical Co., Ltd. (三亞海富製藥有限公司), Hainan Haifu Pharmaceutical Co., Ltd. (海南海富製藥有限公司) and Simcere Pharmaceutical Co., Ltd. (先聲藥業有限公司)), a limited liability company established in the PRC on April 28, 1993 and an indirectly wholly-owned subsidiary of the Company
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Idorsia” or “Licensor”	Idorsia Pharmaceuticals Ltd., a company incorporated under the laws of Switzerland with limited liability, the shares of which are listed on the SIX Swiss Exchange (ticker symbol: IDIA)
“Initial Indication”	the diagnosis, treatment, prevention, or palliation of insomnia in human adult patients
“License Agreement”	the license agreement entered into between Hainan Simcere as the Licensee and Idorsia as the Licensor on November 16, 2022
“Licensed Compound”	daridorexant hydrochloride a dual orexin receptor antagonist
“Licensed Products”	any pharmaceutical product containing the Licensed Compound as an active pharmaceutical ingredient in any formulation or dosage form and for any mode of administration
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operates in parallel with the GEM of the Stock Exchange

<p>“Net Sales”</p>	<p>the gross amounts billed, received or invoiced for sales of the Licensed Products by or for the benefit of the Licensee, its affiliates, or sublicensees to independent or unaffiliated third parties which are not sublicensees in bona fide, arms-length transactions, after deducting the following items, in each case, actually granted and deducted with respect to the Licensed Products: (a) customary and reasonable trade, quantity, and cash discounts in connection with the sale of Licensed Products that are not otherwise attributable to other products of Licensee, its affiliates, or sublicensees; (b) customary and reasonable price reductions, refunds, credits or rebates, retroactive or otherwise, in cash or trade, where the foregoing are actually allowed or taken in connection with the sale of Licensed Products that are not otherwise attributable to other products of Licensee, its affiliates, or sublicensees, either on the invoice or the separate credit note; (c) sales tax (such as value-added tax), excise tax, tariffs, duties, and other taxes and government charges, if any, in each case directly related to the sale paid by the Licensee, its affiliates, or sublicensees and cannot be credited by the Licensee, its affiliates, or sublicensees as their input value-added tax under the applicable laws; and (d) amounts deducted, repaid or credited to independent or unaffiliated third parties which are not sublicensees by reason of defects, recalls, or rejections of Licensed Products (for quality issues only) and not in excess of the selling price of such Licensed Products on account of such defects, recalls, returns, or rejections of such Licensed Products</p>
<p>“NMPA”</p>	<p>the National Medical Products Administration of the PRC</p>
<p>“R&D”</p>	<p>research and development</p>

“Retained Territory”	any country or regulatory jurisdiction of the world other than the Territory
“RMB”	Renminbi, the lawful currency of the PRC
“Royalty Term”	commencing upon the First Commercial Sale of a Licensed Product in the Field and in each Region in the Territory (or the Hainan Sale in Mainland China, if the Hainan Sale takes place before the First Commercial Sale in Mainland China), and expiring on a Licensed Product-by-Licensed Product, Region-by-Region and indication-by-indication basis within the Territory, on the later of (i) twelve (12) years after the First Commercial Sale of the applicable Licensed Product in a Region in the Territory, (ii) the expiration or the nullification of the last to expire Valid Claim of the Licensor’s patents that covers the composition of matter (including crystalline forms) of the Licensed Product in such Region in the Territory, where the make, use, sale, or offer to sell of the applicable Licensed Product would be covered by such Valid Claim, and (iii) the expiry of any exclusive marketing rights or data exclusivity rights conferred by applicable laws or any regulatory authority with respect to a Licensed Product, on an indication-by-indication basis, other than patents in a specific Region in the Territory
“Shareholder(s)”	holder(s) of the share(s) of the Company
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Territory”	Mainland China, Hong Kong and Macau Special Administrative Region, each of which may be referred to as a “Region”
“US\$”	U.S. dollars, the lawful currency of the United States of America

“Valid Claim”

a claim in (a) an issued and unexpired patent which has not been permanently revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be or has been taken within the time allowed for appeal, and which has not been disclaimed, donated to the public or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) an issued and unexpired supplementary protection certificate or equivalent instrument, or (c) a pending patent application which was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, in each case within the licensed patents

“%”

per cent

By order of the Board
Simcere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and Chief Executive Officer

Hong Kong, June 23, 2025

As at the date of this announcement, the Board comprises Mr. REN Jinsheng as the Chairman and executive Director; Mr. TANG Renhong, Mr. WAN Yushan and Ms. WANG Xi as the executive Directors; Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.