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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)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023

FINANCIAL HIGHLIGHTS

For the year ended December 31, 2023:

- Revenue of the Group was approximately RMB6,608 million, representing an increase of approximately 4.5% as compared to RMB6,324 million for 2022. Of which, revenue from the sales and promotion service of drugs amounted to RMB6,567 million, license income amounted to RMB28 million and research service income amounted to RMB13 million.

- Revenue from the innovative pharmaceutical business was approximately RMB4,756 million, accounting for 72.0% of the total revenue and representing an increase of approximately 15.2% as compared to RMB4,128 million for 2022.

- Revenue of the Group was mainly derived from the therapeutic areas where its businesses are focused. Of which, revenue from the field of nervous system was approximately RMB1,969 million, accounting for 29.8% of the total revenue and representing a decrease of approximately 13.1% as compared to 2022. Revenue from the field of oncology was approximately RMB1,576 million, accounting for 23.9% of the total revenue and representing an increase of approximately 10.2% as compared to 2022. Revenue from the field of autoimmune was approximately RMB1,415 million, accounting for 21.4% of the total revenue and representing an increase of approximately 10.5% as compared to 2022. Revenue from other fields was approximately RMB1,648 million, accounting for 24.9% of the total revenue and representing an increase of approximately 22.3% as compared to 2022.

- Research and development costs amounted to approximately RMB1,563 million, representing a decrease of approximately RMB165 million or approximately 9.6% as compared to RMB1,728 million for 2022. The research and development costs to revenue ratio[2] was approximately 23.7% (approximately 27.3% for 2022).

- Profit for the year attributable to equity shareholders of the Company was approximately RMB715 million, representing a decrease of approximately RMB216 million or approximately 23.2% as compared to RMB931 million for 2022.

- Basic earnings per share was approximately RMB0.27, representing a decrease of approximately 25.0% as compared to RMB0.36 for 2022.

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[1] All comparative information in this announcement has been adjusted according to the restated comprehensive financial information as of December 31, 2022. In November 2023, the Group completed the acquisition of Nanjing Jiayuantang Biological Technology Co., Ltd., and such acquisition was regarded as a business combination under common control by the Group in accordance with the principles of merger accounting as set out in Accounting Guideline 5 "Merger Accounting for Common Control Combinations" issued by the Hong Kong Institute of Certified Public Accountants. The financial information of the Group for the year ended December 31, 2022 was restated accordingly to comply with the relevant accounting standards.

[2] Research and development costs divided by revenue

The board (the "**Board**") of directors (the "**Directors**") of Simcere Pharmaceutical Group Limited (the "**Company**") is pleased to announce the consolidated financial results of the Company together with its subsidiaries (collectively the "**Group**") for the year ended December 31, 2023 (the "**Reporting Period**"), together with the comparative figures for 2022. The consolidated financial statements for the Reporting Period have been reviewed by the audit committee of the Company (the "**Audit Committee**") and audited by KPMG, the Company's auditor.

KEY MILESTONES

As of the date of this announcement, the Group has achieved following key milestones and achievements:

COMMERCIALIZATION

The Group devotes to establishing its product portfolios and brand value with a focus on nervous system, autoimmune, oncology and anti-infection, and its innovative drugs that has entered the commercialization stage increased to six. The innovative pharmaceutical business experienced continuous growth and its revenue hit a record high. For the year ended December 31, 2023, the proportion of revenue from innovative pharmaceuticals of the Group increased to 72.0%.

- The product portfolio of nervous system products has been enriching continuously and the penetration rate of Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) among patients has been increasing. During the Reporting Period, Sanbexin® has benefited approximately 1.07 million patients and covered approximately 5,000 medical institutions. The new drug application ("**NDA**") of Sanbexin® sublingual tablets was accepted on June 28, 2023. Based on the positive results of a number of clinical trials, such as TASTE, TASTE II and TASTE-SL, products of Sanbexin® series are consolidating the evidences for the management of the whole course of stroke continuously and exploring new indications and overseas markets proactively.

- The product portfolio of oncology products is clinical value-oriented, and it continues to accelerate the layout of lung cancer, gastrointestinal tumors and gynecological tumors constantly. During the Reporting Period, COSELA® (Trilaciclib Hydrochloride for Injection) was made commercially available in China, and was approved to change from conditional approval to regular approval on October 27, 2023. Endostar® (Recombinant Human Endostatin Injection), an anti-angiogenesis drug with low bleeding risk, and ENWEIDA® (Envafolimab Injection), the first PD-(L)1 antibody drug to be administered by subcutaneous injection in the world, further verified commercialization capacity of the Group leveraging on differentiated advantages, which resulted in the continuous increase in the Group's market share.

- In the field of autoimmune, Iremod® (Iguratimod Tablets) continued to benefit the patients with rheumatoid arthritis in China and recorded a year-on-year increase of approximately 21%, which further consolidated its leading position in the traditional DMARDs sector.

- On January 28, 2023, XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)), the first domestic 3CL anti-SARS-CoV-2 innovative drug, was conditionally approved for marketing. In December 2023, XIANNUOXIN® was officially included in the New National Reimbursement Drug List (the "**NRDL**"). In February 2024, the supplemental application of transiting to regular approval of XIANNUOXIN® was accepted by the National Medical Products Administration (the "**NMPA**"). As of the date of this announcement, XIANNUOXIN® has covered 31 provinces, 306 cities and over 3,800 hospitals nationwide, and has benefited 670,000 patients.

RESEARCH AND DEVELOPMENT

The Group pays high attention and commits to the research and development of innovative pharmaceuticals, focusing on higher efficiency and adhering to differentiation. In the focused therapeutic areas, the Group has established a pipeline of innovative products with over 60 types of new drugs and is initiating registrational clinical studies for 15 innovative drugs. The efficient clinical operation and registration teams continuously facilitated the global research and development of product pipelines under research, which expedited the achievement of innovation value.

- The Group's research and development pipelines gradually entered the critical harvest period, which provided growth momentum for the sustainable development of the Company. As of the date of this announcement, three new drug molecules were under the NDA or phase III clinical study stage[1]: Sanbexin® sublingual tablets, ENZESHU (Suvemcitug for injection) and Daridorecant hydrochloride tablets. Two new indications of marketed products were developed: COSELA®'s triple-negative breast cancer and Endostar®'s malignant thoracoabdominal effusions.

- The Group expedited the promotion of its in-house pipelines to enter the clinical stage and various types of products entered the critical period of POC data. For the year ended December 31, 2023, the Group has added seven PCC molecules[2], three INDs of new molecules[3], six new indications/combinations entered the clinical stage[4] and completed six FIHs[5].

- The research and development of six innovative drugs is being simultaneously conducted in the U.S. and China, namely COSELA®, Sanbexin® sublingual tablets, SIM0235 (humanized anti-TNFR2 monoclonal antibody), SIM0237 (anti-PD-L1/IL-15 bispecific antibody), SIM0501 (USP1 small-molecule inhibitor) and SIM0500 (humanized GPRC5D-BCMA-CD3 tri-specific antibody).

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1 Excluding products with commercial rights, namely ENLITUO, ADC189 and LNK01001.

2 A total of seven new pre-clinical candidate compounds ("**PCC**"), namely SIM0500, SIM0501, SIM0505, SIM0508, SIM0810, SIM0391 and SIM0682.

3 A total of three INDs of additional new molecules were approved, namely Daridorexant (insomnia, July 20), SIM0278 (moderate-to-severe atopic dermatitis, July 27) and SIM0501 (solid tumors, December 2, the United States).

4 Six additional new indications/combinations entered the clinical stage, namely SIM0270 (in combination with SERD, January 28), SIM0235 (in combination with TNFR2, April 10), Sanbexin® (ICH, April 27), SIM0348 (in combination with TIGIT/PVRIG, October 12), SIM0237 (NMIBC, October 15) and Sanbexin® sublingual tablets (PSCI, November 28).

5 Six studies completed First-in-Human ("**FIH**") (including first populations and new indications), namely SIM0237 (solid tumors, March 8), SIM0348 (solid tumors, March 30), Sanbexin® (ICH, July 3), SIM0278 (healthy population, August 26), Sanbexin® sublingual tablets (healthy population in the United States, September 6) and Daridorexant (healthy population in China, November 30).

The Group has been expediting the development schedules of multiple innovative drugs under pivotal clinical trials. As of the date of this announcement, one phase III study achieved key data readout and has met the primary endpoints and two phase III data have been published in well-known academic journals.

- On January 3, 2024, the phase III clinical trial of ENZESHU (Suvemcitug for injection) combined with chemotherapy in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (the "**SCORES Study**") has met the primary endpoint. Based on the positive results of the study, the Group submitted the new drug application of ENZESHU to the NMPA on March 11, 2024 and it was accepted on March 15, 2024. ENZESHU is expected to become the first anti-VEGF monoclonal antibody applicable to PROC in China, which add another blockbuster drug to the portfolio of oncology drugs.

- On January 18, 2024, the New England Journal of Medicine published the complete data of XIANNUOXIN® for phase II/III clinical trials. The results showed that, for adult patients with mild-to-moderate new coronavirus infection ("**COVID-19**") in China, XIANNUOXIN® could accelerate recovery from symptoms, shorten the duration of the disease cause, reduce viral load rapidly and significantly and demonstrate good safety and tolerance.

- On February 19, 2024, the Journal of American Medical Association • Neurology (JAMA NEUROLOGY) published the key results of the phase III clinical study of Sanbexin® sublingual tablets used for the treatment of acute ischemic stroke ("**AIS**") (the TASTE-SL Study). The results showed that the Sanbexin® sublingual tablets group showed a significantly higher proportion of patients experiencing good functional outcomes (mRS score 0~1) on day 90 after randomization, compared with the placebo group (64.4% vs. 54.7%).

MANUFACTURING

The Group improves its production capacity and efficiency continuously, so as to adapt to the development strategy of "Innovation 2.0" and provide solid security for global supply chains.

- COSELA® achieved localization successfully: On December 20, 2023, Hainan Simcere Pharmaceutical Co., Ltd. (海南先聲藥業有限公司) was approved to produce COSELA® by the NMPA, and it is now capable of commercial supply.

- Jiangsu Xiansheng Biology Medical Co., Ltd. (江蘇先盛生物醫藥有限公司) (a pharmaceutical ingredient base) only spent 12 months from initiation to completion, which is far exceeding the industry average. It is now capable of production, and the production transfer and process validation of key products are progressing at an accelerated pace.

BUSINESS DEVELOPMENT

The Group had reached a number of strategic cooperation to expand its product pipelines and covered therapeutic areas. For the year ended December 31, 2023, the Group had entered into cooperation agreements in respect of three new drug molecules.

- On August 18, 2023, the Group entered into a cooperation agreement with Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司) ("**Mabpharm**") in respect of ENLITUO (CMAB009), pursuant to which, the Group obtained the exclusive commercial rights in respect of the product in the Chinese mainland. In March 2023, the marketing application of ENLITUO was accepted by the NMPA.

- On October 10, 2023, the Group entered into a cooperation agreement with Jiaxing AnDiCon Biotech Co., Ltd.* (嘉興安諦康生物科技有限公司) ("**AnDiCon**") in relation to ADC189, an innovative drug. The Group obtained the exclusive commercialization rights of the product in China for indications related to influenza, which further strengthened the product layout of the Group in the field of anti-infection.

- On November 21, 2023, the Group entered into an exclusive license and collaboration agreement with Connect Biopharma HongKong Limited (香港康乃德生物醫藥有限公司) ("**Connect Biopharma**") in relation to Rademikibart (IL-4R α), an innovative drug. The Group obtained the exclusive rights in relation to the development, manufacturing and commercialization of all indications of the product in Greater China.

- As of the date of this announcement, the Group has reached cooperation with leading universities and institutions, such as Mass General Brigham in the United States and Stanford University in the United States, so as to jointly promote the exploratory projects in the focused areas with an aim to develop more innovative therapies for patients.

THE EXPENDITURE ON RESEARCH AND DEVELOPMENT ACTIVITIES

The expenditure on research and development activities of the Group includes research and development costs and the addition of in-licensed rights of intangible assets.

- During the Reporting Period, the total expenditure on research and development activities of the Group amounted to approximately RMB1,960 million, representing an increase of approximately 1.2% as compared to approximately RMB1,938 million for 2022. During the Reporting Period, the expenditure on research and development activities to revenue ratio was approximately 29.7%, representing a decrease of 0.9 percentage points as compared to approximately 30.6% for 2022.

- During the Reporting Period, the research and development costs of the Group amounted to approximately RMB1,563 million, representing a decrease of approximately 9.6% as compared to approximately RMB1,728 million for 2022. During the Reporting Period, the research and development costs to revenue ratio was approximately 23.7%, representing a decrease of 3.6 percentage points as compared to approximately 27.3% for 2022.

- During the Reporting Period, the addition of in-licensed rights of intangible assets amounted to approximately RMB397 million, representing an increase of approximately 89.4% as compared to the approximately RMB210 million for 2022. During the Reporting Period, the addition of in-licensed rights of intangible assets to revenue ratio was approximately 6.0%, representing an increase of 2.7 percentage points as compared to approximately 3.3% for 2022.

MANAGEMENT DISCUSSION AND ANALYSIS

INDUSTRY REVIEW

2023 was a year when medical policies were introduced intensively, and it was also a year when the Group's innovative achievements continued to emerge. On one hand, a number of policies encouraging medical innovation were introduced, thus the success rate of medical insurance negotiation reached a record high and the time of new drugs being included into the list was shortened. A series of policies, such as the Regulations of the Drug Review Centre on Accelerating the Application and Evaluation of Innovative Drugs for Marketing Approval (《藥審中心加快創新藥上市許可申請審評工作規範》), further facilitated the acceleration of time-to-market of new drugs with real clinical value. On the other hand, the centralized rectification of corruption in the pharmaceutical field of China was launched and the National Catalog of the Second Batch of Drugs under Close Monitoring of Rational Drug Use (《第二批國家重點監控合理用藥藥品目錄》) was promulgated, which purified the industry environment continuously and improved the compliance level of the industry. At the same time, more than 80 new drugs were approved for marketing, coupled with numerous overseas licensing and licensing-out, which indicated that local innovative drugs will experience an explosive period. Looking forward, pharmaceutical corporations are required to incessantly driving for innovative transformation, improving its efficiency of research and development as well as marketing, and adapting to the development strategy of upgrading the innovative drug industry with proactive actions.

COMPANY OVERVIEW

The Company is an innovation and R&D-driven pharmaceutical company with capabilities in R&D, production and professional marketing. The Group primarily focuses on the therapeutic areas of oncology, nervous system, autoimmune and anti-infection, with forward-looking layout of disease areas that have significant clinical needs in the future, aiming to achieve the corporate mission of "providing today's patients with medicines of the future".

In the focused areas, the Group has six innovative drugs approved for marketing and sale. As of December 31, 2023, the Group has 14 products recommended in guidelines and pathways issued by over 100 government authorities or prestigious professional associations, and has over 40 products included in the NRDL.

The Group pays high attention to the establishment of innovative drug research and development ("**R&D**") capacity, and has established R&D innovation centers in Shanghai, Nanjing, Beijing, Boston and Hong Kong respectively, as well as a State Key Laboratory of Neurology and Oncology Drug Development. The Group's R&D system has achieved functions covering the whole process of drug discovery, preclinical development, clinical trial and registration, and owns leading platforms of protein engineering, PAb/TCE, PAb/NKCE, AI-aided drug discovery, protein degradation and ADC. As of December 31, 2023, the Group had a R&D team of approximately 1,000 employees in total with approximately 170 doctors and 490 masters.

The Group has a nationwide marketing network and leading commercialization capacity, and will continuously strengthen its professional marketing capacity, so as to enhance coverage and access to medicines. As of December 31, 2023, the Group's sales team had a total of approximately 4,200 employees divided into four business units (neuroscience, oncology, autoimmune & comprehensive and retail grossroots) and other support departments across 32 provinces, municipalities and autonomous regions, covering over 2,800 Class III hospitals, approximately 17,000 other hospitals and medical institutions as well as more than 200 large-scale national or regional chain pharmacies in China.

The Group has established manufacturing infrastructures and quality management systems in line with international standards and has continuously improved its manufacturing capabilities of pharmaceuticals. The five production facilities that have been put into use all meet the requirements of Chinese GMP, and part of the production lines have received EU GMP certification or passed the inspection of the U.S. Food and Drug Administration (the "**FDA**").

Driven by its in-house R&D efforts and synergistic innovation, the Group has established strategic cooperation partnerships with many innovative companies and research institutes, exploring multiple collaborative modes such as cooperative R&D and achievement transfer and continuously developing products that patients urgently need and have significant market potential. The Group established the Scientific Advisory Board (SAB) comprising over 10 world-renowned scientists in the areas of oncology, nervous system and autoimmune etc., so as to bring their professional capabilities and experiences to provide scientific advice for early drug discovery and clinical development of the Group, and aim to attract global leaders of life science to explore and create unprecedented treatments.

BUSINESS PROSPECTS

In 2024, the Group will carry out comprehensive deployments and accelerate the implementation of the "Innovation 2.0" strategy, maximize the innovation value of China, expand global innovation capacity, address the market changes of innovative drugs proactively, strengthen its product innovation and enhance its team capabilities, so as to strive to achieve the following management objectives:

Based on the existing six innovative drugs, the Group will promote the marketing of new products continuously, so as to reserve for the sustainable development of business. The Group will actively increase the scale of its innovative pharmaceutical business and enhance product coverage, while integrating resources and streamlining operations to achieve a high degree of focus and synergy, thereby providing more affordable solutions for a broader and more complex patient population.

The Group will continue to strive for innovative transformation, adhere to the two-wheel drive and relentlessly improve the project level and organizational capacity in respect of research and development as well as business development (BD). The Group will seek for differentiated mechanisms, targets and drug forms, so as to further expand the clinical value and synergistic advantages of its product pipelines and continue to improve the effectiveness of research and development investments and the efficiency of project propulsion and expediting the products under pivotal clinical stage to benefit patients as soon as possible, while broadening its innovation boundaries and paying attention to its late-stage products as well as exploring licensing-out opportunities, aiming to achieve synergies, innovation and win-win cooperation with industry partners.

The Group will continue to improve its production quality management and meet the international advanced standards, so as to produce safe and effective drugs for patients. The newly-established pharmaceutical ingredient base and antibody factory will further improve the production efficiency and cost advantages of the Group, so as to better support the expansion of the Group's product pipelines and enhance its market competitiveness.

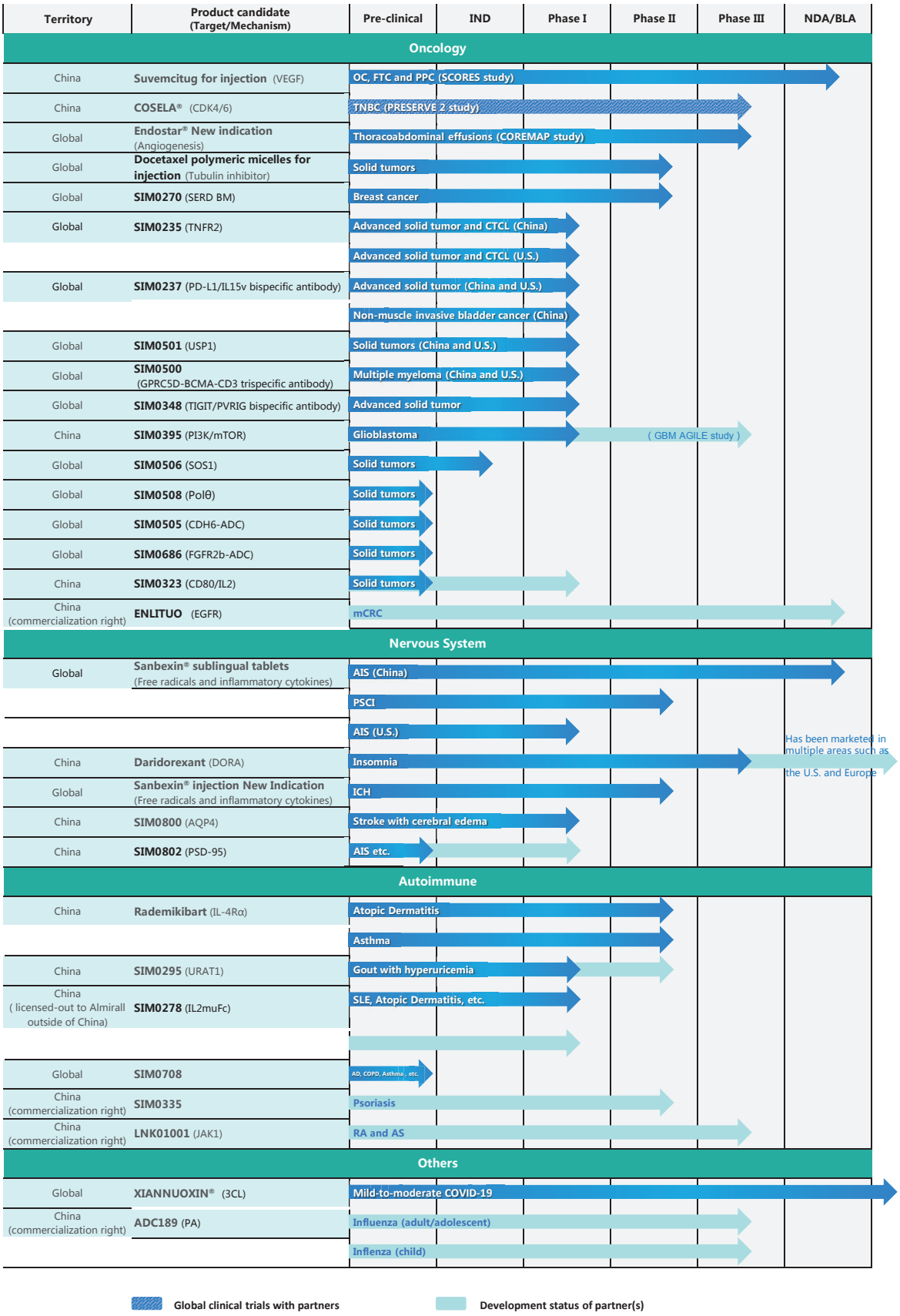
The Group will continue to promote management upgrades to enhance the efficiency of R&D and marketing operations, so as to explore sustainable innovative development pathway unceasingly.

SUMMARY OF PRODUCT PIPELINES

As of the date of this announcement, the Group has six commercialized innovative drugs, nearly 60 product pipelines of innovative drugs and is currently initiating registrational clinical studies for 15 new drug molecules, of which, there are three new drug molecules under NDA or phase III clinical study stage[1], 12 new drug molecules under phase I/II and approximately 40 pre-clinical drug candidates. The forms of innovative drugs under development contain monoclonal antibodies, bispecific antibodies, multi-specific antibodies, fusion proteins, ADC and small-molecule drugs. The extensive pipeline reserves have huge clinical and commercialization potential, which are expected to help more patients.

[1] Excluding products with commercial rights, namely ENLITUO, ADC189 and LNK01001

The table below summarizes the therapeutic targets, therapeutic areas, rights and development of the principal innovative drugs of the Group as of the date of this announcement.



COMMERCIALIZATION STAGE INNOVATIVE PRODUCTS

As of the date of this announcement, the Group has successfully expanded its commercialized portfolio into six innovative products spanning over multiple therapeutic areas, including nervous system, oncology, autoimmune and anti-infection, which have significant market potentials and synergistic effects. For the year ended December 31, 2023, revenue from the innovative pharmaceutical business was approximately RMB4,756 million, accounting for 72.0% of the total revenue.

Nervous System Products

Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection)

Sanbexin® is a category I innovative drug developed by the Group with proprietary intellectual property right used to treat Acute Ischemic Stroke. Sanbexin® was approved for marketing in China in July 2020 and has been included in the NRDL since December 2020. The results of phase III pivotal clinical TASTE study of Sanbexin®, which are published in STROKE, an international authoritative medicine journal, showed that, Sanbexin® can significantly increase the proportion of patients with a mRS score of 0-1 after 90 days of treatment of patients, i.e. reduce the proportion of patients disabled by AIS. Sanbexin® was recommended by the Guidelines for the Clinical Management of Cerebrovascular Diseases in China (《中國腦血管病臨床管理指南》), the Specialists' Consensus on the Clinical Assessment and Treatment of Acute Cerebral Infarction Ischemic Penumbra in China (《急性腦梗死缺血半暗帶臨床評估和治療中國專家共識》) and the Guidelines on Establishment of Stroke Prevention and Treatment System (《腦卒中防治體系建設指導規範》) and other guidelines and consensuses, and multiple relevant studies were presented at the European Stroke Organization Conference (ESOC), the scientific meeting of the American Heart Association (AHA) Hypertension Council and the World Congress of Neurology (WCN).

- On April 27, 2023, the new indication of intracerebral hemorrhage ("**ICH**") of Sanbexin® obtained the clinical trial approval issued by the NMPA, which is intended for the multi-center, randomized, double-blind and placebo-controlled phase II clinical trial to evaluate the efficacy and safety of Edaravone and Dexborneol Concentrated Solution for Injection with different dosages in combination of conventional medical therapies to treat ICH patients.

- On July 3, 2023, the above phase II clinical trial completed the FPI in the First Affiliated Hospital of Sun Yat-sen University (中山大學附屬第一醫院). As of the date of this announcement, over 80 subjects were enrolled.

- On May 19, 2023, the TASTE II study, led by Beijing Tiantan Hospital of the Capital Medical University (首都醫科大學附屬北京天壇醫院) with the participation of approximately 100 research centers in China conducted after the launch of Sanbexin®, has completed the follow-up of the last subject. Such study aimed at evaluating the efficacy and safety of Sanbexin® combined with reperfusion in the treatment of AIS patients and enrolled more than 1,300 AIS patients within 24 hours of onset and undergone early endovascular recanalization therapy. In February 2024, the protocol of the TASTE II study was published in the "Stroke and Vascular Neurology" magazine. The detailed data of the TASTE II study results are expected to be published in academic journals or conferences in the future.

- On June 24, 2023, the Guidelines for Clinical Management of Cerebrovascular Diseases in China (second edition) (《中國腦血管病臨床管理指南(第2版)》) prepared and issued by the Chinese Stroke Association (中國卒中學會) upgraded the concept of "neurological protection" in the 2019 edition by the treatment of "brain cell protection" and recommended the use of Edaravone and Dexborneol. Based on the positive result of the TASTE study, i.e. "the Edaravone and Dexborneol Concentrated Solution for Injection can further improve the clinical outcomes of patients with AIS", Sanbexin® becomes the only brain cell protection drug that received Level IIa recommendation in such guidelines currently.

- On July 4, 2023, the EXPAND study, a post-market real-world study ("**RWS**") led by Xuanwu Hospital of the Capital Medical University (首都醫科大學宣武醫院), has completed the enrollment of all 4,750 subjects. The primary objective of such a study is to observe the clinical effectiveness of AIS patients using Edaravone and Dexborneol in the real world environment, while its secondary objective is to monitor the safety of the clinical application of Edaravone and Dexborneol. The initial results of the study were included in the 2024 European Stroke Organization Conference (ESOC) for oral presentation.

- For the year ended December 31, 2023, Sanbexin® injection covered approximately 1.07 million patients and covers over 5,000 medical institutions currently.

Oncology Products

Endostar® (Recombinant Human Endostatin Injection)

Endostar® is the first anti-angiogenic targeted drug in China and the only endostatin approved for sale worldwide. Endostar® has been included in the NRDL since 2017 and is recommended as a first-line treatment for patients with advanced non-small-cell lung cancer ("**NSCLC**") by a number of oncology clinical practice guidelines issued by the National Health Commission of the PRC ("**NHC**"), Chinese Medical Association (中華醫學會) and Chinese Society of Clinical Oncology ("**CSCO**"). Also, it is recommended by various guidelines in relation to nasopharyngeal carcinoma, melanoma, esophageal carcinoma and osteosarcoma. At present, the Group is actively exploring the expansion of new indications of this product in thoracoabdominal effusions.

- In June 2023, the American Society of Clinical Oncology ("**ASCO**") published two studies relating to the combination of Endostar® with immunotherapy, and one of the real-world data in relation to Endostar® in combination with PD-1 for the first-line treatment of NSCLC is encouraging, while another real-world data in relation to Endostar® in combination with autoimmune treatment for the second-line treatment of advanced NSCLC show a clinical result which is better than autoimmune in combination with chemotherapy.

- On July 4, 2023, Guangdong Pharmaceutical Association (廣東省藥學會) published the Catalog for the Off-label Use of Drugs (2023) (《超藥品説明書用藥目錄(2023版)》), which included continuous intravenous infusion of Recombinant Human Endostatin Injection for NSCLC. The reference basis includes the "Guidelines for the Clinical Application of New Anti-tumor Drugs (2022)" (《新型抗腫瘤藥物臨床應用指導原則(2022年版)》) issued by the National Health Commission of the PRC, etc.

- On July 18, 2023, the Chinese Medical Association (中華醫學會) published the Guideline for Clinical Diagnosis and Treatment of Lung Cancer (2023) (《肺癌臨床診療指南(2023版)》), which recommended that during the treatment of negative patients with driver genes of non-squamous cell cancer, for those patients with a PS score of 0-1, patients with no contraindication can choose between Bevacizumab or Recombinant Human Endostatin in combination with chemotherapy and receive maintenance treatment (Class I or IIa).

- In September 2023, two clinical studies in relation to Endostar® were released at the 23rd World Conference on Lung Cancer (WCLC), of which, the ENPOWER study showed that, the use of Endostar® in combination with PD-1 inhibitor and chemotherapy as the first-line treatment of EGFR/ALK negative, advanced or metastatic non-squamous NSCLC can achieve good clinical efficacy and tolerable toxicity, which brings new hope of treatment for such group. Another study indicates that chemotherapy in combination with immunotherapy and Endostar® achieves good efficacy and safety in the treatment of advanced NSCLC patients, which may be a feasible treatment clinically.

- In December 2023, the Chinese Medical Association (中華醫學會) published the Specialists' Consensus on the Treatment of Malignant Pleural Effusions in China 2023 (《恶性胸腔積液治療的中國專家共識(2023年版)) and various therapies, such as Endostar®, are recommended by the consensus, which bring new treatment options for the patients with malignant pleural effusions.

- In January 2024, China Association of Health Promotion and Education (中國健康促進與教育協會) and China Anti-Cancer Association published the Expert Consensus on Diagnosis and Treatment for Lung Cancer and Malignant Pleural Effusions (《肺癌合併恶性胸腔積液診療專家共識》) and Endostar® was included in the consensus for the first time, which was recommended by experts to be used in the treatment of lung cancer and malignant pleural effusions.

ENWEIDA® (Envafolimab Injection)

ENWEIDA® is the world's first PD-(L)1 antibody to be administered by subcutaneous injection approved for marketing. Its unique method of injection differentiates itself from other PD-(L)1 products currently on the market, with the differentiation advantages of short administration time and good safety. On March 30, 2020, the Group entered into a tripartite cooperation agreement in relation to Envafolimab with 3D (Beijing) Medicines Inc. and Jiangsu Alphamab Biopharmaceuticals Co., Ltd.. The above-mentioned agreement provides the Group with the exclusive right to promote Envafolimab for all oncology indications and the right of first refusal of external licensing or assignment in the Chinese mainland.

- In January 2023, two studies of ENWEIDA® relating to liver cancer and colorectal cancer were selected to exchange by way of posters in the ASCO Gastrointestinal Cancers Symposium and the title of the study was: (1) the treatment of MSS locally advanced rectal cancer by Envafolimab in combination with CAPEOX before neoadjuvant therapies and after radiotherapy in short regimens: an open-label and forward-looking single-arm study; and (2) the efficacy and safety of treating unresectable hepatocellular cancer by Envafolimab in combination with Lenvatinib and TACE: an open-label, single-arm and phase II CISLD-12 study.

- In April 2023, ENWEIDA® continued to be included in six CSCO important guidelines: CSCO Diagnosis and Treatment Guidelines for Gastric Cancer 2023 (《CSCO胃癌診療指南2023版》) (Level I, Class 2A); CSCO Diagnosis and Treatment Guidelines for Colorectal Cancer 2023 (《CSCO結直腸癌診療指南2023版》) (Level II, Class 2A); CSCO Immune Checkpoints Guidelines for Clinical Use of Inhibitors 2023 (《CSCO免疫檢查點抑制劑臨床應用指南2023版》) (Level I, Class 2A); CSCO Diagnosis and Treatment Guidelines for Endometrial Carcinoma 2023 (《CSCO子宮內膜癌診療指南2023版》) (Level II); CSCO Diagnosis and Treatment Guidelines for Cervical Cancer 2023 (《CSCO宮頸癌診療指南2023版》) (Level II); and CSCO Diagnosis and Treatment Guidelines for Ovarian Cancer 2023 (《CSCO卵巢癌應用指南2023版》) (Level III, Class 2B).

- On April 13, 2023, the Gynecological Tumors Immune Checkpoints Guidelines for Clinical Use of Inhibitors 2023 (《婦科腫瘤免疫檢查點抑制劑臨床應用指南(2023版)》) was published. In the article, based on the CN006 study, it recommended patients with gynecological tumors with advanced/recurrent MSI-H/dMMR who failed the previous treatments to use Envafolimab (Level 2B).

- In June 2023, two relevant studies of ENWEIDA® were published in the annual meeting of the ASCO, which were related to gastric cancer and soft tissue sarcoma. In the study related to gastric cancer, the efficacy of using Envafolimab in combination with SOX (Oxaliplatin and TGOP) for the first-line treatment of PD-L1 positive advanced gastric adenocarcinoma emerges, which has a promising future.

- On July 31, 2023, the Gynecological Oncology of Chinese Medical Association (中華醫學會婦科腫瘤學分會) published the 7th Edition of the Clinical Guidelines for Gynecological Oncology of Chinese Medical Association (2023) (《中華醫學會婦科腫瘤臨床指南7版(2023)》). ENWEIDA® is recommended as a therapy drug for MSI-H/dMMR patients with advanced/recurrent endometrial cancer (Level 2B).

- In September 2023, three clinical studies in relation to ENWEIDA® were released at the 23rd World Conference on Lung Cancer (WCLC), of which, the Endouble study showed that ENWEIDA® in combination with Endostar® shows good efficacy and tolerability of patients with advanced NSCLC (PD-L1≥1%). This combination therapy provides new choice to the patients with advanced NSCLC with positive PD-L1 expression, which is worthy of further studies and exploration in the future. The second study indicates that the treatment of patients with advanced NSCLC who had failed prior immunotherapy by ENWEIDA® in combination with Endostar® and β-glucans is safe and controllable, and encouraging anti-tumor activity is shown, thus it is expected to become the new therapy for patients with advanced NSCLC who had failed prior immunotherapy. The third study indicates that the use of ENWEIDA® in combination with carboplatin and etoposide as the first-line treatment of patients with extensive-stage small cell lung cancer ("**ES-SCLC**") has shown significant efficacy and controllable toxicity, which provides a new treatment strategy for ES-SCLC patients.

- In October 2023, five studies in relation to ENWEIDA® were released at the congress of European Society for Medical Oncology (ESMO), of which, the open-label, multi-cohort and multi-center phase II clinical study of ENWEIDA® in combination of Suvemcitug has achieved anti-tumor efficacy and good safety in the hepatocellular carcinoma cohort, NSCLC cohort and colorectal cancer cohort. ENWEIDA® in combination of Lenvatinib has shown preliminary efficacy and controllable safety among NSCLC patients who are PD-1 resistant. ENWEIDA® in combination of standard chemoradiotherapy has achieved good safety and tolerability among patients with locally advanced nasopharyngeal carcinoma.

COSELA® (Trilaciclib Hydrochloride for Injection)

COSELA® is an effective, selective and reversiblecycl in-dependent kinases 4 and 6 (CDK4/6) inhibitor. COSELA® is the world's first-in-class comprehensive myeloprotection innovative drug that can de-administered prior to a chemotherapy and transiently retard hematopoietic stem cells and progenitor cells in G1 phase of cell cycle, thereby protect bone marrow cells from damage caused by cytotoxic chemotherapy. In August 2020, the Group entered into the exclusive license agreement with G1 Therapeutics, Inc. ("**G1 Therapeutics**") to develop and commercialize COSELA® in the Greater China region. On February 13, 2021, the product was approved for sale by the FDA. Currently, the product has been recommended by the related key guidelines of National Comprehensive Cancer Network Guidelines (NCCN), CSCO and other organizations.

- On May 10, 2023, a phase II clinical trial led by G1 Therapeutics showed that, COSELA®, for the use of patients with unresectable and locally advanced or metastatic triple-negative breast cancer ("**TNBC**"), decreased the incidence of various adverse events related to ADC by over 50%, including neutropenia, anemia and diarrhea. Trilaciclib generates targeted effects with clinical value, which provides important and long-term benefits to patients.

- In May 2023, a study analyzing the population pharmacokinetics of Trilaciclib in ES-SCLC and the relationship between the exposure and myeloprotection, anti-tumor and safety of Trilaciclib was published in the British Journal of Clinical Pharmacology. Such analysis of the pharmacokinetics of Trilaciclib showed that, under current clinical application scenarios, it is not necessary to adjust the dose pursuant to the difference in age, gender as well as liver and renal function. Under the recommended dose (240mg/m^2), Trilaciclib can bring about stable myeloprotection.

- On May 11, 2023, the European Society for Medical Oncology Breast Cancer Symposium (ESMO BC) published the initial results of a phase II study in relation to the use of Trilaciclib in combination with sacituzumab govitecan-hziy ("**SG**") in the treatment of metastatic triple-negative breast cancer ("**mTNBC**"). The study results indicate that, the combination of Trilaciclib before applying SG in the treatment of mTNBC may decrease the incidence of adverse events (AEs), such as neutropenia, anemia, nausea and diarrhea.

- On May 25, 2023, the "Frontiers of Pharmacology" published a Systematic Assessment and Meta analysis. The result showed that Trilaciclib was able to effectively reduce the incidence of CIMs like severe neutropenia (SN) and febrile neutropenia (FN), decrease the usage of supportive caring measures like red blood cell transfusions and transfusions of granulocyte colony-stimulating factors (G-CSF) and performed well in terms of safety.

- In June, 2023, the ASCO published two study results about Trilaciclib at its 59th annual meeting, namely the studies in the field of early TNBC and ES-SCLC, respectively.

- On July 18, 2023, the Chinese Medical Journal published the Guideline for Clinical Diagnosis and Treatment of Lung Cancer of Chinese Medical Association (2023) (《中華醫學會肺癌臨床診療指南(2023版)》), pursuant to which, COSELA® was recommended by the guideline for the first time and it was recommended to be administered prior to chemotherapy in order to decrease the incidence of chemotherapy-induced myelosuppression (Class 1).

- On August 14, 2023, the marketing application for the new indication of COSELA® was accepted by the NMPA, which is intended for decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/topotecan-containing regimen for patients with ES-SCLC. Such new indication will expand the application of COSELA® in ES-SCLC patients receiving two or more lines of chemotherapies.

- In September 2023, the proposal of Trilaciclib in combination with chemotherapy and immunity as the first-line treatment of advanced non-small-cell lung cancer was published in the World Conference on Lung Cancer.

- In October, 2023, the TRACES study of COSELA® for ES-SCLC patients in China receiving chemotherapy was updated in the European Society for Medical Oncology (ESMO) Congress, which pointed out that receiving Trilaciclib before chemotherapy can improve the tolerability of chemotherapy among patients with extensive-stage small cell lung cancer and improve the survival benefits of patients potentially, which is expected to reshape the chemotherapy trend of patients with small cell lung cancer.

- On October 27, 2023, COSELA® has fulfilled the supplemental application conditions and has been approved by the NMPA to change from conditional approval to regular approval.

- On December 20, 2023, the localization application of COSELA® has been approved by the NMPA. In the future, COSELA® can be produced by the production enterprises of the Group in Haikou, Hainan Province, which will further improve its accessibility to patients with cancer in China.

Autoimmune Products

Iremod® (Iguratimod Tablets)

Iremod® is the category 1.1 new drug independently developed by the Group, and also the first Iguratimod pharmaceutical product approved for marketing in the world. Iremod® has been included in the National Medical Insurance Catalogue since 2017. The indication is the active rheumatoid arthritis. Iremod® is recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinicalpractice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and Labor and Welfare of Japan.

- On May 31, 2023, the 2023 EULAR meeting published seven study results relating to Iguratimod, which involved indications like rheumatoid arthritis ("**RA**") and secondary osteoporosis, osteoarthritis (OA), common interstitial pneumonia (ILD) relating to RA, axial spinal arthritis and systemic sclerosis.

- In August 2023, a study for the first-time investigation of the efficacy and safety of tofacitinib in combination of Iremod® for the treatment of common interstitial pneumonia (UIP) in relation to rheumatoid arthritis was published in the "Frontiers in Immunology". The study results showed that the use of tofacitinib in combination of Iremod® can relieve RA and RA-UIP and it is better than Methotrexate/ Leflunomide in combination of other traditional conventional synthetic disease modifying antirheumatic drugs (csDMARDs) in respect of treatment responses of RA-UIP, which may be a potential option for achieving "double target-hit treatments".

- In September 2023, Iremod® was included in the new edition of the "Primary Sjögren's Syndrome Diagnosis and Treatment Standards" (《原發性乾燥綜合征診療規範》). In November 2023, Iremod® was included in the "China's Clinical Practice Guideline on the Off-label Use of Drugs for Sjögren's Syndrome (2023 Edition) (《乾燥綜合征超藥品説明書用藥中國臨床實踐指南(2023版)》) and the "Expert Consensus on the Use of Drugs in Super-drug Labels in Shandong Province (2023 Edition) (《山東省超藥品説明書用藥專家共識(2023年版)》), which provided more options for the patients with Sjögren's Syndrome in China.

Anti-infection Products

XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged))

XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) is an oral small molecule anti-SARS-CoV-2 innovative drug. Of which, Simnotrelvir targets 3CL protease which is essential for SARS-CoV-2 virus replication, and its combination with low-dose Ritonavir helps to slow down the metabolism and clearance of Simnotrelvir in body in order to improve the antiviral effect. On November 17, 2021, the Group entered into a technology transfer contract with Shanghai Institute of Materia Medica and Wuhan Institute of Virology, Chinese Academy of Sciences, pursuant to which, the Group obtained the development, production and commercialization rights on an exclusive basis of Simnotrelvir worldwide.

- On January 28, 2023, XIANNUOXIN® was conditionally approved for marketing in China by NMPA (Approval No. H20230001) with urgent review and approval under Special Examination and Approval of Drugs (藥品特別審批程序) for the treatment of adult patients infected with mild-to-moderate COVID-19.

- On February 8, 2023, the National Healthcare Security Administration issued a notice that the XIANNUOXIN® was included into the scope of medical insurance reimbursement temporarily.

- On March 2, 2023, the NHC and the National Administration of Traditional Chinese Medicine issued a notice that the XIANNUOXIN® was included in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 10) (《新型冠狀病毒感染診療方案(試行第十版)》).

- On March 21, 2023, XIANNUOXIN®'s 105 study completed the FPI and completed the enrollment of all 37 subjects on May 16, 2023. Such study is a multi-center, non-randomized, open, parallel and controlled phase I clinical study for evaluating the safety, tolerability and pharmacokinetic characteristics after single-dose administration of SIM0417 in combination with Ritonavir to subjects with mildto-moderate renal insufficiency, moderate hepatic insufficiency, normal renal function and normal hepatic function.

- On April 11, 2023, XIANNUOXIN®'s 108 study completed the FPI and completed the enrollment of all 14 subjects on June 15, 2023. Such study is a single-center, non-randomized and open phase I clinical study aiming at evaluating the safety and pharmacokinetic characteristics after single-dose administration of SIM0417 in combination with Ritonavir to healthy elderly subjects.

- Since April 2023, two real-world studies of XIANNUOXIN® were commenced, namely "the study on the therapeutic effects of anti-COVID-19 drugs in Chinese medical and health institutions on COVID-19" and "the standard treatment in combination with immunomodulation strategy for mild-to-moderate COVID-19 elderly patients (≥65 years old) - A multi-center, randomized, controlled and adaptive platform study". As of the date of this announcement, the exposure of XIANNUOXIN® in the above study was approximately 2,200 subjects.

- On June 15, 2023, institutions like Guangzhou Institute of Respiratory Health of the First Affiliated Hospital of Guangzhou Medical University (廣州醫科大學附屬第一醫院廣州呼吸健康研究院), the National Center for Respiratory Medicine (國家呼吸醫學中心) and the National Clinical Research Center for Respiratory Disease (國家呼吸疾病臨床研究中心) jointly published the "Chinese Expert Consensus on Diagnosis and Treatment Strategies for SARS-CoV-2 Infection in Immunocompromised Populations (2023 edition)" (《免疫缺陷人群新型冠狀病毒感染診治策略中國專家共識(2023版)), which indicated that XIANNUOXIN® was one of the priorities of small-molecule drugs to treat COVID-19 for those immunocompromised population.

- On July 11, 2023, the Lancet Regional Health - Western Pacific Magazine digitally published the results of the phase Ib clinical study for the evaluation of effectiveness and safety of XIANNUOXIN® for the treatment of COVID-19 (NCT05369676) (DOI: 10.1016/j.lanwpc.2023.100835).

- On August 24, 2023, as approved by the CDE, the storage conditions of XIANNUOXIN® was changed from "sealed and kept under 25°C" to "sealed and kept under 30°C", and its effective period was extended from 12 months to 18 months.

- On September 19, 2023, Guangdong Pharmaceutical Association (廣東省藥學會) published the Evaluation of and Selected Specialists'Consensus on COVID-19 Small-molecule Antiviral Drugs (《COVID-19小分子抗病毒藥物評價與遴選專家共識》). Through a multi-dimensional scoring, XIANNUOXIN® ranked among the first in the domestic COVID-19 small-molecule antiviral drugs with a total score of 70.1.

- On September 30, 2023, the European Journal of Pharmaceutical Sciences digitally published the results of the phase I clinical study to investigate the safety, tolerability and pharmacokinetics of Simnotrelvir among healthy adult subjects (NCT05339646) (DOI: 10.1016/j.ejps.2023.106598).

- On October 13, 2023, the Nature Communications digitally published the discovery process of Simnotrelvir, an active ingredient of XIANNUOXIN®, and its pre-clinical study results (DOI: 10.1038/s41467-023-42102-y).

- On December 13, 2023, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security published the "Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2023)" (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2023年)》), pursuant to which, XIANNUOXIN® was officially included in the NRDL. The price of XIANNUOXIN® per box/therapy was reduce to RMB479. The New NRDL officially came into effect from January 1, 2024.

- On January 18, 2024, the New England Journal of Medicine digitally published the complete data of the Group's phase II/III, double-blind, randomized, placebo-controlled clinical trial (NCT05506176) of XIANNUOXIN® for the treatment of adult patients with mild-to-moderate COVID-19 (DOI: 10.1056/NEJMoa2301425).

  From August 19, 2022 to December 16, 2022, a total of 1,208 patients were enrolled at 35 research sites in China, with 603 patients in the XIANNUOXIN® group (received 750mg of Simnotrelvir plus 100mg of Ritonavir, twice daily for 5 days) and 605 patients in the placebo group. The results showed that, for adult patients with mild to moderate COVID-19 in China, XIANNUOXIN® could accelerate recovery from symptoms, and shorten the duration of the disease cause, reduce viral load rapidly and significantly, and demonstrate good safety and tolerance:

  (1) Significantly shortened the median time to sustained resolution of 11 targeted COVID-19 symptoms (the "**Duration**"), with greater effectiveness in patients with high risk factors: In the modified intention-to-treat 1 (the "**mITT1**") population who received the first dose within 72 hours after COVID-19 symptom onset, XIANNUOXIN® could significantly shorten the Duration by 35.8 hours; In the subgroup of patients with risk factors for severe COVID-19, XIANNUOXIN® could shorten the Duration by 60.4 hours.

  (2) Demonstration of rapid and significant decrease in viral load: in the mITT1 population, the additional change in viral load from baseline in the XIANNUOXIN® group was 96.9% (-1.51 $\log_{10}$ copies/mL) compared with placebo group on day 5.

  (3) Good safety profile: the safety data showed the XIANNUOXIN® group reported a slightly higher occurrences of adverse events than placebo group, most of these events were of mild or moderate severity and could be recovered without any medical intervention, which suggested that XIANNUOXIN® was safe and tolerable.

  The median age of the patients included in the Study was 35 years, and 1,092 patients (95.9%) had completed primary vaccination, with 874 patients (76.7%) had received a booster dose. Meanwhile, various Omicron variants were covered in the Study, which demonstrated the application value of XIANNUOXIN® in clinical practice. The publication of the Study with great success signifies that XIANNUOXIN® has become the first domestically-made 3CL target anti-SARS-CoV-2 drug with a complete evidence chain.

- On February 2, 2024, the registration application for the change from conditional approval to regular approval of XIANNUOXIN® was accepted by the NMPA.

NDA TRIAL STAGE DRUG CANDIDATES

Nervous system products

Sanbexin® sublingual tablets

Sanbexin® sublingual tablets is an innovative drug jointly developed by the Group and Neurodawn Pharmaceutical Co., Ltd. (南京寧丹新藥技術有限公司). It contains edaravone and dexborneol as two active ingredients, which can disintegrate quickly under the tongue and can be absorbed into the blood through the sublingual venous plexus. Its key pharmacologic activities are anti-inflammations and free radicals scavenging, thus minimizing the cascading injury caused by AIS and protecting brain cells. Such unique sublingual formulation is expected to increase the flexibility of stroke treatment and improve medication compliance. The Sanbexin® sublingual tablets is expected to form a sequential therapy with the Company's marketed Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) and enable patients to receive a complete course of treatment in and outside of the hospital.

- On June 28, 2023, the NDA of the Sanbexin® sublingual tablets was accepted by the NMPA. The first indication is for the improvement of the neurological symptoms, activities of the daily living and dysfunction caused by AIS.

- On November 28, 2023, the IND of the new indication of Sanbexin® sublingual tablets was approved by the NMPA, which was intended for the clinical trials of the preventive treatment of post stroke cognitive impairment ("**PSCI**") among AIS patients.

- On February 19, 2024, the Journal of American Medical Association • Neurology (JAMA NEUROLOGY, IF: 29.0) published online the key results of the multi-center, randomized, double-blind and placebo-controlled phase III clinical study (the TASTE-SL Study) of Sanbexin® sublingual tablets used for the treatment of acute ischemic stroke. The results showed that, compared with placebo, Sanbexin® sublingual tablets have significantly improved the recovery of neurological function and ability to live independently in AIS patients after treatment. The Sanbexin® sublingual tablets group showed a significantly higher proportion of patients experiencing good functional outcomes (mRS score 0~1) on day 90 after randomization, compared with the placebo group (64.4% vs. 54.7%; OR=1.50; 95% CI 1.15~1.95; P=0.003). For the subgroups in different ages (≤65 or >65), genders, times from onset to treatment (≤24h or >24h), history of hypertension, history of hyperlipemia, history of diabetes, history of heart disease, and renal functions, the benefits of Sanbexin® sublingual tablets group in improving neurological function are consistent. Sanbexin® sublingual tablets have shown good safety profile in AIS patients, with similar rates of adverse events (AE) within 90 days and treatment related adverse events between the two groups.

Oncology products

ENZESHU (Suvemcitug for Injection)

Suvemcitug for injection is a new-generation recombinant humanized anti-VEGF rabbit monoclonal antibody developed by the Group and Apexigen, Inc. (now part of Pyxis Oncology, Inc.) Pre-clinical studies have shown that Suvemcitug has higher affinity and anti-tumor efficacy than Bevacizumab at the same dose in multiple tumor models. The phase Ib clinical studies of Suvemcitug conducted in China for the treatment of ovarian cancer preliminary demonstrated its favorable safety profile and efficacy signals.

- On June 27, 2023, the LPI for the phase III clinical trial (the SCORES Study) of Suvemcitug for injection combined with chemotherapy versus placebo combined with chemotherapy in patients with recurrent and platinum-resistant epithelial ovarian, fallopian tube cancer, or primary peritoneal cancer was achieved. This study was led by the Cancer Hospital Chinese Academy of Medical Sciences, and has enrolled 421 patients at 55 research centers in China.

- On January 3, 2024, the SCORES Study has met the primary study endpoint. The results include the final analysis of progression-free survival (the "**PFS**") as the primary endpoint, the first analysis of overall survival (the "**OS**") as the key secondary endpoint, and the safety analysis. The results showed: (1) the SCORES study has met the primary endpoint PFS which is assessed by the Blinded Independent Review Committee (BIRC) according to the RECIST 1.1 criteria. Compared with the Placebo Group, the improvement of PFS in the Experimental Group is both statistically and clinically significant, and Suvemcitug has shown consistent PFS benefits among all pre-defined sub-groups. The PFS benefit of the Experimental Group evaluated by the researchers is consistent with those evaluated by BIRC; (2) the OS data are immature, but there is a trend of OS benefit in the Experimental Group; and (3) the safety is manageable, no new safety signals are identified. The study results are expected to be released in academic journals or conferences in the future.

- On March 15, 2024, the new drug application of ENZESHU has been accepted by the NMPA. The indication is Suvemcitug combined with chemotherapy for the treatment of recurrent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer.

ENLITUO (EGFR)[1]

ENLITUO is a recombinant anti-epidermal growth factor receptor ("**EGFR**") chimeric monoclonal antibody for first-line treatment of metastatic colorectal cancer ("**mCRC**") in combination with FOLFIRI. It is prepared using a specific expression process, effectively avoiding glycosylation modification that may lead to hypersensitivity. Its safety and efficacy has been confirmed from the results of two completed clinical trials. In March 2023, the drug marketing application of ENLITUO was accepted by the National Medical Products Administration of China. After the launch of the product, it is expected to be the first home-made anti-EGFR monoclonal antibody drug for treatment of mCRC launched in the Chinese market, and provides affordable biological targeted drug with better efficacy for hundreds of thousands of Chinese patients with tumors.

- On August 18, 2023, the Group entered into a cooperation agreement with Mabpharm in respect of the product, pursuant to which, the Group obtained the exclusive commercial rights in respect of ENLITUO in the Chinese mainland.

PHASE III TRIAL STAGE DRUG CANDIDATES

Nervous system products

Daridorexant hydrochloride tablets (DORA)

Daridorexant hydrochloride tablets is an insomnia drug jointly developed by the Group and Idorsia Pharmaceuticals Ltd. ("**Idorsia**"), and is a dual orexin receptor antagonist ("**DORA**") that blocks orexin neuropeptides that promote wakefulness (orexin A and orexin B) from binding to their receptors. Unlike generally promoting sleep by calming the brain, Daridorexant only blocks orexin neuropeptide activation of orexin receptors. Thus, Daridorexant reduces the arousal drive and induces sleep development without altering sleep architecture. The phase III oversea clinical data has been published in The Lancet Neurology: the main studies demonstrated that Daridorexant significantly improved sleep onset, sleep maintenance and self-reported total sleep time compared with placebo during the first and third months of treatment without changing sleep architecture. In addition, Daridorexant was shown to be safe and well-tolerated with no evidence of dependence, rebound insomnia, withdrawal symptoms or drug abuse, distinguishing significantly from what has been reported with benzodiazepine receptor agonists. Daridorexant has clinical data available for up to 12 months of continuous treatment, supporting the long-term use of Deradoorian. In addition to improving nighttime sleep in the adult population with chronic insomnia disorder, Daridorexant also improves daytime functioning, which is the only DORA class insomnia drug approved by the European Medicines Agency (EMA). Daridorexant is currently approved in the United States, Great Britain, Italy, Germany, Switzerland and Canada.

[1] The original code is CMAB009, and is a product with commercial right

- On July 20, 2023, Daridorexant hydrochloride tablets received a notice of approval for Drug Clinical Trials issued by the National Medical Products Administration, which is intended for the treatment of adult insomnia patients who have persistent symptoms for at least three months and have an impact on daytime function.

- On November 30, 2023, the phase I clinical study of Daridorexant in China completed the FPI.

- On December 17, 2023, the randomized, double-blind, placebo-controlled and multi-center phase III clinical study of Daridorexant for the treatment of adult insomnia patients who have persistent symptoms for at least three months and have an impact on daytime function completed the FPI. This study was led by Xuanwu Hospital of the Capital Medical University which was conducted in 33 centers in China.

- On March 15, 2024, the above phase III clinical trial of Daridorexant hydrochloride tablets completed the enrollment of all 205 patients (LPI).

Autoimmune products

LNK01001 (JAK1)[1]

LNK01001 is a highly selective JAK1 inhibitor which has completed 3 phase II clinical studies for patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS) and atopic dermatitis (AD), all of which have successfully met their corresponding primary and secondary endpoints. No related adverse effects of approved JAK1 inhibitors, such as major adverse cardiovascular events, blood clots, serious infection or formation of malignant tumors, were observed. On March 18, 2022, the Group entered into a cooperation agreement with Lynk Pharmaceuticals Co., Ltd. (淩科藥業(杭州)有限公司) ("**Lynk Pharmaceuticals**"), pursuant to which, the Group obtained the exclusive commercialization interest of LNK01001 for rheumatoid arthritis and ankylosing spondylitis indications in China and be responsible for promotion after regulatory approval.

- On August 23, 2023, the randomized, double-blind, placebo-controlled and multi-center phase II clinical study of LNK01001 among adult patients with active ankylosing spondylitis (AS) achieved positive topline results.

- On December 20, 2023, the randomized, double-blind and placebo-controlled phase III study to evaluate the efficacy and safety of LNK01001 for treating patients with mild-to-moderate active rheumatoid arthritis who have an inadequate response to or are unable to tolerate bDMARDs completed the FPI. The clinical study was led by the Peking Union Medical College Hospital of Chinese Academy of Medical Sciences (中國醫學科學院北京協和醫院), and the Company assisted Lynk Pharmaceuticals to promote this study in clinical research centers across the country.

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[1] A product with commercial right

Anti-infection products

ADC189 (PA)[1]

ADC189 is a polymerase acidic (PA) protein inhibitor for anti-influenza, by suppressing cap-dependent endonuclease (CEN) of influenza virus. ADC189 can inhibit the replication of influenza virus directly, and suppress both influenza A and B. As shown in the pre-clinical research, ADC189 demonstrates several benefits, including the absence of central nervous system side effects, no effect of food intake on oral drug absorption and higher safety dose. The entire oral dose of ADC189 is merely "one tablet" and is capable of stopping influenza virus replication in 24 hours, having a prospect of bringing great convenience to a large number of patients, including child patients.

- On October 10, 2023, the Group entered into a cooperation agreement with AnDiCon in relation to ADC189. Pursuant to the agreement, the Group will obtain the exclusive commercialization rights of the Product in China for indications related to influenza. Currently, AnDiCon is about to complete the phase III clinical trials of ADC189 for the treatment adult/adolescent patients with influenza.

- In February 2024, children's granules of ADC189 has received the clinical approval and is initiating the bridging of bioavailability (BA) and phase III clinical trials of ADC189.

PHASE II STAGE DRUG CANDIDATES

Rademikibart (IL-4Rα)

Rademikibart is a fully human monoclonal antibody targeting IL-4Rα, a common subunit of IL-4 receptor and IL-13 receptor. By binding with IL-4Rα, Rademikibart can block the functions of IL-4 and IL-13 effectively, thereby blocking the Th2 inflammatory pathway, thus achieving the goal of treating Th2 related inflammatory diseases such as atopic dermatitis and asthma.

- On November 21, 2023, the Group entered into an exclusive license and collaboration agreement with Connect Biopharma in relation to Rademikibart. Pursuant to the agreement, the Group obtained the exclusive rights in relation to the development, manufacturing and commercialization of all indications of Rademikibart in Greater China.

- As of the date of this announcement, the clinical trial of Rademikibart for atopic dermatitis and indications of asthma is being conducted in China simultaneously.

[1] A product with commercial right

SIM0270 (SERD)

SIM0270 is the second-generation oral selective estrogen receptor degrading agent ("**SERD**") with blood-brain barrier-penetrating properties independently developed by the Group. The efficacy of SIM0270 in the in vivo model is significantly better than an intramuscular SERD drug already on the market, and is equivalent to the efficacy of the leading compound in the clinical trial stage. It reflects a brain-to-blood ratio significantly better than competing compounds and also shows a tumor- inhibiting drug therapy far superior to fulvestrant on the brain orthotropic model of breast cancer. It is expected to be used for the treatment of breast cancer with brain metastases.

- On February 3, 2023, the treatment of estrogen receptor positive breast cancer using SIM0270 in combination with piperacil or ivimox has obtained the Clinical Trial Approval issued by the NMPA, and it is planned to begin the enrollment of combined dose group in the second half of 2023. As of the date of this announcement, dose escalation of the combination study and enrollment for dose-expansion stage were completed.

SIM0335[1]

SIM0335 is a drug candidate developed by BCY Pharm Co., Ltd. ("**BCY**") that controls fatty acid metabolism and works on IL-17A-related pathways. SIM0335 is a topical ointment with 3-Ocyclohexanecarbony1-11-keto-β-boswellic acid (CKBA) being the active ingredient. Phase I clinical results showed that the systematic exposure was low and the systematic safety risk was expected to be small.

- On January 12, 2023, the phase IIa clinical trial of SIM0335 for the treatment of plaque psoriasis completed the enrollment of all patients. The study is designed to evaluate the safety, efficacy, and pharmacokinetics of SIM0335 in mild-to-moderate plaque psoriasis patients.

- On March 2, 2023, Guangdong Taienkang Pharmaceutical Co., Ltd. acquired 50% equity interests in BCY and BCY was no longer a subsidiary of the Group.

[1] A product with commercial right

PHASE I STAGE DRUG CANDIDATES

SIM0235 (humanized anti-TNFR2 monoclonal antibody)

SIM0235 is a tumor-immune target human immunoglobulin G1 ("**IgG1**") humanized anti-tumor necrosis factor receptor type 2 ("**TNFR2**") monoclonal antibody independently developed by the Group. The preclinical pharmacodynamics model shows significant single-agent efficacy and the potential and superior safety in combination with PD-1. SIM0235 can specifically recognize TNFR2 expressed on the cell surface and kill immunosuppressive cells such as Treg and myeloid derived suppressor cells ("**MDSC**") with high expression of TNFR2 through Fc end functions including antibody dependent cell-mediated cytotoxicity (ADCC) and antibody dependent cell-mediated phagocytosis (ADCP). At the same time, it can also block the activation of endogenous tumor necrosis factor (TNF) on TNFR2, inhibit the immunosuppressive function mediated by TNFR2 and the proliferation of related TNFR2+ immunosuppressive cells Treg and MDSC, enhance the body's killing immune response to tumor and play an anti-tumor role. In addition, SIM0235 can specifically recognize TNFR2 expressed on the surface of tumor cells and directly kill tumor cells with high expression of TNFR2 through the effector function mediated by Fc end of antibody.

- On March 13, 2023, the Group reached a clinical development cooperation agreement with MSD to explore the possibility of using SIM0235 in combination with KEYTRUDAR (Pembrolizumab), a PD-1 antibody drug in the above phase I trial.

- As of the date of this announcement, the phase I clinical trial of SIM0235 for relapsed or refractory advanced solid tumors and cutaneous T-cell lymphoma (CTCL) progressed smoothly in China and the United States, which has completed the enrollment plan for the single-dose escalation stage and obtained the recommended dose for combination, and is proceeding to the dose exploration study stage of combination therapies currently.

SIM0237 (PD-L1/IL15v bispecific antibody)

SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL-15/IL-15Rα sushi protein and developed in-house by utilizing the Group's protein engineering platform. It can block the PD-1/PD-L1 immunosuppressive pathway via binding to PD-L1 and activate the immune system through its IL-15 part, thus playing a synergistic role of relieving immunosuppression and boosting the immune system to exhibit antitumor effect. Preclinical studies showed that SIM0237 is more effective than PD-L1 or IL-15 mono treatment in mouse tumor models, suggesting a high potential for clinical development.

- On March 8, 2023, a phase 1 first-in-human, open-label and multi-center study for the assessment of safety, tolerability, pharmacokinetics and preliminary anti-tumor activity among adult subjects of SIM0237 advanced solid tumors completed the FPI in Hunan Cancer Hospital. Currently, the MRCT clinical trial of SIM0237 for the treatment of advanced solid tumors is being conducted in the U.S. and China.

- On October 15, 2023, a new indication of SIM0237 for injection has obtained the Clinical Trial Approval issued by the NMPA, which is intended to be applicable to patients with non-muscle invasive bladder cancer ("**NMIBC**").

- On January 23, 2024, SIM0237 for patients with NMIBC completed the FPI.

SIM0501 (USP1 small molecule inhibitor)

SIM0501 is an oral, non-covalent and highly selective inhibitor of Ubiquitin Specific Peptidase 1 ("**USP1**") independently developed by the Group. USP1 is found to be over-expressed in various tumors and plays a key role in DNA damage response and repair. The inhibition of USP1 can promote apoptosis in tumors, especially in the tumors with homologous recombination deficiency ("**HRD**"). Following the success of PARP inhibitor ("**PARPi**"), the USP1 inhibitor is expected to provide innovative solutions for more patients with solid tumors in the field of "synthetic lethality". In preclinical in vitro and in vivo pharmacology studies, SIM0501 has shown significant anti-proliferation activity against HRD tumors as a monotherapy or in combination with PARPi, which demonstrates high potential for clinical development.

- On December 2, 2023, the IND application of SIM0501 to initiate clinical trials for advanced solid tumors was approved by the FDA.

- On January 10, 2024, SIM0501 tablets has obtained the Clinical Trial Approval issued by the NMPA, pursuant to which, SIM0501 tablets have been approved to initiate clinical trials for advanced malignant solid tumors as monotherapy.

- On March 19, 2024, the above clinical trial completed the FIH.

SIM0500 (humanized GPRC5D-BCMA-CD3 trispecific antibody)

SIM0500 is a humanized GPRC5D-BCMA-CD3 trispecific antibody, which is a potential best-in-class (BIC) drug for the treatment of multiple myeloma based on the preclinical data. Through the research and development platform of multispecific antibody drugs with the Group's own T-cell engagers, SIM0500 is a tumor-targeted T-cell activating drug, composed with the Group's self-developed CD3 antibody with the feature activated by low affinity and high target activation and the antibody with anti-tumor associated antigen. It has the advantages of excellent tumor-killing effect and good tolerance. SIM0500 can potentially overcome the drug resistance caused by the existing treatments, and show excellent anti-tumor activity in various animal pharmacodynamic models with different expression levels and has multiple advantages such as low effective dose and no recurrence of tumors after drug withdrawal.

- On January 2, 2024, the IND application of SIM0500 injection in China was accepted by the NMPA.

- On March 9, 2024, the IND application of SIM0500 in the U.S. was approved by FDA. SIM0500 is intended to be investigated in a clinical trial in patients with relapsed or refractory multiple myeloma.

SIM0348 (humanized TIGIT/PVRIG bispecific antibody)

SIM0348 is an IgG1-based humanized TIGIT/PVRIG bispecific antibody developed in-house by utilizing the Group's protein engineering platform. It can specifically bind two novel immune checkpoint proteins, human TIGIT and PVRIG at the same time, aiming to block the interaction between CD155/TIGIT and CD112/PVRIG, and improve the anti-tumor activity of immune cells. SIM0348 has Fc-mediated effector function and can kill immunosuppressive Treg cells with high expression of TIGIT and dual expression of TIGIT and PVRIG, while better mediating the activation and killing effect of NK cells and further enhancing the tumor-killing ability of dual antibodies.

- On March 29, 2023, a first-in-human, open-label and multi-center phase 1 study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of SIM0348 in advanced solid tumors reached the FPI in the Cancer Center of Sun Yat-sen University (中山大學). Currently, the study has completed the study for single-dose exploration stage and proceeds to the study for dose exploration of combination therapies.

SIM0395 (PI3K/mTOR)

SIM0395 is a BBB-penetrant inhibitor of the PI3K/mTOR pathway. A phase II clinical study showed that Paxalisib has shown highly encouraging signals of clinical efficacy among glioblastoma patients with unmethylated MGMT promoter status. Paxalisib was awarded the GBM orphan drug certification by FDA in 2018 and the fast track certification by FDA, the rare childhood disease and orphan drug certification of diffuse intrinsic pontine glioma (DIPG) in 2020. In March 2021, the Group entered into an exclusive licensing agreement with Kazia to introduce the development and commercialization rights of SIM0395 for all indications in the Greater China region. At present, the partner Kazia is in the international multi-center pivotal phase III clinical trial for glioblastoma (GBM AGILE Study).

SIM0278 (IL2 mu Fc)

SIM0278 is an Fc fusion protein with an IL-2 mutein of Treg, developed based on the Group's protein engineering technology platform. By introducing the mutation, the affinity of SIM0278 to effector T cells is reduced, while the high affinity of Treg cells is retained. Pre-clinical studies have showed that SIM0278 can selectively activate Treg cells in vitro without activating effector T cells or NK cells, so as to achieve the effect of restoring the body's immune balance and has the potential to be developed for the treatment of various autoimmune diseases. On September 28, 2022, the Group entered into a licensing agreement with Almirall, S.A. ("**Almirall**"). Under the agreement, the Group grants Almirall an exclusive rights and interests in the development and commercialization of SIM0278 outside Greater China, while the Group retains all rights and interests in the Greater China Territory.

- On July 27, 2023, SIM0278 injection obtained the clinical trial approval issued by the NMPA, which is indicated for moderate-to-severe Atopic Dermatitis.

- On August 26, 2023, the phase I clinical study of SIM0278 achieved FIH in China.

- On December 21, 2023, Almirall officially launched the phase I clinical trial of SIM0278 overseas, aiming to evaluate the safety, pharmacokinetics, immunogenicity and pharmacodynamics of SIM0278.

SIM0800 (AQP4)

SIM0800 is an Aquaporin-4 (AQP4) inhibitor developed based on the Aquaporin water channel theory which has been awarded the Nobel Prize. It is intended for the treatment of acute severe ischaemic stroke complicated by cerebral oedema, as a first-in-class small molecule drug with a novel mechanism of action for brain oedema therapy. The Group entered into a license agreement with Aeromics, Inc. in October 2019, pursuant to which, the Group obtained a proprietary and sublicensable license for its self-funded research, development, production and commercialization of SIM0800 in the Greater China region.

- On February 25, 2023, the phase I clinical trial of SIM0800 completed the enrollment of the last subject, and the phase I data demonstrated that the safety and tolerance of such drug was good.

SELECTED IND/PRE-CLINICAL STAGE DRUG CANDIDATES

The Group has approximately 40 pre-clinical drug candidates and its in-house pipelines focus on differentiated targets with FIC and BIC potential, which provide strong and diversified product pipelines for the long-term sustainable growth of the Group. Certain research and development assets with high potential are as follows.

SIM0506 (SOS1 small molecule inhibitor)

SIM0506 is an effective and highly selective SOS1 inhibitor independently developed by the Group with global intellectual property rights for the treatment of various solid tumors. SOS1 is one of the main targets that indirectly inhibits the activity of KRAS, catalyze GTP to swap with GDP in RAS, thus activating KRAS. Pre-clinical studies showed that SIM0506 demonstrates pan-KRAS inhibitory activity and its synergistic effect was remarkable after combination, which is safe and tolerant with low effective dose and good anti-tumor effect. The combination with KRAS and MEK inhibitors both showed good synergistic effect. In clinical applications, it can be used in combination with KRAS inhibitors or ERK inhibitors or MEK inhibitors or chemotherapeutics for the treatment of solid tumors with KRAS mutation.

- On February 7, 2024, the IND of SIM0506 capsules was accepted by the NMPA.

SIM0508 (Pol θ small molecule inhibitor)

Pol θ is a DNA polymerase, whose mediation of MMEJ repair pathway is one of the important approaches for repairing DNA double strand breaks. When tumor cells experience homologous recombination repair deficiency (HRD), MMEJ, a major compensation pathway, is upregulated to help tumors escape from DNA damage and reduce the synthetic lethal effect of PARP inhibitor and HRD. Through the combined use of Pol θ inhibitor and PARP inhibitor, the repair pathways of single-chain recovery and double-chain compensation in HRD tumor cells can be inhibited at the same time, which will lead to the accumulation of a large amount of DNA damages and induce the death of tumor cells, thereby creating enhanced synergistic effects. As compared with other DDR targets, Pol θ inhibitors has relatively less impacts on normal cells. In addition, while Pol θ inhibitors can enhance efficacy when using in combination with PARP inhibitors, the possibility of creating additional safety risk is relatively lower. For patients with solid tumors of various HRDs, it is a new therapeutic strategy which is potentially effective and safe. The Group plans to submit the IND to NMPA and FDA in the first half of 2024.

SIM0505 (CDH6-ADC)

CDH6 is a type II classical cadherin, also known as K-cadherin, located in the lateral basement membrane of epithelial cells and mediates calcium-dependent cell-cell adhesion. The group has developed a targeted CDH6 antibody-drug conjugate (ADC) by connecting CDH6 monoclonal antibody specifically binding to tumor cells with camptothecin toxoid molecules with independent intellectual property rights, which combines the tumor targeting of antibodies with the high-efficiency killing effect of toxin molecules, while avoiding the defects of low curative effect of the former and excessive toxic side effects and poor drug-making performance of the latter. Compared with traditional chemotherapy drugs, it can target tumor cells accurately, reduce the toxic side effects on normal cells and achieve a safer and more effective anti-tumor effect. Such ADC is intended to be developed for the treatment of malignant tumors like ovarian cancer and renal cancer, and the Group plans to submit the IND application to the NMPA and FDA at the end of 2024 and in the first half of 2025, respectively.

SIM0686 (FGFR2b-ADC)

Fibroblast growth factor receptor (FGFR) is a transmembrane tyrosine kinase receptor of fibroblast growth factor (FGF). At present, there are four known subtypes, namely FGFR1, FGFR2, FGFR3 and FGFR4. When FGFR integrates with ligand and heparin, it will induce FGFR to form dimer which make tyrosine kinase domain in cells autophosphorylate, activate multiple signal transduction pathways in cells and promote cell proliferation, survival and differentiation. FGFR2b is a splicing isomer of FGFR2, which is mainly expressed in epithelial tissues and has high affinity for FGF7 subfamily. The Group has developed an ADC targeting FGFR2b, which connects monoclonal antibodies specifically binding to tumor cell surface antigen FGFR2b with camptothecin toxoid molecules with independent intellectual property rights through a linker. Such ADC can kill cells and inhibit tumors by binding antibodies to receptors on the surface of tumor cells and inducing endocytosis to release toxins. Such ADC is intended to be developed for the treatment of advanced malignant tumors like gastric cancer and lung cancer, and the Group plans to submit the IND application to the NMPA and FDA in the first half of 2025.

SIM0323 (CD80/IL2)

SIM0323 is the first-in-class CD80/IL-2 bifunctional fusion protein developed by the Group and GI Innovation, Inc. The preclinical pharmacodynamic model shows significant single-drug efficacy and the potential for combined use with other anticancer drugs, such as PD-1 inhibitors and chemotherapeutics. In 2021, the partner was approved for clinical trials by the Korean Ministry of Food and Drug Safety and the FDA to carry out phase I/II clinical trials of the drug.

SIM0802 (PSD-95)

SIM0802 is a dimer peptide candidate drug that the Group cooperates with Avilex, a Danish biotechnology company, and is intended to be used for the treatment of a variety of neurological diseases such as AIS and Subarachnoid Hemorrhage (SAH). The action target is PSD-95. PSD-95 can induce the production of neuroexcitotoxic substances and damage neurons by forming a complex with N-methyl-D-aspartate ("**NMDA**") receptor and neuronal nitric oxide synthase ("**nNOS**"), one of the subtypes of glutamate receptor. SIM0802, as a dimer inhibitor of PSD-95, can simultaneously bind to two PDZ domains in PSD-95 and block the interaction between PSD-95, NMDA and nNOS. Its molecular structure has been optimized to have higher affinity, higher stability and stronger neuroprotective activity.

GENERIC PHARMACEUTICALS

For the year ended December 31, 2023, the Group obtained approvals for four new generic pharmaceuticals, including bedaquiline fumarate tablets (0.1g (calculated by $C_{32}H_{31}BrN_2O_2$)), sevelamer carbonate tablets (0.8g), posaconazole injection (16.7ml:0.3g) and Apremilast tablets (10mg, 20mg and 30mg), and one consistency evaluation application regarding Palonosetron Hydrochloride Injection (5ml:0.25mg (calculated by $C_{19}H_{24}N_2O$)). In addition, the supplemental application of Tofacitinib Citrate Tablets (5mg (calculated by $C_{16}H_{20}N_6O$)) for additional indication (active psoriatic arthritis) has been approved.

INTELLECTUAL PROPERTY RIGHTS

Meanwhile, the Group attaches great importance to the protection of intellectual property rights. For the year ended December 31, 2023, the Group had 310 new patent applications (including domestic and overseas unpublished patent applications), including 300 invention patent applications, three utility model patent applications and seven appearance design patent applications. As of December 31, 2023, the Group has accumulatively obtained 247 invention patents, 95 utility model patents and 27 appearance design patents.

PROFIT FOR THE YEAR ATTRIBUTABLE TO EQUITY SHAREHOLDERS OF THE COMPANY

The profit for the year attributable to equity shareholders of the Company was approximately RMB715 million for 2023, representing a decrease of approximately RMB216 million or approximately 23.2% from approximately RMB931 million for 2022. Such decrease in profit for the year attributable to equity shareholders of the Company was mainly attributable to the following investment projects and one-off gain items: (1) net realized and unrealized losses (before tax) on financial assets at fair value through profit or loss of approximately RMB742 million recorded for 2023 due to the change in fair value of the investment in the shares of 3D Medicines Inc., which is measured based on the closing price of the shares of 3D Medicines as of December 31, 2022 and December 31, 2023, while the net realized and unrealized gains (before tax) on financial assets at fair value through profit or loss recorded for such investment in FY2022 was approximately RMB394 million; and (2) one-off gain (before tax) of approximately RMB789 million recorded by the Group from the disposal of subsidiaries in the first half of 2023.

LIQUIDITY AND FINANCIAL RESOURCES

The Group maintained a sound financial position. As at December 31, 2023, the Group had cash and cash equivalents of approximately RMB2,007 million (as at December 31, 2022: approximately RMB1,658 million), time deposits of approximately RMB12 million (as at December 31, 2022: approximately RMB975 million). As at December 31, 2023, the Group had a balance of bank loans of approximately RMB1,221 million (as at December 31, 2022: approximately RMB1,292 million), of which, RMB1,015 million (as at December 31, 2022: RMB1,292 million) would mature within one year. As of December 31, 2023, all of the Group's bank loans bore interest at fixed rates, and the effective interest rate range for these loans was 0.85% to 2.70% per annum. As at December 31, 2023, the gearing ratio of the Group (total liabilities divided by total assets) was approximately 33.5% (as at December 31, 2022: approximately 33.7%).

Currently, the Group follows a set of funding and treasury policies to manage its capital resources and prevent risks involved. The Group expects to fund its working capital and other capital requirements from a combination of various sources, including but not limited to external financing at reasonable market rates. In order to better control and minimize the cost of funds, the Group's treasury activities are centralized.

The assets and liabilities of the Group were denominated in RMB, USD, GBP and HKD. During the Reporting Period, the Group did not employ financial derivatives or enter into foreign derivative contracts to hedge against foreign exchange risk. However, the Group manages the foreign exchange risks by closely monitoring the net exposure of foreign exchange risk to minimize the impact of foreign exchange fluctuations.

PLEDGE OF GROUP'S ASSETS

As at December 31, 2023, the Group pledged bills receivable of approximately RMB76 million for issuance of bank acceptance bills and pledged bank deposits of approximately RMB53 million for issuance of letter of guarantee. As at December 31, 2023, leasehold land with net book value of approximately RMB113 million was pledged as security for banking facilities, which were not used at the reporting date. Save as disclosed above, as at December 31, 2023, none of the Group's assets were pledged.

CONTINGENT LIABILITIES

As at December 31, 2023, the Group had no contingent liabilities.

SIGNIFICANT INVESTMENTS HELD

During the Reporting Period, the Group did not have any significant investments.

FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

Save as disclosed in "Use of Proceeds from the Listing" in this announcement, as at December 31, 2023, the Group did not have any other future plans for material investments and capital assets.

MATERIAL ACQUISITIONS AND DISPOSALS

For the year ended December 31, 2023, the Group had no material acquisition or disposal of subsidiaries, associates and joint ventures.

EMPLOYEES AND REMUNERATION POLICY

As at December 31, 2023, the Group had a total of 7,027 full-time employees. The Group attached great importance to the recruitment, training and retention of outstanding employees, maintained a high standard in selecting and recruiting talents worldwide, and offered competitive compensation packages. The remuneration of employees mainly included basic salary, performance-based bonus and long- term incentives. Remuneration of the full-time Directors and senior management of the Company shall be determined by the Remuneration and Appraisal Committee under the Board with reference to the principal duties of relevant managerial positions, the results of performance assessment, as well as the remuneration level in the market. For the year ended December 31, 2023, staff costs (including emoluments, social insurance and other benefits of the Directors) amounted to approximately RMB2,402 million. The Group established Simcere Institute, providing employees with training on a regular basis, including orientation programs and technical training for new employees, professional and management training for middle and senior management, and health and safety training across all staff. In addition, the Group has also adopted a restricted share unit scheme on May 20, 2021, with an aim to (1) incentivise the existing and incoming directors, senior management and employees for their contribution to the Group; and (2) attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of the Group by providing them with the opportunity to own equity interests in the Company.

DEFINED CONTRIBUTION RETIREMENT PLAN

The Group only operates defined contribution pension plans. Employees of the Group's PRC subsidiaries are required to participate in a defined contribution retirement plan administered and operated by the local municipal government. The Group's PRC subsidiaries contribute funds which are calculated on certain percentages of the average employee salary as agreed by the local municipal government to the plan to fund the retirement benefits of the employees.

No forfeited contribution (by the Group on behalf of its employees who leave the scheme prior to vesting fully in such contributions) is available to be utilized by the Group to reduce the contributions payable in the future years or to reduce the Group's existing level of contributions to the defined contribution retirement plan.

FINAL DIVIDENDS

On March 20, 2024, the Board declared the payment of final dividend of RMB0.16 per Share for the year ended December 31, 2023 to shareholders whose names are on the register of members of the Company on Tuesday, June 25, 2024. Based on the total number of shares of the Company (the "**Share(s)**") in issue as of the date of this announcement, the total final dividend to be paid by the Company amounts to approximately RMB417,561,858.88. The proposed final dividend will be subject to the approval by the shareholders of the Company (the "**Shareholder(s)**") at the annual general meeting of the Company (the "**AGM**") to be held on Friday, June 14, 2024 and is expected to be distributed to Shareholders on or before Monday, July 15, 2024.

USE OF PROCEEDS FROM THE LISTING

The net proceeds from the initial public offering of the shares of the Company in October 2020 and allotment and issuance of shares of the Company pursuant to the partial exercise of the over-allotment option in November 2020 (the "**Net Proceeds**") amounted to approximately HK$3,513.09 million in aggregate. The proposed use of the net proceeds was disclosed in the prospectus of the Company dated October 13, 2020 (the "**Prospectus**").

The following table sets out the utilization of the Net Proceeds as of the December 31, 2023 and the expected timeline for utilization:

Purpose	Percentage of the total amount	Amount of Net Proceeds received (HK$ in million)	Amount of Net Proceeds utilized during the year ended December 31, 2023 (HK$ in million)	Amount of Net Proceeds utilized as of December 31, 2023 (HK$ in million)	Amount of Net Proceeds unutilized as of December 31, 2023 (HK$ in million)	Expected timeline for utilization
Continued research and development of the Group's selected product candidates in its strategically focused therapeutic areas	60%	2,107.85	378.56	1,575.47	532.38	The actual Net Proceeds are expected to be fully utilized by 2027.
Reinforcement of the Group's sales and marketing capabilities	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Investment in companies in the pharmaceutical or biotechnology sector	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Repayment of certain of the Group's outstanding bank loans	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Working capital and other general corporate purposes	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Total	**100%**	**3,513.09**	**378.56**	**2,980.71**	**532.38**	

For more details, please refer to the section headed "Future Plans and Use of Proceeds — Use of Proceeds" of the Prospectus. On April 15, 2021, the Board resolved to reallocate the net proceeds amounted to approximately HK$325.62 million for the selected cell therapy product candidates, including CD19 CART-cell therapy (Indication 1), CD19 CART-cell therapy (Indication 2), BCMA CART-cell therapy and SIM0325, to the selected oncology product candidates that are currently under development, including COSELA® (SCLC, metastatic CRC and TNBC), SIM0395 and Docetaxel Polymeric Micellar for Injection. On August 31, 2022, the Board resolved to reallocate part of the unutilized Net Proceeds amounted to approximately HK$530 million which originally proposed to be used in selected innovative oncology product candidate at pre-clinical stages (including SIM-200, SIM-203-1, SIM-203-2, SIM-203-3 and SIM-236) to continuous R&D of Sanbexin® sublingual tablets, Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection), XIANNUOXIN® and SIM0278. For details, please refer to the announcements of the Company dated April 15, 2021 and August 31, 2022 in relation to the change in use of proceeds (the "**Announcements**"). As of December 31, 2023, the Net Proceeds utilized was approximately HK$2,980.71 million and the Net Proceeds unutilized was approximately HK$532.38 million. The Company intends to apply the unutilized Net Proceeds as of December 31, 2023 in the manner and proportion set out in the Prospectus and the Announcements.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

The Directors have been granted a general mandate by the Shareholders at the annual general meeting of the Company held on June 15, 2023 (the "**2022 AGM**") to repurchase up to 266,404,561 Shares on the Stock Exchange (the "**Repurchase Mandate**"), representing 10% of the total number of issued Shares as of the date of the 2022 AGM. During the Reporting Period, the Company repurchased a total of 47,323,000 Shares on the Stock Exchange pursuant to the Repurchase Mandate at a total consideration (excluding expenses) of HK$312,456,420.00 (the "**Share Repurchase**"), which was funded by internal resources of the Company. As of the date of this announcement, the 47,323,000 Shares repurchased by the Company during the Reporting Period were all cancelled. Details of the Shares repurchased by the Company during the Reporting Period are as follows:

Month of Share Repurchase	**Total number of Shares repurchased**	**The highest purchase price per Share** *(HK$)*	**The lowest purchase price per Share** *(HK$)*	**Total consideration (excluding expenses)** *(HK$)*
June 2023	7,043,000	7.77	7.20	53,079,460
September 2023	21,028,000	6.62	6.05	134,310,160
October 2023	14,375,000	6.82	5.92	91,606,080
November 2023	2,019,000	7.36	6.80	14,496,730
December 2023	2,858,000	7.15	6.24	18,963,990
Total	**47,323,000**	**–**	**–**	**312,456,420**

The Board believes that the Share Repurchase demonstrates the Company's confidence in its own business outlook and prospects and would, ultimately, benefit the Company and create value to the Shareholders. In addition, the Board believes that the current financial resources of the Company enables it to implement the Share Repurchase while maintaining a solid financial position.

Save as disclosed above, during the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities.

IMPORTANT EVENTS AFTER THE REPORTING PERIOD

On January 1, 2024, Jiangsu Simcere Biologics Co., Ltd. (江蘇先聲生物製藥有限公司) ("**Simcere Biologics**"), an indirectly wholly-owned subsidiary of the Company, entered into the equity transfer agreement with Jiangsu Simcere Diagnostics Technology Co., Ltd. (江蘇先聲診斷技術有限公司) ("**Jiangsu Diagnostics Technology**"), pursuant to which Simcere Biologics has agreed to acquire, and Jiangsu Diagnostics Technology has agreed to sell, the entire equity interest in Nanjing BioSciKin Innovative Medical Technology Co., Ltd. (南京百家匯創新醫療科技有限公司) ("**Nanjing BioSciKin**") for a cash consideration of RMB42,306,500 (the "**Acquisition**"). The Acquisition was completed on January 31, 2024. Since then, Nanjing BioSciKin has become an indirectly wholly-owned subsidiary of the Company. For details, please refer to the announcement of the Company dated January 1, 2024.

On February 24, 2024, the Company, Simcere Pharmaceutical (Shandong) Co., Ltd. (先聲藥業(山東)有限公司) (a directly wholly-owned subsidiary of the Company), Hainan Simcere Pharmaceutical Co., Ltd. (海南先聲藥業有限公司) (an indirectly wholly-owned subsidiary of the Company) and Hainan Simcere Zaiming Pharmaceutical Co., Ltd. (海南先聲再明醫藥股份有限公司) ("**Simcere Zaiming**", formerly known as Simcere Zaiming Pharmaceutical Co., Ltd. (先聲再明醫藥有限公司) and an indirectly wholly-owned subsidiary of the Company before the Capital Contribution) and each of its subsidiaries (collectively, the "**Simcere Zaiming Group**") entered into the capital contribution agreement, the shareholders' agreement and other relevant transaction documents with Future Industry Investment Fund II (Limited Partnership) (先進製造產業投資基金二期(有限合夥)), Shenzhen Zhongshen Xinchuang Equity Investment Partnership (Limited Partnership) (深圳中深新創股權投資合夥企業(有限合夥)), Suzhou Apricot Xingyong Emerging Medical Industry Investment Fund Management Partnership (Limited Partnership) (蘇州杏澤興湧新興醫療產業投資基金管理合夥企業(有限合夥)) and Quanzhou Dingxin Zhonghe Investment Partnership (Limited Partnership) (泉州鼎信中和投資合夥企業(有限合夥)) (collectively, the "**Investors**"). Pursuant to the capital contribution agreement, the Investors have conditionally agreed to make capital contribution, by way of cash, to Simcere Zaiming in the aggregate amount of RMB970 million in return for approximately 11.45% of the enlarged issued share capital of Simcere Zaiming in aggregate (the "**Capital Contribution**"). Upon completion of the Capital Contribution, Simcere Zaiming will become an indirectly wholly-owned subsidiary of the Company and the financial results of Simcere Zaiming will continue to be consolidated into the financial statements of the Group. For details, please refer to the announcement of the Company dated February 24, 2024.

In addition, as a step of pre-completion restructurings of the Capital Contribution, the board of directors and shareholders of Simcere Zaiming have resolved to adopt an employee incentive scheme to recognize the past and present contributions and to incentivize the future contributions by senior management and core employees of Simcere Zaiming Group. On March 20, 2024, the Board has resolved to grant the incentive interest, representing approximately 5% of the enlarged issued share capital of Simcere Zaiming immediately upon completion of the Capital Contribution, to the selected participants by way of subscribing for registered capital in Simcere Zaiming either directly or through the ESOP platform, subject to acceptance by the relevant selected participants. For details, please refer to the announcement of the Company dated March 20, 2024.

Save as disclosed above, after the Reporting Period and up to the date of this announcement, there were no material events affecting the Company or any of its subsidiaries.

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Group is committed to maintaining and promoting stringent corporate governance. The principles of the Group's corporate governance are to promote effective internal control measures, uphold a high standard of ethics, transparency, responsibility and integrity in all aspects of business operation, so as to ensure that its business and operation are conducted in accordance with applicable laws and regulations, enhance the transparency of the Board and strengthen the accountability to all Shareholders. The Group's corporate governance practices are based on the principles and code provisions prescribed in the Corporate Governance Code (the "**CG Code**") as set out in Appendix C1 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**").

Save as disclosed in this announcement, the Group has complied with the code provisions contained in the CG Code for the year ended December 31, 2023.

Under Code Provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive officer should be separate and should not be performed by the same individual. As of December 31, 2023, the roles of Chairman and Chief Executive Officer of the Company were not separated and Mr. REN Jinsheng ("**Mr. REN**") currently performs these two roles. Mr. REN is the founder of the Group, the Chairman of the Board and the Chief Executive Officer of the Company. He has been primarily responsible for developing overall corporate business strategies and business operation of the Group and making significant business and operational decisions of the Group. The Directors jointly consider that vesting the roles of both the Chairman of the Board and the Chief Executive Officer of the Company in Mr. REN is beneficial to the business prospects of the Group by ensuring consistent leadership to the Group as well as prompt and effective decision making and implementation, given that: (1) any decision to be made by the Board requires approval by at least a majority of Directors; (2) Mr. REN and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that he acts for the benefit and in the best interests of the Company and will make decisions for the Company accordingly; (3) the balance of power and authority is ensured by the operations of the Board, which consists of four executive Directors (including Mr. REN) and four independent non-executive Directors, and has a fairly strong independence element; and (4) the overall strategic and other key business, financial, and operational policies of the Company are made collectively after thorough discussion at both Board and senior management levels. The Directors jointly believe that this structure will not impair the balance of power and authority between the Board and the management of the Company.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS

The Group has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix C3 to the Listing Rules as the Company's code of conduct regarding the Directors' securities transactions. Having made specific enquiry of all the Directors of the Company, all the Directors confirmed that they have strictly complied with the Model Code for the year ended December 31, 2023.

AUDIT COMMITTEE AND REVIEW OF FINANCIAL INFORMATION

The Group established the Audit Committee with written terms of reference in compliance with the CG Code. The Audit Committee consists of three members as of the date of this announcement, all of which are independent non-executive Directors, namely Mr. WANG Xinhua, Mr. SONG Ruilin and Mr. WANG Jianguo. The chairperson of the Audit Committee is Mr. WANG Xinhua who possesses the appropriate professional qualifications and accounting and related financial management expertise. The main duties of the Audit Committee are to review and supervise the financial reporting process and internal control system of the Group, oversee the audit process, review and oversee the existing and potential risks of the Group and perform other duties and responsibilities as assigned by the Board.

The Audit Committee has reviewed the financial reporting processes of the Group and the annual results and consolidated financial statements of the Group for the the year ended December 31, 2023, and is of the opinion that these statements have complied with the applicable accounting standards, the Listing Rules and legal requirements, and that adequate disclosure has been made.

SCOPE OF WORK OF KPMG

The financial figures in respect of the Group's consolidated statement of profit or loss, consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position and the related notes thereto for the year ended December 31, 2023 as set out in the preliminary announcement have been agreed by the Group's auditor, KPMG, Certified Public Accountants, to the amounts set out in the Group's consolidated financial statements for the year. The work performed by KPMG in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by KPMG on the preliminary announcement.

ANNUAL GENERAL MEETING

The AGM will be held on Friday, June 14, 2024. A notice convening the AGM will be published and dispatched to the Shareholders in the manner required by the Listing Rules in due course.

CLOSURE OF REGISTER OF MEMBERS

For the purpose of ascertaining the Shareholders' eligibility to attend and vote at the AGM, the register of members of the Company will be closed from Tuesday, June 11, 2024 to Friday, June 14, 2024 (both days inclusive), during which no transfer of Shares will be registered. The record date will be Friday, June 14, 2024. In order to be eligible to attend and vote at the AGM, all transfer documents accompanied by the relevant share certificates must be lodged with the Company's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong Kong for registration not later than 4:30 p.m. on Friday, June 7, 2024.

In order to determine the entitlement of Shareholders to the proposed final dividend, the register of members of the Company will be closed from Thursday, June 20, 2024 to Tuesday, June 25, 2024 (both days inclusive), during which no transfer of Shares will be registered. The record date will be Tuesday, June 25, 2024. All transfer documents together with the relevant share certificates must be lodged with the Company's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Wednesday, June 19, 2024.

PUBLICATION OF THE ANNUAL RESULTS AND ANNUAL REPORT

The annual results announcement is published on the website of the Stock Exchange (www.hkexnews.hk) as well as the website of the Group (www.simcere.com). The Group's 2023 annual report will be dispatched to Shareholders according to their requirements and will be published on the aforementioned websites in due course.

APPRECIATION

The Board would like to express its gratitude to all Shareholders for their understanding, support and trust, with which all employees of the Group, guided by patient needs, will continue to work diligently as one in the long run.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the year ended December 31, 2023

	Note	**2023**	2022
		RMB'000	*RMB'000*
			(restated)
			(Note 15)
Revenue	*4*	**6,607,805**	6,324,082
Cost of sales		**(1,623,652)**	(1,327,404)
Gross profit		**4,984,153**	4,996,678
Other income	*5(a)*	**166,221**	172,814
Other net (loss)/gain	*5(b)*	**(20,636)**	254,264
Research and development costs		**(1,563,138)**	(1,728,283)
Selling and distribution expenses		**(2,356,386)**	(2,402,764)
Administrative and other operating expenses		**(499,279)**	(446,076)
Reversal of impairment loss on trade and other receivables		**867**	13,972
Profit from operations		**711,802**	860,605
Finance income	*6(a)*	**54,960**	59,867
Finance costs	*6(a)*	**(34,568)**	(34,408)
Net finance income		**20,392**	25,459
Share of profits of associates		**5,823**	115
Share of profits of joint ventures		**2,021**	75

	Note	2023	2022
		RMB'000	*RMB'000* (restated) *(Note 15)*
Profit before taxation	*6*	**740,038**	886,254
Income tax	*7*	**(26,088)**	40,478
Profit for the year		**713,950**	926,732
Attributable to:			
Equity shareholders of the Company		**714,761**	930,868
Non-controlling interest		**(811)**	(4,136)
Profit for the year		**713,950**	926,732
Earnings per share	*8*		
Basic (RMB)		**0.27**	0.36
Diluted (RMB)		**0.27**	0.36

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2023

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Profit for the year	**713,950**	926,732
Other comprehensive income for the year (after tax adjustments)		
Items that will not be reclassified to profit or loss:		
Financial assets at fair value through other comprehensive income (FVOCI) – net movement in fair value reserves (non-recycling), net of tax	**31,045**	(156,346)
Exchange difference on translation of company level financial statements	**36,306**	142,973
Items that will be reclassified to profit or loss:		
Exchange difference on translation of financial statements of overseas subsidiaries	**10,109**	33,840
Other comprehensive income for the year	**77,460**	20,467
Total comprehensive income for the year	**791,410**	947,199
Attributable to:		
Equity shareholders of the Company	**792,221**	951,335
Non-controlling interest	**(811)**	(4,136)
Total comprehensive income for the year	**791,410**	947,199

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	**December 31, 2023**	December 31, 2022
		RMB'000	*RMB'000*
			(restated)
			(Note 15)
Non-current assets			
Property, plant and equipment		**2,170,339**	2,138,952
Intangible assets		**715,786**	379,896
Goodwill		**142,474**	172,788
Interest in associates		**52,502**	4,978
Interest in joint ventures		**98,069**	4,477
Prepayments, deposits and other receivables		**188,954**	97,470
Financial assets at fair value through other comprehensive income		**174,267**	137,774
Financial assets at fair value through profit or loss		**1,254,331**	2,056,700
Loan to a third party		**100,326**	–
Time deposits	*10(c)*	**673**	10,752
Deferred tax assets		**317,002**	326,713
		5,214,723	5,330,500
Current assets			
Inventories		**614,562**	304,780
Contract assets		**13,000**	–
Trade and bills receivables	*9*	**2,631,645**	2,338,830
Prepayments, deposits and other receivables		**286,777**	165,860
Taxation recoverable		**–**	6,506
Pledged deposits	*10(b)*	**52,513**	560
Restricted deposits	*10(b)*	**22,148**	19,378
Time deposits	*10(c)*	**11,137**	964,226
Cash and cash equivalents	*10(a)*	**2,007,162**	1,658,312
		5,638,944	5,458,452

	Note	December 31, 2023 RMB'000	December 31, 2022 RMB'000 (restated) (Note 15)
Current liabilities			
Bank loans	*11*	**1,015,133**	1,292,067
Lease liabilities		**79,848**	58,756
Trade and bills payables	*12*	**317,218**	335,433
Other payables and accruals	*13*	**1,229,812**	1,269,800
Taxation payable		**17,899**	10,562
Provisions		**25,990**	–
		2,685,900	2,966,618
Net current assets		**2,953,044**	2,491,834
Total assets less current liabilities		**8,167,767**	7,822,334
Non-current liabilities			
Bank loans	*11*	**205,846**	–
Lease liabilities		**128,397**	155,921
Deferred income		**393,112**	403,350
Deferred tax liabilities		**102,676**	115,291
Other non-current liability		**115,000**	–
		945,031	674,562
NET ASSETS		**7,222,736**	7,147,772

	December 31, 2023	December 31, 2022
	RMB'000	*RMB'000* (restated) *(Note 15)*
CAPITAL AND RESERVES		
Share capital	**3,173,805**	3,081,131
Reserves	**4,048,931**	4,050,579
Total equity attributable to equity shareholders of the Company	**7,222,736**	7,131,710
Non-controlling interest	**–**	16,062
TOTAL EQUITY	**7,222,736**	7,147,772

NOTES TO THE FINANCIAL STATEMENTS

(Expressed in Renminbi)

1 GENERAL INFORMATION

Simcere Pharmaceutical Group Limited (the "**Company**") was incorporated in Hong Kong on November 30, 2015 as a limited liability company with its registered office at Room 703, 7/F, Block 20E, Hong Kong Science Park Phase 3, Pak Shek Kok, New Territories, Hong Kong. The Company's shares were listed on the Main Board of the Stock Exchange of Hong Kong Limited on October 27, 2020. The Company is an investment holding company. The Company and its subsidiaries (together, "**the Group**") are principally engaged in the research and development, manufacturing and sales of pharmaceutical products as well as rendering promotion service of pharmaceutical products that are not manufactured by the Group.

2 STATEMENT OF COMPLIANCE AND BASIS OF PREPARATION

These financial statements have been prepared in accordance with all applicable Hong Kong Financial Reporting Standards ("**HKFRSs**") which collective term includes all applicable individual Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards ("**HKAS**") and Interpretations issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**") and the requirements of the Hong Kong Companies Ordinance. These financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

The financial information relating to the financial year ended December 31, 2023 and 2022 that is included in this preliminary annual results announcement does not constitute the Company's statutory annual consolidated financial statements for those years but is derived from those financial statements. Further information relating to these statutory financial statements required to be disclosed in accordance with section 436 of the Companies Ordinance is as follows:

The Company has delivered the financial statements for the year ended December 31, 2022 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Companies Ordinance and will deliver the financial statements for the year ended December 31, 2023 in due course.

The Company's auditor has reported on the consolidated financial statements of the Group for both years. The auditor's reports were unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its reports; and did not contain a statement under sections 406(2), 407(2) or (3) of the Companies Ordinance.

The HKICPA has issued certain amendments to HKFRSs that are first effective or available for early adoption for the current accounting period of the Group. Note 3 provides information on any changes in accounting policies resulting from initial application of these developments to the extent that they are relevant to the Group for the current accounting periods reflected in these financial statements.

The consolidated financial statements of the Group for the year ended December 31, 2023 comprise the Company and its subsidiaries and the Group's interest in associates and joint ventures.

3 CHANGES IN ACCOUNTING POLICIES

The HKICPA has issued the following new and amended HKFRSs that are first effective for the current accounting period of the Group:

- HKFRS 17, *Insurance contracts*
- Amendments to HKAS 8, *Accounting policies, changes in accounting estimates and errors: Definition of accounting estimates*
- Amendments to HKAS 1, *Presentation of financial statements* and HKFRS Practice Statement 2, *Making materiality judgements: Disclosure of accounting policies*
- Amendments to HKAS 12, *Income taxes: Deferred tax related to assets and liabilities arising from a single transaction*
- Amendments to HKAS 12, *Income taxes: International tax reform – Pillar Two model rules*

In July 2023, the HKICPA published "Accounting implications of the abolition of the MPF-LSP offsetting mechanism in Hong Kong" that provides guidance on the accounting considerations relating to the offsetting mechanism and the abolition of the mechanism.

Apart from the impacts of the adoption of the amended HKFRSs discussed below, none of these developments have had a material effect on how the Group's results and financial position for the current or prior periods have been prepared or presented. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

Amendments to HKAS 1, *Presentation of financial statements* and HKFRS Practice Statement 2, *Making materiality judgements: Disclosure of accounting policies*

The amendments require entities to disclose material accounting policy information and provide guidance on applying the concept of materiality to accounting policy disclosure. The Group has revisited the accounting policy information it has been disclosing and considered it is consistent with the amendments.

Amendments to HKAS 12, *Income taxes: Deferred tax related to assets and liabilities arising from a single transaction*

The amendments narrow the scope of the initial recognition exemption such that it does not apply to transactions that give rise to equal and offsetting temporary differences on initial recognition such as leases and decommissioning liabilities. For leases and decommissioning liabilities, the associated deferred tax assets and liabilities are required to be recognized from the beginning of the earliest comparative period presented, with any cumulative effect recognized as an adjustment to retained earnings or other components of equity at that date. For all other transactions, the amendments are applied to those transactions that occur after the beginning of the earliest period presented.

Prior to the amendments, the Group did not apply the initial recognition exemption to lease transactions and had recognized the related deferred tax, except that the Group previously determined the temporary difference arising from a right-of-use asset and the related lease liability on a net basis on the basis they arise from a single transaction. Following the amendments, the Group has determined the temporary differences in relation to right-of-use assets and lease liabilities separately. The change primarily impacts disclosures of components of deferred tax assets and liabilities, but does not impact the overall deferred tax balances presented in the consolidated statement of financial position as the related deferred tax balances qualify for offsetting under HKAS 12.

4 REVENUE AND SEGMENT REPORTING

(a) Revenue

(i) Disaggregation of revenue

Disaggregation of revenue from contracts with customers by business lines is as follows:

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Revenue from contracts with customers within the scope of HKFRS 15		
Sales of pharmaceutical products	**5,974,933**	5,617,050
Promotion service income	**591,407**	601,487
License income	**28,465**	105,545
Research service income	**13,000**	–
	6,607,805	6,324,082

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Timing of revenue recognition		
At a point in time	**6,594,805**	6,324,082
Over time	**13,000**	–
	6,607,805	6,324,082

The Group's customer base is diversified and nil (2022: nil) customers with whom transactions have exceeded 10% of the Group's revenues for the year ended December 31, 2023.

(ii) Revenue expected to be recognized in the future arising from contracts with customers in existence at the reporting date

The Group has applied the practical expedient in paragraph 121 of HKFRS 15 to its sales contracts for goods such that information about revenue expected to be recognized in the future is not disclosed in respect of revenue that the Group will be entitled to when it satisfies the remaining performance obligations under the contracts for sales of goods that had an expected duration of one year or less.

(b) Segment reporting

Operating segments are identified on the basis of internal reports that the Group's most senior executive management reviews regularly in allocating resources to segments and in assessing their performances.

The Group's most senior executive management makes resources allocation decisions based on internal management functions and assess the Group's business performance as one integrated business instead of by separate business lines or geographical regions. Accordingly, the Group has only one operating segment and therefore, no segment information is presented.

HKFRS 8, *Operating Segments*, requires identification and disclosure of information about an entity's geographical areas, regardless of the entity's organization (i.e. even if the entity has a single reportable segment). The Group operates within one geographical location because primarily all of its revenue was generated in the PRC and primarily all of its non-current operating assets and capital expenditure were located/incurred in the PRC. Accordingly, no geographical information is presented.

5 OTHER INCOME AND OTHER NET (LOSS)/GAIN

(a) Other income

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Government grants *(Note)*	**134,181**	125,172
Rental income	**5,070**	17,738
Property management income	**7,053**	11,573
Consulting and technology service income	**11,450**	6,682
Others	**8,467**	11,649
	166,221	172,814

Note:

During the year ended December 31, 2023, the Group received unconditional government grants of RMB90,952,000 (2022: RMB80,130,000) as rewards of the Group's contribution to technology innovation and regional economic development.

During the year ended December 31, 2023, the Group received conditional government grants of RMB26,181,000 (2022: RMB1,927,000) as subsidies for construction and equipment and recognized such grants of RMB32,843,000 (2022: RMB33,894,000) in the consolidated statements of profit or loss when related conditions were satisfied. During the year ended December 31, 2023, the Group received conditional government grants of RMB7,450,000 (2022: RMB32,942,000) as encouragement of technology research and development and recognized such type of grants of RMB10,386,000 (2022: RMB11,148,000) in the consolidated statements of profit when related conditions were satisfied.

(b) Other net (loss)/gain

	2023	2022
	RMB'000	*RMB'000*
Net foreign exchange loss	**(13,283)**	(57,215)
Net gain/(loss) on disposal of property, plant and equipment	**2,433**	(10,571)
Net realized and unrealized (losses)/gains on financial assets at fair value through profit or loss	**(744,816)**	113,112
Compensation from contract termination	**–**	208,938
Net gain on disposal of interest in subsidiaries *(Note i)*	**789,491**	–
Impairment loss on a manufacturing plant *(Note ii)*	**(6,871)**	–
Impairment loss on prepayments	**(21,600)**	–
Provision for litigations	**(25,990)**	–
	(20,636)	254,264

Notes:

(i) On February 24, 2023, the Group entered into an agreement with a third party to dispose its 50% equity interest in BCY Pharm Co., Ltd. ("**BCY**"), one of its controlled subsidiaries, at consideration of RMB200,000,000. Upon the completion of the disposal in March 2023, the Group lost its control on BCY and recognized the remaining 13.57% equity interest in BCY, which amounted to RMB54,150,000, as a financial asset measured at fair value through profit or loss. The net gain on disposal of interest in BCY was RMB197,222,000.

On April 13, 2023, the Group entered into an agreement with a third party to dispose its total equity interest in Simcere (Shanghai) Pharmaceutical Co., Ltd. ("**Simcere (Shanghai)**") at consideration of RMB926,865,000. The disposal was completed in May 2023. The net gain on disposal of interest in Simcere (Shanghai) was RMB592,269,000.

(ii) The Group terminated the operation of one of its manufacturing plants located in the PRC in 2023. A loss of RMB6,871,000 was recorded in the consolidated statement of profit or loss during the year ended December 31, 2023 including the impairment of property, plant and equipment of RMB4,876,000 and scrapped inventories of RMB1,995,000.

6 PROFIT BEFORE TAXATION

Profit before taxation is arrived at after charging/(crediting):

(a) Net finance income

	2023	2022
	RMB'000	*RMB'000*
Interest income from bank deposits	**(54,960)**	(59,867)
Finance income	**(54,960)**	(59,867)
Interest expenses on bank loans	**27,055**	27,654
Interest expenses on lease liabilities	**7,513**	6,754
Finance costs	**34,568**	34,408
Net finance income	**(20,392)**	(25,459)

(b) Staff costs

	2023	2022
	RMB'000	*RMB'000* (restated) *(Note 15)*
Salaries, wages and other benefits	**2,253,154**	1,903,727
Contributions to defined contribution retirement plans *(Note)*	**137,048**	95,265
Equity settled share-based payment expenses	**12,119**	138,290
	2,402,321	2,137,282

Note:

Employees of the Group's PRC subsidiaries are required to participate in a defined contribution retirement plans administered and operated by the local municipal government. The Group's PRC subsidiaries contribute funds which are calculated on certain percentages of the average employee salary as agreed by the local municipal government to the plan to fund the retirement benefits of the employees.

The Group's contributions to the defined contribution retirement plans are expensed as incurred and not reduced by contributions forfeited by those employees who leave the plans prior to vesting fully in the contributions. The Group has no other material obligation for the payment of retirement benefits associated with the scheme beyond the annual contributions described above.

(c) Other items

	2023	2022
	RMB'000	*RMB'000* (restated) *(Note 15)*
Cost of inventories recognized as expenses *(Note i)*	**1,173,985**	884,571
Depreciation charge		
– owned property, plant and equipment	**214,286**	209,036
– right-of-use assets	**77,221**	59,626
Amortization of intangible assets	**18,087**	14,985
Research and development costs *(Note ii)*	**1,563,138**	1,728,283
Reversals of impairment on trade and other receivables	**(867)**	(13,972)
Auditors' remuneration		
– audit services	**4,940**	4,200
– non-audit services	**234**	294

Notes:

(i) Cost of inventories recognized as expenses includes amounts relating to staff costs, depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in Note 6(b) for each of these types of expenses.

(ii) Research and development costs include amounts relating to staff costs, depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in Note 6(b) for each of these types of expenses.

7 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

Taxation in the consolidated statements of profit or loss represents:

	2023	2022
	RMB'000	*RMB'000*
Current tax		
PRC Corporate Income Tax		
Provision for the year	**27,249**	11,262
Over provision in respect of prior years	**(4,927)**	(13,677)
	22,322	(2,415)
Overseas Corporate Income Tax		
Provision for the year	**1,704**	9
Deferred tax		
Origination and reversal of temporary differences	**2,062**	(38,072)
Total income tax	**26,088**	(40,478)

Income tax for the PRC operations is charged at the statutory rate of 25% of the assessable profits under tax rules and regulations in the PRC. Certain PRC subsidiaries are subject to a preferential income tax of 15% under the relevant tax rules and regulations.

Taxation in other jurisdiction is calculated at the rates prevailing in the relevant jurisdictions.

8 EARNINGS PER SHARE

(a) Basic earnings per share

The calculation of basic earnings per share is based on the profit attributable to equity shareholders of the Company of RMB714,761,000 (2022: RMB930,868,000, as restated) and the weighted average of 2,608,533,908 ordinary shares (2022: 2,611,171,592 shares) in issue during the year, calculated as follows:

Weighted average number of ordinary shares

	2023	2022
Issued ordinary shares at January 1	**2,660,376,618**	2,628,290,618
Effect of shares issued to Trustee	**2,362,233**	17,704,132
Effect of purchase of own shares	**(13,192,041)**	–
Effect of vested shares under 2021 RSU Scheme	**3,603,748**	2,529,974
Effect of unvested shares under 2021 RSU Scheme	**(44,616,650)**	(37,353,132)
Weighted average number of ordinary shares at December 31	**2,608,533,908**	2,611,171,592

(b) Diluted earnings per share

The calculation of diluted earnings per share is based on the profit attributable to equity shareholders of the Company of RMB714,761,000 (2022: RMB930,868,000, as restated) and the weighted average of ordinary shares of 2,608,533,908 shares (2022: 2,620,375,892 shares), calculated as follows:

Weighted average number of ordinary shares (diluted)

	2023	2022
Weighted average number of ordinary shares at 31 December	**2,608,533,908**	2,611,171,592
Effect of deemed issuance of shares under 2021 RSU scheme for nil consideration	**–**	9,204,300
Weighted average number of ordinary shares (diluted) at 31 December	**2,608,533,908**	2,620,375,892

9 TRADE AND BILLS RECEIVABLES

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Trade receivables	**1,996,245**	1,872,701
Bills receivable	**658,575**	490,804
	2,654,820	2,363,505
Less: loss allowance	**(23,175)**	(24,675)
	2,631,645	2,338,830

All of the trade and bills receivables are expected to be recovered within one year.

As at December 31, 2023, bills receivable of RMB75,977,000 were pledged for issuance of bills payable (2022: RMB115,465,000).

Aging analysis

As of the end of the reporting period, the aging analysis of trade and bills receivables, based on the invoice date and net of loss allowance, is as follows:

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Within 3 months	**2,014,485**	1,822,014
Over 3 months but within 6 months	**564,369**	514,009
Over 6 months but within 9 months	**47,761**	1,739
Over 9 months but within 12 months	**5,030**	418
Over 12 months	**–**	650
	2,631,645	2,338,830

Trade and bills receivables are due within 30 – 90 days from the date of billing.

10 CASH AND CASH EQUIVALENTS, PLEDGED DEPOSITS, RESTRICTED DEPOSITS, AND TIME DEPOSITS

(a) Cash and cash equivalents comprise:

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Cash at bank	**2,007,162**	1,658,312

As at December 31, 2023, cash and cash equivalents situated in Chinese Mainland amounted to RMB1,843,969,000 (2022: RMB1,495,666,000). Remittance of funds out of Chinese Mainland is subject to relevant rules and regulations of foreign exchange control.

(b) Pledged deposits and restricted deposits comprise:

	2023	2022
	RMB'000	*RMB'000*
Pledged deposits for		
– issuance of letter of guarantee	**52,513**	560

	2023	2022
	RMB'000	*RMB'000*
Restricted deposits for		
– research and development projects	**7,926**	13,435
– litigations	**3,990**	–
– 2021 RSU Scheme	**10,232**	5,943
	22,148	19,378

(c) Time deposits comprise:

	2023	2022
	RMB'000	*RMB'000*
Current portion	**11,137**	964,226
Non-current portion	**673**	10,752
	11,810	974,978

11 BANK LOANS

The maturity profile for the interest-bearing bank loans of the Group at the end of each reporting period is as follows:

	2023	2022
	RMB'000	*RMB'000*
Short-term bank loans	**762,427**	1,183,700
Current portion of long-term bank loans	**252,706**	108,367
Within 1 year or on demand	**1,015,133**	1,292,067
After 1 year but within 2 years	**197,655**	–
After 2 years but within 5 years	**1,965**	–
After 5 years	**6,226**	–
	205,846	–
	1,220,979	1,292,067

Notes:

(i) As at December 31, 2023 and 2022, the bank loans were unsecured.

(ii) Fulfilment of loan covenants

Certain banking facilities of the Group are subject to the fulfilment of certain covenants, as are commonly found in lending arrangements with financial institutions. The Group regularly monitors its compliance with these covenants. As at December 31, 2023 and 2022, none of the covenants relating to drawn down facilities was breached.

12 TRADE AND BILLS PAYABLES

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Trade payables	**228,585**	227,148
Bills payable	**88,633**	108,285
	317,218	335,433

As of the end of the reporting period, the aging analysis of trade and bills payables, based on the invoice date, is as follows:

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Within 3 months	**220,812**	240,701
3 to 12 months	**94,377**	93,289
Over 12 months	**2,029**	1,443
	317,218	335,433

All of the trade and bills payables are expected to be settled within one year or repayable on demand.

13 OTHER PAYABLES AND ACCRUALS

	2023	2022
	RMB'000	*RMB'000*
		(restated)
		(Note 15)
Accrued expenses *(Note i)*	**495,241**	583,739
Contract liabilities *(Note ii)*	**43,311**	63,338
Payable for employee reimbursements	**18,236**	28,884
Payables for staff related costs	**335,832**	335,601
Payables for purchase of property, plant and equipment	**29,675**	21,877
Other tax payables	**152,670**	134,133
Payables for research and development costs	**43,516**	41,695
Payable for in-licensed rights	**47,170**	–
Others	**64,161**	60,533
	1,229,812	1,269,800

All of the other payables and accruals are expected to be settled within one year or repayable on demand.

Notes:

(i) Accrued expenses primarily comprise marketing and promotion expenses, research and development costs and other expenses.

(ii) Contract liabilities represent customers' advances received for goods that have not yet been transferred to the customers.

14 DIVIDENDS

(i) Dividend payable to equity shareholders of the Company attribute to the year:

	2023	2022
	RMB'000	*RMB'000*
Dividends proposed after the end of the reporting period of RMB0.16 per ordinary share (2022: RMB0.16 per ordinary share)	**418,675**	425,660
Less: Dividends for unvested shares under 2021 RSU scheme	**(5,462)**	(6,761)
	413,213	418,899

The final dividend proposed after the end of the reporting period has not been recognized as a liability at the end of the reporting period.

(ii) Dividends payable to equity shareholders of the Company attributable to the previous financial years, declared and approved during the year:

	2023	2022
	RMB'000	*RMB'000*
Dividends in respect of previous financial years approved and paid during the year, of RMB0.16 per share (2022: RMB0.15 per share)	**419,218**	391,296

15 BUSINESS COMBINATION UNDER COMMON CONTROL

In November 2023, the Group agreed to acquire the entire equity interest of Nanjing Jiayuantang Biotechnology Co., Ltd., which is principally engaged in manufacturing and sales of healthcare products in the PRC, from Jiangsu Xianhui Pharmaceutical Research Co., Ltd. at a consideration of RMB5,022,600. The acquisition was completed on November 17, 2023. Upon completion of the acquisition, Nanjing Jiayuantang Biotechnology Co., Ltd. and its subsidiary (together, "**Nanjing Jiayuantang Group**") became subsidiaries of the Group. As Nanjing Jiayuantang Group and the Group was ultimately controlled by Mr. Ren Jinsheng before and after the business combination and the control is not transitory, the acquisition of Nanjing Jiayuantang Group was considered as a business combination involving entities under common control.

The Group has consistently adopted the accounting policy for business combination under common control that merger accounting is applied to account for the acquisition of Nanjing Jiayuantang Group in preparing the financial statements of the Group. By applying the principles of merger accounting, the comparative amounts in the consolidated financial statements are presented as if the entities or businesses had been consolidated at the earliest balance sheet date presented or when they first came under common control, whichever is later.

The financial position previously reported by the Group as December 31, 2022 has been restated to include the assets and liabilities of the combining entities recognized at the carrying value based on the controlling shareholder's financial statements.

The financial performance previously reported by the Group for the year ended December 31, 2022 have been restated to include the operating results of the combining entities from the earliest date presented or since the date when combining entities first came under common control, where this is a shorter period, regardless of the date of the common control combination.

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

Hong Kong, March 20, 2024

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; and Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.