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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 INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2022

## **BUSINESS HIGHLIGHTS**

Our innovative pharmaceutical portfolio has expanded to six products. In July 2022, the new COSELA<sup>®</sup> (Trilaciclib hydrochloride for injection) obtained the conditional approval for marketing. For the six months ended June 30, 2022, our revenue amounted to approximately RMB2,700 million, representing an increase of approximately 27.3% as compared with that for the same period of last year, of which revenue from innovative pharmaceuticals amounted to RMB1,767 million, contributing 65.4% of the total revenue for the same period and representing an increase of approximately 44.8% as compared to the revenue from innovative pharmaceuticals for the same period of last year. Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection) enhanced our leading market position in the field of nervous system by driving revenue from nervous system products to increase approximately 74.7% as compared with the same period of last year. Meanwhile, the revenue contribution from ENWEIDA and other products further testified our commercialization ability.

Focusing on higher efficiency and persisting in differentiation, we have rapidly promoted nearly 60 innovative drug research pipelines. For the six months ended June 30, 2022, we added 5 INDs, completed FPI/FIH for 9 trials, and enrolled over 1,000 patients for clinic trials. As of the date of this announcement, the phase III pivotal clinical trial of Sanbexin sublingual tablets completed all patients enrollment in only 10 months, while the anti-COVID-19 pharmaceutical candidate SIM0417(3CL) is carrying out phase III clinical trials.

## FINANCIAL HIGHLIGHTS

For the six months ended June 30, 2022, the Group recorded the following unaudited financial results:

- Revenue of approximately RMB2,700 million, representing an increase of approximately 27.3% as compared with that for the same period of last year;
- Research and development costs of approximately RMB652 million, representing an increase of approximately 3.9% as compared with that for the same period of last year, and accounting for approximately 24.1% of the revenue;
- Profit for the period of approximately RMB62 million, representing a decrease of approximately 88.8% as compared with that for the same period of last year;
- Basic earnings per share of approximately RMB0.02, representing a decrease of approximately 90.5% as compared with that for the same period of last year.

The board of directors (the "**Board**" or the "**Directors**") of Simcere Pharmaceutical Group Limited (the "**Company**") is pleased to announce the unaudited condensed consolidated financial results of the Company together with its subsidiaries (collectively the "**Group**") for the six months ended June 30, 2022 (the "**Reporting Period**" or the "**Period**"), together with the comparative figures for the corresponding period in 2021. The unaudited condensed consolidated financial information for the Reporting Period have been reviewed by the audit committee of the Company (the "**Audit Committee**").

## **COMPANY OVERVIEW**

Simcere Pharmaceutical Group Limited is an innovation and R&D-driven pharmaceutical company, has R&D, production and professional marketing capabilities.

The Group focuses on three therapeutic areas including oncology, nervous system, and autoimmune with forward-looking layout of disease areas that have significant clinical needs in the future. In these three major areas, the Group has 6 innovative pharmaceuticals approved for marketing and sale (including 2 imported innovative pharmaceuticals). As of June 30, 2022, the Group has over 10 products included in over 90 guidelines and pathways issued by government authorities or prestigious professional associations, and has over 40 products included in the Drugs Catalogue for the National Reimbursement Drug List (the "**NRDL**").

The Group pays high attention to the building of innovative pharmaceutical R&D capability, has realized functions covering the whole process from drug discovery, preclinical development, clinical trial to registration, and has established a State Key Laboratory of Translational Medicine and Innovative Drug Development. The Group has established R&D innovation centers in Shanghai, Nanjing, Beijing and Boston. The Group has nearly 60 innovative pharmaceutical R&D pipelines, and is conducting 20 registration clinical trials for 16 potential innovative pharmaceuticals. As of the date of this announcement, the Group had a R&D team of approximately 1,100 persons in total.

The Group has leading commercial capabilities with a nationwide sales and distribution network. As innovative pharmaceuticals continue to be approved for marketing, the Group has constantly enhanced training and improved the professional academic promotion capabilities of its marketing team so as to ensure the speed and efficiency of commercial promotion and to increase product coverage. As of the date of this announcement, the Group had a total of approximately 4,400 sales persons across 31 provinces, municipalities and autonomous regions in China, covering over 2,700 Class III hospitals, approximately 17,000 other hospitals and medical institutions, as well as more than 200 large-scale national or regional pharmacy chains in China.

The Group establishes manufacturing infrastructures and quality control standards in line with international standards and has continuously improved its manufacturing capabilities of pharmaceuticals. The Group has put into use of 5 PRC GMP certified production facilities for the manufacturing of its pharmaceutical products, and has received EU GMP certification or passed the U.S. FDA inspection for some of its production workshops.

Driven by our in-house R&D efforts and R&D collaborations, the Group continuously develops products that patients urgently need and have significant market potential, striving to perform the corporate mission of "providing today's patients with medicines of the future".

## **MAJOR PRODUCTS**

Nervous System Products	Sanbexin <sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection)
Oncology Products	Endostar <sup>®</sup> (Recombinant Human Endostatin Injection) ENWEIDA <sup>®</sup> (Envafolimab Injection) COSELA <sup>®</sup> (Trilaciclib Hydrochloride for Injection)
Autoimmune Products	Iremod <sup>®</sup> (Iguratimod Tablets) ANTINE <sup>®</sup> (Diclofenac Sodium Sustained Release Capsules/Gel) Orencia <sup>®</sup> (Abatacept Injection)
Other Products	Softan <sup>®</sup> (Rosuvastatin Calcium Tablets) ZAILIN <sup>®</sup> (Amoxicillin Granules/Dispersible Tablets/Capsules)

## MANAGEMENT DISCUSSION AND ANALYSIS

## **INDUSTRY REVIEW**

In the first half of 2022, the "Linkage of Three Medical Systems" regarding medical care, medical insurance and medicine has been deepened with various emerging variables such as the COVID-19 pandemic, international and domestic macro political and economic environment. China's medical innovation is at a "critical period". The reform of centralized and volume-based procurement has been accelerated into a new stage of normalization and institutionalization. The innovation and development of the pharmaceutical industry has been sped up to promote pharmaceutical enterprises to optimize R&D pipelines, increase R&D investment. The implementation of policies such as the 14th Five-Year Plan for Bio-Economic Development (《"十四五"生物經濟發展規劃》), the Work Plan for the Adjustment to 2022 Catalogue of Drugs for National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《2022年國家基本醫療保險、工傷保 險和生育保險藥品目錄調整工作方案》) and the Guiding Principles for Clinical Research and Development of anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤 藥物臨床研發指導原則》) guides enterprises to avoid low-level repetitive follow-up research and development, encourages more differentiated innovative drugs to enter medical insurance quickly, promotes a virtuous cycle of input-output of innovative drugs, and creates more space for development of the pharmaceutical enterprises which continuously markets innovative drugs and pursues actual clinical value.

## **KEY MILESTONES**

During the six months ended June 30, 2022, the Group made a series of advances in respect of its product candidates and business operations, including the following key milestones and achievements:

- January 29, 2022 SIM0235 (TNFR2) obtained the Investigational New Drug ("IND") approval issued by the U.S. Food and Drug Administration ("FDA"), which is intended to be used for clinical trials of advanced solid tumors and cutaneous T-cell lymphoma ("CTCL"). This is the Group's first self-developed drug ,which was approved for clinic trials by FDA.
- February 23, 2022 A randomized, double-blind, placebo-controlled, multi-center phase III clinical trial (TRACES study) evaluating safety, efficacy and pharmacokinetics of Trilaciclib Hydrochloride for Injection in extensive small-cell lung cancer ("**ES-SCLC**") patients who are receiving carboplatin in combination with etoposide or topotecan treatment, has met the primary endpoint in clinical study.
- February 24, 2022 SIM0408(QPCT) obtained the Clinical Trial Approval issued by the National Medical Products Administration of China (the"NMPA") in China, and is proposed for the treatment of mild cognitive impairment ("MCI") and dementia at mild stage caused by Alzheimer's disease ("AD").
- March 18, 2022 The Group entered into a cooperation agreement with Lynk Pharmaceuticals Co., Ltd., pursuant to which, the Group will obtain the exclusive commercial promotion right of selective JAK1 inhibitor for rheumatoid arthritis and ankylosing spondylitis indications in China.
- March 21, 2022 The anti-tumor oral protein arginine methyltransferase 5 ("**PRMT5**") inhibitor SIM0272 self-developed by the Group has obtained the Clinical Trial Approval issued by the NMPA, which is intended to be used in the clinical trial for the treatment of advanced malignant tumors.
- March 28, 2022 SIM0417, a candidate drug against severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2"), for which the Group holds license from Shanghai Institute of Materia Medica and Wuhan Institute of Virology, Chinese Academy of Sciences, obtained approval from the NMPA to conduct the clinical trial on Mild-to-Moderate patients affected Coronavirus Disease 2019 ("COVID-19") at a high risk of developing severe illness (including hospitalization or death).
- May 13, 2022 SIM0417 further obtained the Clinical Trial Approval issued by the NMPA in China, and is proposed for Post-exposure prophylaxis for close contacts of individuals who test positive for COVID-19.

From the end of the Reporting Period to the date of this announcement, the Group reached the following milestones:

July 12, 2022 The marketing of COSELA<sup>®</sup> (generic name: Trilaciclib Hydrochloride for Injection) in China, which is a cyclin-dependent kinase CDK4/6 inhibitor developed by the Group in collaboration with G1 Therapeutics, INC. ("G1 Therapeutics"), has obtained the conditional approval by the NMPA. As the first therapy with function of protecting existing bone marrow when administered prior to treatment with chemotherapy, COSELA<sup>®</sup> will protect more cancer patients by reducing the damage caused by chemotherapy to bone marrow hematopoietic stem/progenitor cells and immune cells, thereby will fill a gap in the market.

For details of each milestone above, please refer to this announcement and, where appropriate, previous announcements of the Company published on the websites of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company.

## REVENUE

For the six months ended June 30, 2022, the revenue of the Group was approximately RMB2,700 million. In particular, the revenue from innovative pharmaceuticals became the main source of revenue for the Group, and amounted to approximately RMB1,767 million, representing a vigorous increase of approximately 44.8% as compared to the revenue from innovative pharmaceuticals for the same period of 2021. The revenue from innovative pharmaceuticals contributed 65.4% of the total revenue for the same period to set a historic high (45.1% and 62.4% for 2020 and 2021, respectively).

The Group's revenue primarily concentrated on the strategically focused therapeutic areas: nervous system, oncology and autoimmune. The Group generates revenue from sales of pharmaceutical products and provision of promotion services. The increase of our total revenue during the first half of 2022 was mainly due to the rapid increase in revenue from an innovative drug Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection).

### **Nervous System Products**

Main products in this therapeutic area include Sanbexin<sup>®</sup>. For the six months ended June 30, 2022, revenue from sales of pharmaceutical products from the nervous system product portfolio reached approximately RMB1,040 million, accounting for approximately 38.5% of the Group's total revenue.

## Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection)

Sanbexin<sup>®</sup> is a category I innovative drug developed by the Group with proprietary intellectual property right, which was approved to marketing in China in July 2020 and used to treat Acute Ischemic Stroke ("AIS"). According to Frost & Sullivan, it is the only pharmaceutical for the treatment of stroke which has obtained the approval worldwide since 2015. On December 28, 2020, Sanbexin<sup>®</sup> was included in the NRDL. In 2021, data from the results of phase III TASTE clinical trial relating to Sanbexin<sup>®</sup> were published in STROKE, a leading international authoritative medicine journal. In the same year, Sanbexin<sup>®</sup> was recommended by the Specialists' Consensus on the Clinical Assessment and Treatment of Acute Cerebral Infarction Ischemic Penumbra in China and Guidelines on Primary Diagnosis and Treatment of Ischemic Stroke (Practical Edition, 2021) 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**").

- The TASTE II study (for evaluation of the efficacy and safety of Sanbexin<sup>®</sup> combined with reperfusion in the treatment of AIS patients), led by Beijing Tiantan Hospital, Capital Medical University with the participation of approximately 100 research centers in China, has progressed as planned. On March 21, 2022, the study completed the first patient in ("**FPI**") for the clinical trial. As of the date of this announcement, the study has enrolled approximately 400 subjects for the clinical trial. It is expected that 80% of the cases will be enrolled within 2022.
- In May 2022, a research result of the 8th European Stroke Organization Conference ("**ESOC**") indicated that whether thrombolysis treatment is received or not, Sanbexin<sup>®</sup> significantly lowers the inflammatory factor level of AIS patients and improves nervous functions, for which the improvement made by the treatment group of Sanbexin<sup>®</sup> combined with thrombolytic drugs is distinct.
- On May 21, 2022, Sanbexin<sup>®</sup> was recommended by the 2022 Guidelines on Establishment of Stroke Prevention and Treatment System (《腦卒中防治體系建設指導規範 (2022版)》). The recommended contents are: Edaravone and dexborneol concentrated solution blocks the cerebral ischemia cascade through multiple targets such as free radical scavenging, inflammation resistance, glutamate excitotoxicity resistance and mitochondria protection. It can significantly improve the functional outcomes of ischemic stroke patients, and is safe for clinical use, providing a new and more effective clinical treatment for AIS (Level IIa recommendation, level A evidence).

### **Oncology Products**

Main products in this therapeutic area include Endostar<sup>®</sup> (Recombinant Human Endostatin Injection). For the six months ended June 30, 2022, revenue from sales of pharmaceutical products from the oncology product portfolio reached approximately RMB457 million, accounting for approximately 16.9% of the Group's total revenue.

## Endostar<sup>®</sup> (recombinant human endostatin injection)

Endostar<sup>®</sup> is the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide. Endostar<sup>®</sup> 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**"). At present, the Group is actively exploring the expansion of new indications of this product in malignant serous cavity effusion. In September 2020, CSCO's Expert Committee on Antineoplastic Safety Management (中國臨床腫瘤學會抗腫瘤藥物安全管理專家委員會) and Expert Consensus on the Clinical Application of Recombinant Human Endostatin to Treat Malignant Serous Effusion (《重組人血管內皮抑制素治療惡性漿膜腔積液臨床應用專家 共識》) in Chinese Clinical Oncology. Based on the relevant translational research, clinical trial and real world study, the consensus aimed to provide guidance for the reasonable application of Endostar<sup>®</sup> in the clinical practice to treat malignant serous effusions, malignant ascites and malignant pericardial effusions).

- On March 18, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for the phase III clinical trial of Endostar<sup>®</sup> on the new indication of malignant thoracoabdominal effusions, that is, a randomized, controlled and double-blinded multicentre phase III clinical trial (COREMAP study) of intracavitary injection with Endostar<sup>®</sup> in combination with Cisplatin versus Placebo in combination with Cisplatin for the treatment of malignant thoracoabdominal effusions.
- On July 28, 2022, COREMAP study, taken the Shanghai East Hospital as the team leader and participated by more than 70 centers across China, completed FPI. As of the date of this announcement, the study has progressed in line with expectations and has enrolled over 260 subjects.
- In June 2022, the American Society of Clinical Oncology ("ASCO") published 3 important research results in relation to Endostar<sup>®</sup> at its 58th annual meeting in the form of online abstract and poster, including three days intravenous infusion of Endostar<sup>®</sup> in combination with PD-1 monoclonal antibody and chemotherapy for the first-line treatment of EGFR/ALK-negative advanced non-squamous NSCLC, Endostar<sup>®</sup> in combination with whole brain radiotherapy for the treatment of NSCLC brain metastasis patients, and Endostar<sup>®</sup> in combination with radiotherapy for the treatment of low-risk locally advanced nasopharyngeal carcinoma.
- On August 6, 2022, a multicentre retrospective study of Endostar<sup>®</sup> in combination with Camrelizumab and chemotherapy for the treatment of advanced NSCLC was presented at the 2022 World Conference on Lung Cancer ("WCLC").

## ENWEIDA<sup>®</sup> (Envafolimab Injection)

ENWEIDA<sup>®</sup> is a single domain antibody against recombinant humanized PD-L1 and a protein fused with Fc, which was conditionally approved to marketing in China by the NMPA on November 25, 2021. ENWEIDA<sup>®</sup> 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 and Jiangsu Alphamab. 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 mainland China.

- On April 2022, ENWEIDA<sup>®</sup> was firstly included in three CSCO guidelines: CSCO Diagnosis and Treatment Guidelines for Gastric Cancer 2022 (《CSCO 胃癌診療指南 2022 版》) (Level I recommendation, Class 2A evidence); CSCO Diagnosis and Treatment Guidelines for Colorectal Cancer 2022 (《CSCO 結直腸癌診療指南 2022 版》) (Level II recommendation, Class 2A evidence); CSCO Immune Checkpoints Guidelines for Clinical Use of Inhibitors (《CSCO 免疫檢查點抑制劑臨床應用指南 2022 版》) (Level I recommendation, Class 2A evidence) for recommendation.
- As of the date of this announcement, the multiple-cohort and multi-institutional phase II clinical trial led by the Group on the efficacy and safety of Sevacizumab in combination with Envafolimab with or without chemotherapy for the treatment of patients with advanced solid tumors has completed the enrollment of over 60 subjects.

## **COSELA<sup>®</sup>** (trilaciclib hydrochloride for injection)

COSELA<sup>®</sup> is an effective, selective and reversible cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor. COSELA<sup>®</sup> 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 to develop and commercialize Trilaciclib Hydrochloride for Injection in Greater China. On February 13, 2021, the product was approved for sale by the U.S. FDA, with the indication being preventive use in small cell lung cancer patients treated with a platinum-containing regimen in combination with etoposide-containing regimen or topotecan-containing regimen to decrease the incidence of chemotherapy-induced myelosuppression. Currently, the product has been recommended by the related key guidelines of National Comprehensive Cancer Network Guidelines ("NCCN"), Chinese Society of Clinical Oncology ("CSCO"), and other organizations.

• On February 23, 2022, it was announced that COSELA<sup>®</sup> had reached the endpoint for the randomized, double-blind, placebo-controlled, multi-center phase III clinical trial (TRACES study) evaluating the safety, efficacy, and pharmacokinetics of Trilaciclib Hydrochloride for Injection in extensive small-cell lung cancer ("**ES-SCLC**") patients who are receiving carboplatin in combination with etoposide or topotecan treatment.

- On July 12, 2022, COSELA<sup>®</sup> obtained the approval by the NMPA for conditional marketing in China, with the indication of decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen for extensive-stage small cell lung cancer. The approval for marketing of COSELA<sup>®</sup> is based on the data of the safety introduction stage of the TRACES study, the data of the real world study (Trila-CN-RWS-001 study) in the International Medical Tourism Pilot Zone, Boao Hope City, Hainan Free Trade Port, China, and the previous overseas data support from G1 Therapeutics. The Group plans to initiate the commercialization work on the Chinese market in the fourth quarter of 2022.
- In August 2022, the main results of TRACES study on random phase III study as at December 29, 2021 were presented at the World Conference on Lung Cancer ("WCLC"): Compared with placebo, COSELA<sup>®</sup> administered before chemotherapy in Chinese patients resulted in a significant decrease in the duration of severe neutropenia in Cycle 1 (0 day *vs* 2 days; *P*=0.0003). In addition, COSELA<sup>®</sup> also significantly decreased the occurrence of severe neutropenia (SN, 7.3% *vs* 45.2%, *P* < 0.0001), febrile neutropenia (FN, 2.4% *vs* 16.7%, *P*=0.0267) and grade 3/4 hematologic toxicity (53.7% *vs* 88.1%, *P*=0.0005). In terms of safety, among the patients using COSELA<sup>®</sup>, all other treatment-emergent adverse events ("TEAE") were lower than those of the placebo control except for a slight increase in hypertriglyceridemia and γ-glutamyltransferase. Compared with placebo, there are fewer grade ≥ 3 adverse events using COSELA<sup>®</sup> (61% *vs* 88.1%), primarily due to the lower incidence of hematological grade ≥ 3 adverse events (53.7% *vs* 88.1%).

In addition to the ES-SCLC indications above, COSELA<sup>®</sup> is conducting two phase III clinical trials for metastatic colorectal cancer ("**mCRC**") and triple-negative breast cancer ("**TNBC**") in China:

- COSELA<sup>®</sup> was incorporated into an international multi-centre phase III clinical trial program for mCRC with FOLFOXIRI/bevacizumab (PRESERVE1 Study). On September 24, 2021, the Group completed the FPI for this trial in China. On June 6, 2022, PRESERVE1 Study completed all patient enrollment globally, of which 10 research centers in China completed an enrollment of 53 cases in total.
- COSELA<sup>®</sup> was incorporated into an international multi-centre phase III clinical trial program for TNBC with gemcitabine and carboplatin (PRESERVE2 study). On January 7, 2022, the Group completed the FPI for this trial in China. On August 2, 2022, the clinical trial completed an enrollment of 38 cases in total in China.

#### **Autoimmune Products**

Main products in this therapeutic area include Iremod<sup>®</sup> (Iguratimod Tablets), ANTINE<sup>®</sup> (Diclofenac Sodium Sustained Release Capsules/Gel) and Orencia<sup>®</sup> (Abatacept Injection). For the six months ended June 30, 2022, revenue from sales of pharmaceutical products from the autoimmune product portfolio reached approximately RMB495 million, accounting for approximately 18.4% of the Group's total revenue.

## Iremod<sup>®</sup> (Iguratimod Tablets)

Iremod<sup>®</sup> 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<sup>®</sup> has been included in the National Medical Insurance Catalogue (B-List) since 2017. The indication is the active rheumatoid arthritis. Since it launched in 2012, Iremod<sup>®</sup> has benefited over 1 million patients (persons) in China. Iremod<sup>®</sup> is recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinical practice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and Labor and Welfare of Japan. Currently, the Group is actively promoting the new indication expansion program on Sjögren's syndrome for this product. In April 2020, Iremod<sup>®</sup> was adopted in the "Primary Sjögren's Syndrome Diagnosis and Treatment Standards" (《原發性乾燥綜合徵診療規 範》) issued by the Division of Rheumatology of the Chinese Medical Doctor Association (中國醫師協會風濕免疫科醫師分會).

- On January 20, 2022, the phase II clinical trial of Iremod<sup>®</sup> in the treatment of active Primary Sjögren's Syndrome, taken the Peking University People's Hospital as the team leader, enrolled all 144 subjects. Currently, the trial entered the data statistics and analysis stage.
- In January 2022, Rheumatoid Arthritis Diagnosis and Treatment Standards (《類風濕關節炎診療規範》) recommended iguratimod among the conventional synthetic disease modifying antirheumatic drugs ("csDMARDs").
- In June 2022, two important studies on Iremod<sup>®</sup> were selected for the poster of the annual meeting of the European League Against Rheumatism ("EULAR"). One exploratory study on the mechanism of treating rheumatoid arthritis-related interstitial lung disease shows that: The results from randomly dividing the mouse pulmonary fibrosis model into control group and treatment group with different concentrations, indicate that iguratimod could improve pulmonary fibrosis by inhibiting the initiation of EMT process and NLRP3 inflammasome activation, as well as reducing ROS production, which provides new insights for further application of iguratimod in interstitial pulmonary fibrosis. Another claims-based algorithms retrospective real-world study to evaluate the cost-effectiveness of iguratimod among patients with rheumatoid arthritis shows that: This proves that iguratimod combined with methotrexate for the treatment of rheumatoid arthritis patients is a strategy with both curative effect and economic cost.

### **Other Products**

Main products in these therapeutic areas include Softan<sup>®</sup> (Rosuvastatin Calcium Tablets) and, ZAILIN<sup>®</sup> (Amoxicillin Granules/Dispersible Tablets/Capsules). For the six months ended June 30, 2022, revenue from sales of pharmaceutical products from the said product portfolio reached approximately RMB444 million, accounting for approximately 16.5% of the Group's total revenue.

## **RESEARCH AND DEVELOPMENT**

The Group pays high attention to the R&D of innovative pharmaceuticals. We focus on efficiency and adhere to differentiation with the core R&D goal to meet the clinical needs of patients, enrich the pipeline under research with the two-wheel-driven independent and cooperative R&D, and benefit patients around the world with our collaborative innovation.

The Group's R&D strategy continues to focus on the three advantageous therapeutic areas: oncology, nervous system and autoimmune with forward-looking layout of disease areas with significant clinical needs in the future.

During the six months ended June 30, 2022, R&D investment amounted to approximately RMB652 million, accounting for approximately 24.1% of the revenue.

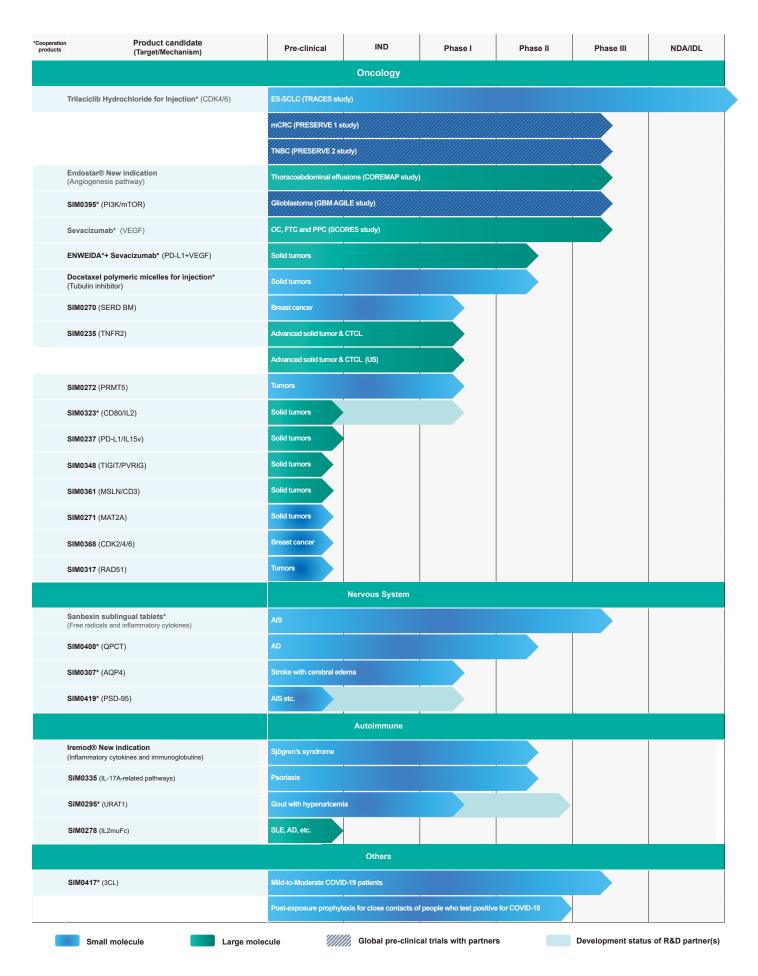
The Group pays high attention to the building of innovative pharmaceutical R&D capability. The Group has established R&D innovation centers in Shanghai, Nanjing, Beijing and Boston respectively, and a State Key Laboratory of Translational Medicine and Innovative Drug Development. The Group's pharmaceutical R&D has realized functions covering the whole process from drug discovery, preclinical development, clinical trial to registration, and owns a leading innovative R&D platform in China with AI-aided drug discovery and optimization, PROTAC targeted protein degradation, protein structure modification and NK cell based treatment. As of the date of this announcement, the Group had a R&D team of approximately 1,100 persons in total (including approximately 130 doctors and 520 masters).

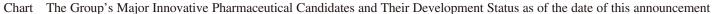
We have also established strategic cooperation with many innovative enterprises and research institutes and clinical centers at home and abroad and are exploring multiple collaborative modes such as cooperative R&D and achievement transfer. Meanwhile, the Group put forward and implemented the "Simcere Project X", aiming to attract professional leaders in the global life sciences field to explore and create unprecedented therapy.

As of the date of this announcement, the Group had nearly 60 innovative pharmaceutical projects in its R&D pipeline, including 8 phase III clinical trials, 5 phase II clinical trials and 6 phase I clinical trials.

For the six months ended June 30, 2022, the Group added 5 INDs, namely SIM0235 (TNFR2/ advanced solid tumors and CTCL/the US), SIM0408 (QPCT/AD/China), SIM0272 (PRMT5/tumor/ China), SIM0417 (3CL/Mild-to-Moderate COVID-19 patients/China) and SIM0417(3CL/post-exposure prophylaxis for close contacts of COVID-19 patients/China).

For the six months ended June 30, 2022, more than 1,000 patients were enrolled in clinical trials, the Group completed clinical the first-in-human trial ("**FIH**") for 4 trials in total, namely SIM0235 (TNFR2, solid tumors, March 16), SIM0417 (3CL, health person, April 10), SIM0270 (SERD, breast cancer, May 18), SIM0272 (PRMT5, tumors, June 27); completed FPI for 5 trials in total, namely Trilaciclib Hydrochloride for Injection (CDK4/6, TNBC phase III, January 7), SIM0417 (3CL, COVID-19 phase Ib, May 14), SIM0335 (IL-17A related passways, psoriasis phase IIa, May 27), SIM0417 (3CL, COVID-19 phase II, June 13), docetaxel polymeric micelles for injection (tubulin inhibitor, solid tumors phase II, June 23).





Meanwhile, the Group attaches great importance to the protection of intellectual property rights. For the six months ended June 30, 2022, the Group had 103 new invention patent applications (including domestic and overseas unpublished patent applications). Currently, the Group has accumulatively obtained 207 invention patents, 81 utility model patents and 20 appearance design patents.

For the six months ended June 30, 2022, the Group obtained approvals for 1 generic pharmaceuticals including amoxicillin and clavulanate potassium for suspension (0.15625g) and 1 consistency evaluation supplemental application regarding Biapenem for Injection (0.3g).

## Drug Candidates in the Clinical Stage

**Sanbexin sublingual tablets** are oral solid dosage containing edaravone dexborneol compound, which can disintegrate quickly under the tongue and absorb into the blood through the sublingual venous plexus, inhibit inflammations, prevent free radicals and, protect the blood-brain barrier, thus minimizing brain cell injury or impairment caused by AIS. Such unique dosage form is expected to increase the flexibility of stroke treatment and improve medication compliance. Sequential therapy consisting of Sanbexin sublingual tablets and Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection) is expected to enable patients to receive a timely and complete treatment. In addition, administration of sublingual tablets is less dependent on medical facility conditions or compliance of patients, which makes it more suitable for research on new indications such as other nervous system diseases.

- On June 28, 2021, the phase III clinical trial of Sanbexin sublingual tablets for the treatment of AIS reached FPI. This multi-center, randomized, double-blind, parallel and placebo-controlled phase III trial was led by Peking University Third Hospital, with participation of approximately 40 research centers across the country. Patients aged 18–80 with AIS within 48 hours of onset were enrolled. The primary end point of the trial was the proportion of participants with a mRS score ≤1 on the 90th day after treatment, i.e. proportion of patients who regained independent living function. At the same time, other efficacy and safety indicators were evaluated and biomarkers for stroke were explored.
- On May 4, 2022, the phase III clinical study of Sanbexin sublingual tablets for the treatment of AIS in China achieved positive progress. It only took ten months to complete the enrollment of all 914 patients, and entered follow-up and data analysis stage. In August 2022, all patients completed the final visits, and the Company planned to rapidly advance the NDA application of Sanbexin sublingual tablets.

**SIM0417** On November 17, 2021, the Group entered into a technology transfer contract with The Shanghai Institute of Materia Medica, Chinese Academy of Sciences, and Wuhan Institute of Virology, pursuant to which the Group obtained development, production and commercialization rights on an exclusive basis of the SARS-CoV-2 drug candidate SIM0417 worldwide. SIM0417 can target 3CL, a key protease essential required for SARS-CoV-2 virus replication, and has shown good safety, in-vivo pharmacokinetics and broad-spectrum antiviral activity in pre-clinical study: (1) No drug toxicity was found in safety pharmacology, 14 day repeated administration toxicity (GLP) toxicology and genotoxicity; (2) Lung tissue is highly exposed and human plasma protein binding rate is lower; (3) Good antiviral activity against a variety of COVID-19 variants, including wild-type, Delta and Omicron strain has been exhibited with the effect to inhibit virus replication in

lung and brain tissue and protect tissue damage caused by virus infection. The research results will be published in academic journals or conferences.

- On March 28, 2022, SIM0417 had obtained the First Clinical Trial Approval for drugs issued by the NMPA for the treatment of Mild-to-Moderate patients affected Coronavirus Disease 2019 ("COVID-19") at a high risk of developing severe illness (including hospitalization or death).
- On April 10, 2022, the FPI for the phase I clinical trial for safety, tolerability and pharmacokinetics of SIM0417 among health adult subjects after single/multiple dose administrations was completed at Shandong Provincial Qianfoshan Hospital. On June 1, 2022, this study completed the enrollment of all patients and in-hospital observation.
- On May 13, 2022, SIM0417 obtained the Second Drug Clinical Trial Approval issued by the NMPA, which is used for post-exposure prophylaxis for close contacts of people who test positive for COVID-19.
- On June 13, 2022, the FPI for the phase II clinic study of SIM0417 for treatment of COVID-19 was completed at Fudan University Zhongshan Hospital. On July 23, 2022, the Phase Ib clinical trial for adults with COVID-19 infection completed the medication of all patients in the Third People's Hospital of Shenzhen, and follow-up observation of all patients was completed. Preliminary data show that SIM0417 has shown positive effects on viral load, negative turning time and elimination of COVID-19-related symptoms.
- As of the date of this announcement, in accordance with the clinical trial proposal approved by the CDE, the Group has been actively conducting two clinical trials of SIM0417 in combination with ritonavir versus placebo.

**Sevacizumab** is a new-generation recombinant humanized anti-vascular endothelial growth factor (anti-VEGF) monoclonal antibody. In its pre-clinical studies, Sevacizumab has shown higher antitumor efficacy than bevacizumab at the same dose in multiple cancer models. In the phase Ib clinical trial conducted in China for the treatment of ovarian cancer, preliminary results showed a favorable safety profile and efficacy signals.

- On June 11, 2021, the FPI for the phase III clinical trial of Sevacizumab in combination with chemotherapy compared with placebo in combination with chemotherapy in patients with recurrent epithelial ovarian cancer, fallopian tube cancer and primary peritoneal cancer who failed to be treated with platinum chemotherapy regimen (SCORES Study) was completed. As of August 11, 2022, SCORES Study enrolled approximately 205 subjects in 53 centers in China as planned.
- On June 8, 2022, the Group completed the enrollment for safety run-in period for a multiple-cohorts and multi-institutional phase II clinical trial to evaluate the safety and efficacy of Sevacizumab in combination with Envafolimab with or without chemotherapy in patients with advanced solid tumors. As of the date of this announcement, the phase II clinical trial completed the enrollment of 60 subjects.

**Docetaxel polymeric micelles for injection** uses solubilizing carrier of docetaxel with the polyethylene glycol monomethyl ether-polylactic acid block copolymer ("**mPEG-PDLLA**"), an amphiphilic biocompatible biodegradable material, to reduce the allergy and hematotoxicity of docetaxel injection, and facilitate clinical application. In September 2020, the Group reached a global cooperation with Suzhou Hightechbio Biotechnology Co., Ltd. on this product.

• On March 31, 2022, the FPI for the open, multiple-cohorts and multi-institutional phased II clinical trial on the dosing of Docetaxel Polymeric Micellar for Injection was completed at Tianjin Medical University Cancer Institute and Hospital.

**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 the only SERD-type fulvestrant for intramuscular injection currently on the market in the world, 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 orthotopic model of breast cancer. It is expected to be used for the treatment of breast cancer with brain metastases.

- On December 27, 2021, SIM0270 obtained the Clinical Trial Approval issued by the NMPA, which is intended for the clinical trial of ER+/HER2-breast cancer.
- On May 18, 2022, SIM0270 completed the FPI of phase I clinical trial in the Tianjin Medical University Cancer Institute & Hospital.

**SIM0235** is a tumor-immune target human immunoglobulin G1 ("**IgG1**") humanized anti-tumor necrosis factor type 2 receptor ("**TNFR2**") monoclonal antibody independently developed by the Group. The preclinical pharmacodynamic 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 regulatory T cells ("**Treg**") and bone marrow 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 December 6, 2021, SIM0235 obtained the Clinical Trial Approval issued by the NMPA, which is designed to be used for clinical trials of relapsed or refractory advanced solid tumors and cutaneous T-cell lymphoma ("CTCL") in China.

- On January 29, 2022, the drug obtained the IND approval issued by the FDA, which is designed to be used for clinical trials of advanced solid tumors and CTCL.
- On March 16, 2022, the FPI for phase I clinical trial of SIM0235 was completed at Sun Yat-sen University Cancer Center. This is the first-in-human dosing of SIM0235 and is the first time that a drug candidate for this target has been used in Chinese subjects. The Phase I clinical trial will evaluate the safety, pharmacokinetics, pharmacodynamic characteristics and anti-tumor efficacy of SIM0235.

**SIM0307** 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 SIM0307 in the Greater China region. On December 8, 2021, the PFI for the phase I clinic trial of SIM0307 was completed.

**SIM0408** is an oral small molecule inhibitor targeting glutamine acyl cyclase ("**QPCT**"). By inhibiting QPCT to prevent the formation of toxic N3pE starch protein. SIM0408 can play a role in the early stage of disease, which may prevent neuronal damage. In June 2021, the Group established a strategic regional licensing partnership with Vivoryon Therapeutics N.V. ("**Vivoryon**") for the development and commercialization of SIM0408 and other drugs in Greater China. In December 2021, the FDA granted "Fast Track" accreditation to the candidate drug.

• On February 24, 2022, SIM0408 obtained the Clinical Trial Approval issued by the NMPA, which is intended for the treatment of MCI or mild dementia caused by AD and the support for the phase I and phase II clinical trials in China.

**SIM0335** is an innovative small molecule drug developed in-house by the Group's subsidiary BCY Pharm Co., Ltd. ("**BCY**"), and also a national Candidate Category 1 drug and the first of its kind in the world that controls fatty acid metabolism and works on IL-17A-related pathways. SIM0335 is a topical ointment with 3-Ocyclohexanecarbony1-11-keto- $\beta$ -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 May 27, 2022, the FPI for the phase IIa clinical trial of SIM0335 for the treatment of plaque psoriasis was completed at Wuxi Second People's Hospital. The trial is designed to evaluate the safety, efficacy and pharmacokinetics of SIM0335 for mild to moderate plaque psoriasis.

**SIM0272** is a PRMT5 inhibitor self-administered by the Group with high PRMT5 inhibitory activity and high selectivity. PRMT5 is overexpressed in many cancers, including lung, breast, gastric, colorectal, ovarian, leukaemia and lymphoma, and is associated with progression and poor prognosis in most cancers. Preclinical pharmacokinetic studies revealed that SIM0272 tended to distribute within the tumor with an intratumoral drug concentration to plasma drug ratio of approximately 10 times that of other in study PRMT5 inhibitors and exhibits proliferation inhibitory activity against a variety of hematologic and solid tumor cells in vitro, with the potential to substantially reduce plasma exposure and target related hematologic toxic side effects while inhibiting tumors.

- On March 21, 2022, SIM0272 obtained the Clinical Trial Approval for drugs issued by the NMPA, which is designed for conducting clinical trials for advanced malignant tumors.
- In April 2022, SIM0272 preclinical key information was presented as an oral report at the American Association for Cancer Research ("AACR").
- On June 27, 2022, the FPI for the multi-institutional phase I clinical trial which evaluated safety, tolerability, effectiveness and pharmacokinetics of SIM0272 in patients with advanced malignant tumors was completed at Shandong Provincial Oncology Hospital.

### Selected Drug Candidates in the Pre-clinical Stage

**SIM0237** is an anti-PD-L1 monoclonal antibody and IL-15/IL-15R $\alpha$  fusion protein. It can block the PD 1/PD-L1 immunosuppressive pathway in combination with PD-L1, while activating the immune system through IL-15, thus playing a dual synergistic role of relieving immunosuppression and activating the immune system, and exhibiting anti-tumor efficacy. Preclinical studies have found that the efficacy is significantly superior to single-dosing PD-L1 and IL-15 in mouse tumor models and toxicity is lower than competitors in cynomolgus monkey toxicology studies.

**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 in 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 U.S. FDA to carry out phase I/II clinical trials of the drug.

**SIM0278** is a Treg-preferred IL2 fusion protein with high activity. Preclinical studies have found that SIM0278 can selectively activate Treg cells but barely initiating Teff/NK cells, and with a larger Treg/Teff treatment window. SIM0278 has an excellent PK and can develop subcutaneous injection type and is expected to have good patient compliance. It is an important cornerstone candidate drug of Treg-Centric strategy.

**SIM0419** is a dimer peptide candidate drug (AVLX-144) 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 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. SIM0419, 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.

**SIM0348** is a self-developed TIGIT/PVRIG dual antibody that more potently activates T/NK cells. It can simultaneously target TIGIT and PVRIG, modulate immunosuppressive signals, enhance CD8+T cell costimulatory signals. Futhermore, it possesses optimized Fc function, and high effectively kill TIGIT+ Treg cells. Preclinical studies have shown that SIM0348 can effectively promote the killing of NK cells on human colorectal cancer cells and significantly enhance the release of IFN- $\gamma$  factor of antigen-specific CD8+T cells, and its vitro activity and efficacy are significantly superior to efficacy of TIGIT monopoly anti-body in combination with PVRIG monopoly anti-body, achieving 1+1>2 efficacy with more superior PD-(L)1 synergy.

**SIM0317** a RAD-51 inhibitor self-administered by the Group. RAD51 is an enzyme that repairs DNA double strand breaks by homologous recombination and is lowly or not expressed in normal tissues but highly expressed in some cancer cells. Downregulation of RAD51 reduces the DNA damage repair ability of tumor cells, thereby improving the efficacy of tumor treatment. SIM0317, as a new generation RAD51 inhibitor, exhibited significant and specific antiproliferative activity against human lymphoma Daudi cells in vitro, resulting in synergistic anticancer responses in lymphoma and solid tumor cell lines when combined with chemotherapeutic or DDR targeting agents.

• On April 2022, the research related to SIM0317 was published at AACR meeting in the form of abstract.

**SIM0361** is a CD3 multispecific antibody targeting MSLN based on SMART, a CD3 multispecific antibody platform independently developed by the Group. Mesothelin (MSLN), a glycoprotein overexpressed on the cell surface of a variety of malignancies, is a potential therapeutic target for haematological neoplasms such as acute myeloid leukaemia (AML) and several solid tumours such as mesothelioma, cholangiocarcinoma, ovarian, pancreatic, lung, breast and gastric cancers. SIM0361 is able to target both the distal and proximal membrane ends of MSLN, and is more conducive to the formation of immunological synapse and tumor cell killing by T cells, in vitro cell killing experiments and in vivo drug efficacy experiments, and all significantly outperformed the positive control antibody targeting the distal membrane end alone. Meanwhile, SIM0361 employed the design of a low affinity CD3 terminus to reduce Treg priming and T cell depletion, enhancing their anti-tumor effects in the solid tumor microenvironment.

• On April 2022, the research related to SIM0361 was published at AACR meeting in the form of abstract.

**SIM0271** is a self-developed MAT2A inhibitor by the Group, which improved target selectivity and demonstrated superior proliferation inhibition activity in a variety of solid tumor cells, as well as superior tumor inhibition in in-vivo models. SIM0271 was well tolerated in preclinical multispecies safety experiments, and elevated bilirubin levels in animals were not observed even at high dose conditions.

• On April 2022, the research related to SIM0271 was published at AACR meeting in the form of abstract.

**SIM0368** is a highly active inhibitor against CDK2/4/6 developed autonomously by the Group, which exhibited high inhibitory activity not only against CDK4/6-resistant cell lines but also against multiple breast cancer tumor cell lines, including HR positive and triple negative breast cancer cell lines. In vivo drug effect studies showed superior or comparable tumor growth inhibition with other CDK2/4/6 inhibitors in OVCAR3 SIM0368 versus CDK4/6-sensitive MCF7 xenograft tumor mouse models at equivalent doses.

• On April 2022, the research related to SIM0368 was published at AACR meeting in the form of abstract.

## **IMPACT OF COVID-19**

Since 2022, COVID-19 cases (including COVID-19 Omicron variant cases) have continuously increased in many Chinese cities, but the COVID-19 epidemic has been brought under control through several regular policy interventions.

Under such circumstances, the Group expects that the COVID-19 epidemic will not have a significant impact on business operations and financial position because the fluctuation to the Group's certain research projects and marketing caused by the sporadic outbreak of the epidemic is minor. Therefore, the Group's adequacy of capital liquidity and working capital can meet the Company's operational needs and capital commitments.

To reduce the risk of cross-infection caused by COVID-19 among the employees, the Group adopts a strict disease prevention plan. The Group will closely monitor the development of the COVID-19 outbreak (including subsequent outbreaks caused by novel variants of COVID-19, if any), further assess its impact, follow the applicable regulatory guidelines for clinical trials during the epidemic, strive to reduce delays and disruptions, and take relevant measures to minimize the impact of the epidemic.

## LIQUIDITY AND FINANCIAL RESOURCES

The Group maintained a sound financial position. As of June 30, 2022, the Group had cash and cash equivalents of approximately RMB1,865 million (as of December 31, 2021: approximately RMB973 million), time deposits of approximately RMB959 million (as of December 31, 2021: approximately RMB1,620 million). As of June 30, 2022, the Group had a balance of bank loans of approximately RMB1,293 million (as of December 31, 2021: approximately RMB1,530 million), of which approximately RMB1,293 million (as of December 31, 2021: approximately RMB1,530 million) would mature within one year. As of June 30, 2022, the gearing ratio of the Group (total liabilities divided by total assets) was approximately 38.1% (as of December 31, 2021: approximately 36.4%).

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 internal financing and external financing at reasonable market rates. In order to better control and minimize the cost of funds, the Group's treasury activities are centralized.

Most assets and liabilities of the Group were denominated in RMB, HKD and Euro. Currently, the Group does not employ any financial instruments or enter into any foreign exchange contracts to hedge against foreign exchange risk. However, by closely monitoring the net exposure of foreign exchange risk, the Group managed the foreign exchange risk, thus minimizing the impact of foreign exchange fluctuations.

## PLEDGE OF GROUP'S ASSETS

As of June 30, 2022, the Group pledged bills receivable of approximately RMB93 million for issuance of bank acceptance bills and pledged bank deposits of approximately RMB2.33 million for issuance of letter of guarantee. Save as disclosed above, none of other assets of the Group were pledged as of June 30, 2022.

## **CONTINGENT LIABILITIES**

As of June 30, 2022, the Group had no contingent liabilities.

## SIGNIFICANT INVESTMENTS HELD

As of June 30, 2022, 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" below in this announcement, as of June 30, 2022, the Group did not have any other plans for material investments and capital assets.

## MATERIAL ACQUISITIONS AND DISPOSALS

During the six months ended June 30, 2022, the Group had no material acquisition or disposal of subsidiaries, associates and joint venture.

## **EMPLOYEES AND REMUNERATION POLICY**

As of June 30, 2022, the Group had a total of 6,542 full-time employees. The Group attached great importance to the recruitment, training and retention of outstanding employees, maintaining 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 Directors and senior management who worked full time for 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. During the six months ended June 30, 2022, staff costs of the Group (including emoluments, social insurance and other benefits of the Directors) amounted to approximately RMB855 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.

The Group adopted a restricted share unit scheme on May 20, 2021 (the "**2021 RSU Scheme**"). The purposes of the 2021 RSU Scheme are to (i) incentivize the existing and incoming directors, senior management and employees for their contribution to the Group; and (ii) attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of the Group, by providing existing and incoming directors, senior management and employees with the opportunity to own equity interests in the Company. The 2021 RSU Scheme shall be valid and effective for a period of ten (10) years commencing from the date of adoption. For details of the 2021 RSU Scheme, please refer to the announcement of the Company dated May 20, 2021.

During the Reporting Period, the Board resolved on May 11, 2022 to grant a total of 6,810,000 RSUs, representing 6,810,000 underlying Shares, to an aggregate of 21 Selected Persons (being the employees of the Group) under the 2021 RSU Scheme at nil consideration. For details of such grant, please refer to the announcement of the Company dated May 11, 2022. As of June 30, 2022, the Company granted a total of 38,300,000 RSUs under the 2021 RSU Scheme, representing approximately 1.447% of the total issued Shares of the Company as of June 30, 2022, of which 2,298,000 RSUs had lapsed. Therefore, as of June 30, 2022, there were 36,002,000 outstanding RSUs, representing approximately 1.360% of the total issued Shares of the Company as of June 30, 2022, 2022.

## **INTERIM DIVIDEND**

The Board resolved not to declare any interim dividend for the six months ended June 30, 2022.

## **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 pursuant to the partial exercise of the over-allotment option in November 2020 (the "**Net Proceeds**") amounted in aggregate to approximately HK\$3,513 million. The proposed use of the net proceeds was disclosed in the prospectus of the Company dated October 13, 2020 (the "**Prospectus**").

Set out below is the utilization of the Net Proceeds as of June 30, 2022 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 as of June 30, 2022 (HK\$ in million)	,	Expected timeline for utilization
Continued research and development of selected product candidates in the Group's strategically focused therapeutic areas	60%	2,107.85	761.95	1,345.90	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 Group's certain 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	2,167.19	1,345.90	

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 CAR T-cell therapy (Indication 1), CD19 CAR T-cell therapy (Indication 2), BCMA CAR T-cell therapy and SIM0325, to the selected oncology product candidates that are currently under development, including Trilaciclib (for SCLC, mCRC and TNBC), SIM0395 and

Docetaxel Polymeric Micellar for Injection. On August 31, 2022, the Board resolved to reallocate part of the unutilized Net Proceeds of approximately HK\$530 million which originally intended to be used in selected innovative oncology product candidate during pre-clinical phase (including SIM-200, SIM-203-1, SIM-203-2, SIM-203-3 and SIM-236) to continuous R&D of Sanbexin sublingual tablets, Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection), SIM0417 and SIM0278. For details, please see the Company's announcement in relation to change in use of proceeds dated April 15, 2021 and the announcement in relation to further change in use of proceeds dated August 31, 2022 (the "**Announcements**"). As of June 30, 2022, the utilized Net Proceeds was approximately HK\$2,167.19 million and the unutilized Net Proceeds was approximately HK\$1,345.90 million. Saved as disclosed in such Announcements, the Company intends to apply the unutilized Net Proceeds as of June 30, 2022 in the manner and proportion set out in the Prospectus and the Announcements.

## **OTHER INFORMATION**

## Purchase, Sale or Redemption of the Company's Listed Securities

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities for the six months ended June 30, 2022.

### **Change in Directors' Information**

Mr. TANG Renhong ("**Mr. Tang**"), an executive Director of the Company has been appointed as a Co-chief Executive Officer of the Company, with effect from May 25, 2022. Mr. Tang assists Mr. Ren Jinsheng ("**Mr. Ren**"), Chairman and the Chief Executive Officer of the Company, in the overall leading of the Group's research and development affairs and will remain as an executive Director. For details, please refer to the announcement of the Company dated May 25, 2022.

Mr. Zhao John Huan has tendered his resignation as a non-executive Director and a member of the strategy committee of the Board (the "**Strategy Committee**") to the Board with effect from August 31, 2022 in order to devote more time to focus on his other business commitments. Following Mr. Zhao John Huan's resignation, Mr. Tang has been appointed as a member of the Strategy Committee with effect from August 31, 2022. For details, please refer to the announcement of the Company dated August 31, 2022.

Save as disclosed above, there is no other change in the Director's information required to be disclosed pursuant to Rule 13.51B of the Rules governing the Listing of Securities on the Stock Exchange of Hong Kong Limited (the "Listing Rules") from the date of the 2021 annual report of the Company to the date of this announcement.

#### **Important Events After the Reporting Period**

As of the date of this announcement, the Group has no important events that are required to be disclosed after the Reporting Period.

## **Compliance With the Corporate Governance Code**

The Group is committed to maintaining and promoting stringent corporate governance. The principle of the Group's corporate governance is to promote effective internal control measures, uphold a high standard of ethics, transparency, responsibility and integrity in all aspects of business, to ensure that its business and operation are conducted in accordance with applicable laws and regulations, to enhance the transparency of the Board, and to strength 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 14 to the Listing Rules.

Save as disclosed below, the Group has complied with the code provisions contained in the CG Code during the Reporting Period.

Under code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive officer should be separated and should not be performed by the same individual. As of June 30, 2022, Mr. Ren served as both Chairman and Chief Executive Officer of the Company. 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. Directors 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. In addition, Directors believe that this structure will not impair the balance of power and authority between the Board and the management of the Company, given that: (i) any decision to be made by the Board requires approval by at least a majority of Directors; (ii) Mr. Ren and the other Directors are aware of and undertake to fulfil 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; (iii) the balance of power and authority is ensured by the operations of the Board, which consists of three executive Directors (including Mr. Ren) and three independent non-executive Directors, and has a fairly strong independence element; (iv) 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; and (v) Mr. Tang was appointed as a Co-chief Executive Officer 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 10 to the Listing Rules as the Group's code of conduct regarding the Directors' securities transactions. Having made specific enquiry of all the Directors of the Group, all the Directors confirmed that they have strictly complied with the Model Code during the Reporting Period.

### Audit Committee and Review of Financial Information

The Group established Audit Committee with written terms of reference in compliance with the CG Code. The Audit Committee consists of 3 members, all of which are independent non- executive Directors, being Mr. WANG Xinhua, Mr. SONG Ruilin and Mr. WANG Jianguo. The chairperson of the Audit Committee is Mr. WANG Xinhua. Mr. WANG Xinhua 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 our 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 unaudited condensed consolidated interim financial statements and interim report of the Group for the six months ended June 30, 2022, 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.

#### **Independent Review of Auditor**

The interim financial report for the six months ended June 30, 2022 is unaudited, but has been reviewed by KPMG, in accordance with Hong Kong Standard on Review Engagements No. 2410 "*Review of interim financial information performed by the independent auditor of the entity*" issued by the Hong Kong Institute of Certified Public Accountants, whose unmodified review report is included in the interim report to be sent to the Shareholders.

### Publication of the Interim Results Announcement and Interim Report

The interim results announcement and the interim report will be 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 2022 interim report will be dispatched to shareholders and will be published on the aforementioned websites in due course.

## PROSPECTS

The innovative drug business has become the major driving force for continuous growth of the Group. In the future, the Company will continue to make intensified efforts in innovation and R&D, and benefit more patients with differentiated and innovative pharmaceuticals:

- (1) The Product portfolio consisting of Sanbexin sublingual tablets, whose pivotal clinical trials are about to be completed and the marketed Sanbexin<sup>®</sup> (Edaravone and Dexborneol Concentrated Solution for Injection) is expected to be achieved to raise the flexibility of stroke treatment in an unique dosage form and to increase patient compliance with stroke therapy, thus further strengthening the Group's dominant position in the field of nervous system;
- (2) COSELA<sup>®</sup> (Trilaciclib Hydrochloride for Injection), a world-in-class comprehensive myeloprotection drug marketed in July 2022 will protect more cancer patients in China. We will also actively explore the possibility of the drug in new indications, quality of life and the combination with ADC drugs to meet unmet market needs;
- (3) In view of the continuing impact of COVID-19 on social economy and public health, we will rapidly advance the development of the anti-COVID-19 drug SIM0417.

In the future, the Company will also concentrate on differentiated innovation, pay attention to global pharmaceutical research and innovation trends, strengthen the deep integration of production, education and research through a variety of collaborative innovation measures, and work hand in hand with partners to create more effective drugs.

## **Consolidated statement of profit or loss** For the six months ended June 30, 2022 — unaudited

		Six months ended June 30,		
	Note	2022 RMB'000	2021 RMB'000	
Revenue	4	2,699,650	2,120,002	
Cost of sales		(557,371)	(456,977)	
Gross profit		2,142,279	1,663,025	
Other revenue	5(a)	87,131	62,670	
Other net (loss)/gain	5(b)	(338,979)	490,504	
Research and development costs		(651,537)	(626,803)	
Selling and distribution expenses		(1,029,335)	(830,178)	
Administrative and other operating expenses Reversals/(recognition) of impairment		(188,481)	(163,478)	
loss on trade and other receivables		20,033	(39,634)	
Profit from operations		41,111	556,106	
Finance income	6(a)	30,260	28,014	
Finance costs	6(a)	(18,514)	(47,396)	
Net finance income/(costs)		11,746	(19,382)	
Share of losses of associates		(387)	(14,750)	
Share of profits/(losses) of a joint venture		53	(134)	
Profit before taxation	6	52,523	521,840	
Income tax	7	9,398	33,055	
Profit for the period		61,921	554,895	
Attributable to:				
Equity shareholders of the Company		63,784	557,814	
Non-controlling interest		(1,863)	(2,919)	
Profit for the period		61,921	554,895	
Earnings per share	8			
Basic (RMB)		0.02	0.21	
Diluted (RMB)		0.02	0.21	

# **Consolidated statement of profit or loss and other comprehensive income** *For the six months ended June 30, 2022 — unaudited*

	Six months end 2022 <i>RMB'000</i>	ed June 30, 2021 <i>RMB</i> '000
Profit for the period	61,921	554,895
Other comprehensive income for the period (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	(124,652)	179,150
Items that may be reclassified subsequently to profit or loss: Exchange difference on translation of financial statements of entities with functional currencies other than Renminbi (" <b>RMB</b> ")	71,589	(12,465)
Other comprehensive income for the period	(53,063)	166,685
Total comprehensive income for the period	8,858	721,580
Attributable to: Equity shareholders of the company Non-controlling interest	10,721 (1,863)	724,499 (2,919)
Total comprehensive income for the period	8,858	721,580

## **Consolidated statement of financial position** *At June 30, 2022 — unaudited*

	Note	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Non-current assets			
Property, plant and equipment		2,036,170	1,931,212
Intangible assets		176,801	59,691
Goodwill		172,788	172,788
Interest in associates		4,476	4,863
Interest in a joint venture		4,455	4,402
Prepayments and deposits		53,902	76,564
Financial assets at fair value through other			
comprehensive income		175,082	291,727
Financial assets at fair value through profit or loss		1,527,535	1,940,375
Time deposits	10(c)	10,558	410,000
Deferred tax assets		334,045	289,972
		4,495,812	5,181,594
Current assets			
Financial assets at fair value through profit or loss		41,782	
Inventories		337,420	235,157
Trade and bills receivables	9	2,106,889	2,398,767
Prepayments, deposits and other receivables		125,039	140,034
Taxation recoverable		6,820	16,789
Pledged deposits	10(b)	2,328	1,580
Restricted deposits	10(b)	10,417	4,005
Time deposits	10(c)	948,586	1,210,078
Cash and cash equivalents	10(a)	1,865,035	973,139
		5,444,316	4,979,549

## **Consolidated statement of financial position (continued)**

At June 30, 2022 — unaudited

Current liabilities  11  1,292,935  1,530,085    Lease liabilities  51,228  31,538    Trade and bills payables  12  378,790  323,951    Other payables and accruals  13  1,310,670  1,162,014    Taxation payable  23,447  16,155		Note	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Lease liabilities  51,228  31,558    Trade and bills payables  12  378,790  323,951    Other payables and accruals  13  1,310,670  1,162,014    Taxation payable  23,447  16,155	Current liabilities			
Trade and bills payables  12  378,790  323,951    Other payables and accruals  13  1,310,670  1,162,014    Taxation payable  23,447  16,155    3,057,070  3,063,763    Net current assets  2,387,246  1.915,786    Total assets less current liabilities  6,883,058  7,097,380    Non-current liabilities  6,883,058  7,097,380    Deferred income  403,925  417,613    Deferred tax liabilities  170,253  74,239    Deferred tax liabilities  170,253  74,239    Deferred tax liabilities  156,568  142,771    Total assets  6,152,312  6,462,757    CAPITAL AND RESERVES  6,152,312  6,462,757    Share capital Reserves  3,002,871  3,002,871  3,002,871    Reserves  3,125,544  3,434,126  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760		11		
Other payables and accruals  13  1,310,670  1,162,014    Taxation payable  23,447  16,155    3,057,070  3,063,763    Net current assets  2,387,246  1,915,786    Total assets less current liabilities  6,883,058  7,097,380    Non-current liabilities  6,883,058  7,097,380    Deferred income  403,925  417,613    Deferred income  403,925  417,613    Deferred tax liabilities  156,568  142,771    730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  3,002,871  3,002,871  3,002,871    Share capital Reserves  3,125,544  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760		12		
Taxation payable  23,447  16,155    3,057,070  3,063,763    Net current assets  2,387,246  1,915,786    Total assets less current liabilities  6,883,058  7,097,380    Non-current liabilities  6,883,058  7,097,380    Deferred income  403,925  417,613    Deferred tax liabilities  170,253  74,239    Metred tax liabilities  170,253  74,239    Deferred income  403,925  417,613    Deferred tax liabilities  176,568  142,771    730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  3,002,871  3,002,871    Share capital Reserves  3,125,544  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760			,	
Net current assets  2,387,246  1,915,786    Total assets less current liabilities  6,883,058  7,097,380    Non-current liabilities  170,253  74,239    Deferred income  403,925  417,613    Deferred tax liabilities  156,568  142,771    730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  3,002,871  3,002,871    Share capital Reserves  3,125,544  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760		10		
Total assets less current liabilities6,883,0587,097,380Non-current liabilities170,25374,239Deferred income403,925417,613Deferred tax liabilities156,568142,771730,746634,623NET ASSETS6,152,3126,462,757CAPITAL AND RESERVESShare capital Reserves3,002,8713,002,871Share capital Reserves3,125,5443,434,126Total equity attributable to equity shareholders of the Company6,128,4156,436,997Non-controlling interest23,89725,760			3,057,070	3,063,763
Non-current liabilitiesLease liabilities170,25374,239Deferred income403,925417,613Deferred tax liabilities156,568142,771730,746634,623NET ASSETS6,152,3126,462,757CAPITAL AND RESERVES53,002,8713,002,871Share capital3,002,8713,002,8713,002,871Reserves3,125,5443,434,126Total equity attributable to equity shareholders of the Company6,128,4156,436,997Non-controlling interest23,89725,760	Net current assets		2,387,246	1,915,786
Lease liabilities  170,253  74,239    Deferred income  403,925  417,613    Deferred tax liabilities  156,568  142,771	Total assets less current liabilities		6,883,058	7,097,380
Deferred income  403,925  417,613    Deferred tax liabilities  156,568  142,771    730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  3,002,871  3,002,871    Share capital Reserves  3,125,544  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760	Non-current liabilities			
Deferred tax liabilities  156,568  142,771    730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  5  5    Share capital Reserves  3,002,871  3,002,871    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760	Lease liabilities		170,253	74,239
730,746  634,623    NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  6,152,312  6,462,757    Share capital Reserves  3,002,871  3,002,871    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760				
NET ASSETS  6,152,312  6,462,757    CAPITAL AND RESERVES  3,002,871  3,002,871    Share capital  3,125,544  3,434,126    Total equity attributable to equity shareholders of the Company  6,128,415  6,436,997    Non-controlling interest  23,897  25,760	Deterred tax liabilities		156,568	142,771
CAPITAL AND RESERVESShare capital Reserves3,002,871 3,125,5443,002,871 3,434,126Total equity attributable to equity shareholders of the Company6,128,415 6,436,9976,436,997Non-controlling interest23,897 25,76025,760			730,746	634,623
Share capital  3,002,871  3,002,871    Reserves  3,125,544  3,434,126    Total equity attributable to equity shareholders  6,128,415  6,436,997    Non-controlling interest  23,897  25,760	NET ASSETS		6,152,312	6,462,757
Reserves3,125,5443,434,126Total equity attributable to equity shareholders of the Company6,128,4156,436,997Non-controlling interest23,89725,760	CAPITAL AND RESERVES			
Reserves3,125,5443,434,126Total equity attributable to equity shareholders of the Company6,128,4156,436,997Non-controlling interest23,89725,760	Share capital		3,002,871	3,002,871
of the Company    6,128,415    6,436,997      Non-controlling interest    23,897    25,760	-			3,434,126
			6,128,415	6,436,997
<b>TOTAL EQUITY</b> <u>6,152,312</u> <u>6,462,757</u>	Non-controlling interest		23,897	25,760
	TOTAL EQUITY		6,152,312	6,462,757

## Notes to the unaudited interim financial report

For the six months ended June 30, 2022

### **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 43/F, AIA Tower, 183 Electric Road, North Point, 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 Basis of preparation

This unaudited interim financial information was extracted from the interim financial report of the Group for the six months ended June 30, 2022.

This interim financial report has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with Hong Kong Accounting Standard ("**HKAS**") 34, *Interim financial reporting*, issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**").

The interim financial report has been prepared in accordance with the same accounting policies adopted in the 2021 annual financial statements, except for the accounting policy changes that are expected to be reflected in the 2022 annual financial statements. Details of any changes in accounting policies are set out in Note 3.

The preparation of an interim financial report in conformity with HKAS 34 requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses on a year to date basis. Actual results may differ from these estimates.

This interim financial report contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2021 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with HKFRSs.

The interim financial report is unaudited, but has been reviewed by KPMG in accordance with Hong Kong Standard on Review Engagements 2410, *Review of interim financial information performed by the independent auditor of the entity*, issued by the HKICPA.

#### 2 Basis of preparation (continued)

The financial information relating to the financial year ended 31 December 2021 that is included in the interim financial report as comparative information does not constitute the Company's statutory annual consolidated financial statements for that financial year but is derived from those financial statements. Further information relating to these statutory financial statements disclosed in accordance with section 436 of the Hong Kong Companies Ordinance (Cap. 622) is as follows:

The Company has delivered the financial statements for the year ended 31 December 2021 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Companies Ordinance.

The Company's auditor has reported on those financial statements. The auditor's report was unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its report; and did not contain a statement under section 406(2), 407(2) or (3) of the Companies Ordinance.

### **3** Changes in accounting policies

The Group has applied the following amendments to HKFRSs issued by the HKICPA to this interim financial report for the current accounting period:

- Amendments to HKAS 16, Property, plant and equipment: Proceeds before intended use
- Amendments to HKAS 37, *Provisions, contingent liabilities and contingent assets: Onerous contracts cost of fulfilling a contract*

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 in this interim financial report. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

## 4 Revenue and segment reporting

#### (a) Revenue

The principal activities of the Group are 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.

#### 4 Revenue and segment reporting (continued)

#### (i) Disaggregation of revenue

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

	Six months ended June 30,		
	2022	2021	
	RMB'000	RMB'000	
Revenue from contracts with customers within			
the scope of HKFRS 15			
Sales of pharmaceutical products	2,436,754	1,945,601	
Promotion service income	262,896	174,401	
	2,699,650	2,120,002	

The Group's revenue from contracts with customers was recognized at point in time for the six months ended June 30, 2022.

#### (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 revenue and other net (loss)/gain

(a) Other revenue

	Six months ended June 30,		
	2022		
	RMB'000	RMB'000	
Government grants	67,394	38,165	
Rental income	8,835	8,341	
Property management income	2,685	2,855	
Consulting and technology service income	4,253	3,759	
Others	3,964	9,550	
	87,131	62,670	

## (b) Other net (loss)/gain

	Six months end	Six months ended June 30,	
	2022	2021	
	RMB'000	RMB'000	
Net foreign exchange(loss)/gain	(8,318)	30,402	
Net (loss)/gain on disposal of property, plant and equipment	(2)	208	
Net realized and unrealized loss on trading securities	_	(119)	
Net realized and unrealized loss on financial assets at			
fair value through profit or loss	(330,659)	(42,658)	
Net gain arising from fair value remeasurement of			
interest in associates	_	103,341	
Net gain on disposal of interest in subsidiaries		399,330	
	(338,979)	490,504	

## 6 **Profit before taxation**

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

## (a) Net finance (income)/costs

	Six months end 2022 <i>RMB'000</i>	ed June 30, 2021 <i>RMB'000</i>
Interest income from bank deposits	(30,260)	(28,014)
Finance income	(30,260)	(28,014)
Interest expenses on bank loans Interest expenses on lease liabilities	15,846 2,668	43,121 4,275
Finance costs	18,514	47,396
Net finance (income)/costs	(11,746)	19,382

## (b) Other items

	Six months ended June 30,	
	<b>2022</b> 20	
	RMB'000	RMB'000
Depreciation charge		
— owned property, plant and equipment	104,480	97,834
— right-of-use assets	21,308	24,230
Amortization of intangible assets	8,362	8,958
Provision for write-down of inventories	13,349	8,893

#### 7 Income tax in the consolidated statements of profit or loss

#### Taxation in the consolidated statements of profit or loss represents:

	Six months ended June 30,		
	2022 <i>RMB'000</i>	2021 RMB'000	
Current tax			
PRC Corporate Income Tax			
Provision for the period	12,686	22,039	
(Over)/under — provision in respect of prior years	(13,493)	4,791	
	(807)	26,830	
Deferred tax			
Origination and reversal of temporary differences	(8,591)	(59,885)	
Total income tax	(9,398)	(33,055)	

The provision for PRC income tax is based on the respective corporate income tax rates applicable to the subsidiaries located in the PRC as determined in accordance with the relevant income tax rules and regulations of the PRC.

#### 8 Earnings per share

#### (a) Basic earnings per share

The calculation of basic earnings per share is based on the profit attributable to ordinary equity shareholders of the Company of RMB63,784,000 (six months ended June 30, 2021: RMB557,814,000) and the weighted average of 2,608,641,618 ordinary shares (six months ended June 30, 2021: 2,608,641,618 ordinary shares) in issue during the interim period.

### (b) Diluted earnings per share

The calculation of diluted earnings per share is based on the profit attributable to ordinary equity shareholders of the Company of RMB63,784,000 (six months ended June 30, 2021: RMB557,814,000) and the weighted average of 2,618,372,285 ordinary shares (six months ended June 30, 2021: 2,608,641,618 shares).

	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Trade receivables Bills receivable	1,813,598 311,929	2,017,320 419,635
	2,125,527	2,436,955
Less: loss allowance	(18,638)	(38,188)
	2,106,889	2,398,767

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

### 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:

	June 30,	December 31,
	2022	2021
	RMB'000	RMB'000
Within 3 months	1,760,723	1,561,742
Over 3 months but within 12 months	342,589	831,220
Over 12 months	3,577	5,805
	2,106,889	2,398,767

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

#### 10 Cash and cash equivalents, time deposits, pledged deposits and restricted deposits

(a) Cash and cash equivalents comprise:

	June 30,	December 31,
	2022	2021
	<i>RMB'000</i>	RMB'000
Cash at bank	1,865,035	973,139

As of the end of the reporting period, cash and cash equivalents situated in Mainland China amounted to RMB1,643,946,000 (2021: RMB571,340,000). Remittance of funds out of Mainland China is subject to relevant rules and regulations of foreign exchange control.

#### (b) Pledged deposits and restricted deposits comprise:

(*c*)

June 30, 2022 <i>RMB</i> '000	December 31, 2021 <i>RMB'000</i>
Pledged deposits for	1 500
- issuance of letter of guarantee 2,328	1,580
2,328	1,580
June 30,	December 31,
2022	2021
<i>RMB'000</i>	RMB'000
Restricted deposits for	
- research and development projects 10,417	4,005
10,417	4,005
Time deposits:	
June 30,	December 31,
2022	2021
<i>RMB'000</i>	RMB'000
Current portion 948,586	1,210,078
Non-current portion 10,558	410,000
959,144	1,620,078

## 11 Bank loans

12

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

	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Short-term bank loans Current portion of long-term bank loans	1,283,908 9,027	991,571 538,514
	1,292,935	1,530,085
The bank loans were secured as follows:		
	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Bank loans — Secured — Unsecured	881,657 411,278	1,134,596 395,489
	1,292,935	1,530,085
Trade and bills payables		
	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Trade payables	275,612	256,131

Trade payables	275,612	256,131
Bills payable	103,178	67,820

378,790	323,951

#### 12 Trade and bills payables (continued)

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

	June 30, 2022	December 31, 2021
	<i>RMB'000</i>	RMB'000
Within 3 months	291,460	252,556
Over 3 months but within 12 months	73,255	70,567
Over 12 months	14,075	828
	378,790	323,951

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

#### 13 Other payables and accruals

	June 30, 2022 <i>RMB'000</i>	December 31, 2021 <i>RMB'000</i>
Accrued expenses (Note i)	394,315	546,992
Contract liabilities (Note ii)	19,235	26,140
Payable for employee reimbursements	36,408	105,691
Payables for staff related costs	273,503	279,064
Payables for purchase of property, plant and equipment	30,526	35,334
Dividends payable	391,296	
Other tax payables	69,271	76,667
Others	96,116	92,126
	1,310,670	1,162,014

#### 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

Dividends payable to equity shareholders of the Company attributable to the previous financial years, declared and approved during the period:

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
Dividends in respect of previous financial years		
declared and approved during the interim period,		
RMB0.15 per share (six months ended June 30, 2021:		
RMB0.15 per share)	391,296	391,296

The directors did not recommend payment of interim dividends for the interim period (no interim dividend for the six months ended June 30, 2021).

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

Hong Kong, August 31, 2022

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