Simcere Pharmaceutical Group Limited
先聲藥業集團有限公司
(Incorporated in Hong Kong with limited liability)
(Stock code: 2096)

FURTHER CHANGE IN USE OF PROCEEDS

References are made to (i) the prospectus (the "**Prospectus**") of Simcere Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") dated October 13, 2020 in relation to listing (the "**Listing**") of the Company's shares on the Main Board of The Stock Exchange of Hong Kong Limited and the global offering (the "**Global Offering**"), (ii) the announcement of the Company dated October 23, 2020 in relation to the offer price and allotment results, (iii) the announcement of the Company dated November 18, 2020 in relation to the partial exercise of the over-allotment option, stabilizing actions and end of stabilization period, (iv) the announcements of the Company dated April 15, 2021 and August 31, 2022 in relation to the change in use of proceeds, and (v) the announcement of interim results for the six months ended June 30, 2024 (together with (ii) to (iv), the "**Previous Announcements**") in which the utilization of the net proceeds from the Global Offering and the partial exercise of the over-allotment option as of June 30, 2024 was disclosed. Unless otherwise defined, the capitalized terms used in this announcement shall have the same meanings as defined in the Prospectus.

PREVIOUS CHANGE IN USE OF PROCEEDS

The net proceeds (the "**Net Proceeds**") from the Global Offering and the partial exercise of the over-allotment option, after deduction of underwriting fees, commissions and other expenses paid by the Company in connection with the Global Offering, amounted to approximately HK$3,513.09 million. The original intended use of the Net Proceeds was disclosed in the section headed "Future Plans and Use of Proceeds" in the Prospectus.

As disclosed in the Previous Announcements, the Board resolved on April 15, 2021 to reallocate part of the unutilized Net Proceeds amounted to approximately HK$325.62 million for the selected product candidates to the selected oncology product candidates that were then under development, and further resolved on August 31, 2022 to reallocate part of the unutilized Net Proceeds amounted to approximately HK$530 million which originally proposed to be used in selected innovative oncology product candidates at pre-clinical stages to the continuous R&D of Sanbexin sublingual tablets, Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection), SIM0417 and SIM0278.

FURTHER CHANGE IN USE OF PROCEEDS

As of November 30, 2024, the Net Proceeds utilized were approximately HK$3,050.74 million and the remaining Net Proceeds unutilized were approximately HK$462.35 million.

In light of the reasons set out in the paragraph headed "Reasons for and Benefits of the Change in Use of Proceeds" below, the Board has resolved that:

(i) part of the unutilized Net Proceeds amounted to approximately HK$228.90 million which originally proposed to be used in selected oncology product candidates that were then in clinical stages or pending clinical trials (including Bevacizumab Biosimilar, PEG-ENDO (Pegylated recombinant human endostatin for injection) and SIM-201),

(ii) part of the unutilized Net Proceeds amounted to approximately HK$180.02 million which originally proposed to be used in selected innovative oncology product candidates that were then pending IND approvals or in pre-clinical stages (including SIM323, subcutaneous PD-L1 single domain antibody combination therapy 1 and subcutaneous PD-L1 single domain antibody combination therapy 2),

(iii) part of the unutilized Net Proceeds amounted to approximately HK$31.74 million which originally proposed to be used in other selected innovative central nervous system product candidates that were then preparing for the IND application or in pre-clinical stages, and

(iv) part of the unutilized Net Proceeds amounted to approximately HK$0.79 million which originally proposed to be used in selected autoimmune disease product candidates SIM-335 (together with the above products, the "**Original Selected Products**"),

to be reallocated to the continuous R&D of selected autoimmune disease product candidates and oncology disease product candidates that are currently under development (including Rademikibart (IL-4Rα), SIM0500 (humanized GPRC5D-BCMA-CD3 trispecific antibody), SIM0270 (oral SERD inhibitor), SIM0237 (PD-L1/IL15v bispecific antibody) and SIM0505 (CDH6 ADC)) (the "**New Selected Products**").

Set out below is the utilization of the Net Proceeds as of November 30, 2024 and the proposed change in the use of unutilized Net Proceeds:

Purpose	Percentage of the total amount	Amount of Net Proceeds received *(HK$ in million)*	Amount of Net Proceeds utilized as of November 30, 2024 *(HK$ in million)*	Amount of Net Proceeds unutilized as of November 30, 2024 *(HK$ in million)*	Expected timeline for utilization
Purpose 1: Continued research and development of selected product candidates in the Group's strategically focused therapeutic areas[(1)]	60%	2,107.85	1,645.50	462.35	The actual Net Proceeds are expected to be fully utilized by 2027.
Purpose 2: Reinforcement of the Group's sales and marketing capabilities	10%	351.31	351.31	—	The actual Net Proceeds have been fully utilized.
Purpose 3: Investment in companies in the pharmaceutical or biotechnology sector	10%	351.31	351.31	—	The actual Net Proceeds have been fully utilized.
Purpose 4: Repayment of the Group's certain outstanding bank loans	10%	351.31	351.31	—	The actual Net Proceeds have been fully utilized.
Purpose 5: 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**	**3,050.74**	**462.35**	

Note:

(1) The unutilized Net Proceeds of approximately HK$441.45 million previously allocated to the Original Selected Products under "Purpose 1" have been reallocated to the continuous R&D of the New Selected Products.

As of the date of this announcement, save as the aforementioned changes, there is no other change in the use of the Net Proceeds and the Company intends to utilize the unutilized Net Proceeds in the manner and proportion set out in the Prospectus, the Previous Announcements and this announcement.

REASONS FOR AND BENEFITS OF THE CHANGE IN USE OF PROCEEDS

The reallocation of the Net Proceeds was primarily due to the following reasons:

(1) Considering that:

(i) the failure of other companies' clinical development of drugs with the same target, it is expected that there is a higher risk of subsequent development of the Original Selected Products;

(ii) the pre-clinical study of products indicated no significant competitive advantages, the Original Selected Products may face intensified competition from other companies with the same or similar products, resulting in a reduction in the expected economic and social benefits; and

(iii) the research and development cost of the Original Selected Products intended to be suspended is controllable, and the Company has adjusted or supplemented relevant pipelines in time according to its strategies, it is expected that no significant impact will be posed on the future product layout of the Company. Therefore, the Company proposed to suspend the relevant R&D projects of the Original Selected Products.

(2) Considering that the New Selected Products have entered or will enter into several key development stages, the Company believes that these products have broad prospects and will allocate the Net Proceeds to accelerate their future R&D.

Product name	**Product description**	**R&D stage**
Rademikibart (IL-4Rα)	Rademikibart is a fully human monoclonal antibody targeting IL-4Rα, a common subunit of IL-4 receptor and IL13 receptor. By binding with IL-4Rα, Rademikibart can block the functions of IL-4 and IL-13 effectively, thereby blocking the Th2 inflammatory pathway, thus achieving the goal of treating Th2 related inflammatory diseases such as atopic dermatitis and asthma.	On July 8, 2024, the phase III clinical study of this product's atopic dermatitis in adults and adolescents completed the First-Patient-in (FPI). On July 23, 2024, Rademikibart's phase III clinical study of asthma in adults and adolescents completed the FPI. The Group is of the view that Rademikibart provides a new treatment option for a wide range of patients and will be explored and applied in more potential indications in the future. Its market prospect will be increasingly wider, which is expected to bring breakthroughs in business growth for the Group.

Product name	Product description	R&D stage
SIM0500 (humanized GPRC5D-BCMA-CD3 trispecific antibody)	SIM0500 is a potential category I innovative drug independently developed by the Group with global intellectual property rights, and it may be the potential best-in-class (BIC) drug for the treatment of multiple myeloma based on the preclinical data.	In March 2024, the new drug applications (IND) of the product in the U.S. has been approved by U.S. Food and Drug Administration (FDA) and its IND application in China has been approved by National Medical Products Administration of China (NMPA). It is intended to be investigated in a clinical trial in patients with relapsed or refractory multiple myeloma. On April 9, 2024, it has been granted a FDA Fast Track Designation for patients with multiple myeloma, who are refractory to, or intolerant of, established therapies known to provide clinical benefit and have received ≥3 prior lines of therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 monoclonal antibody. At present, the above clinical trial completed the First-in-Human (FIH). The Group believes that the successful launch of the product will significantly strengthen the technological advantages and market competitiveness of the Group in the field of hematology oncology treatment, laying the foundation for the development of the market in global multiple myeloma treatment in the future.

Product name	Product description	R&D stage
SIM0270 (oral SERD inhibitor)	SIM0270 is a self-developed an oral brainpenetration selective estrogen receptor down-regulator. It was first approved to commence monotherapy clinical trials on December 2021 and was approved to commence clinical trials in combination with everolimus on January 2023 (SIM1907-02-SERD-101). Such study results demonstrate that, SIM0270 as a monotherapy or in combination with everolimus has shown positive anti-tumor effects and good safety and tolerability in ER+/HER2- locally advanced or metastatic breast cancer subjects who have previously received endocrine therapy, which is expected to further improve the therapeutic benefits of ER-positive breast cancer patients and address the high unmet clinical need of ER+/HER2- breast cancer patients who have failed to receive CDK4/6 inhibitor therapy. It is expected to address the high unmet clinical need in patients with ER+/HER2- breast cancer after the failure of CDK4/6 inhibitors.	The product was approved by the Center for Drug Evaluation of NMPA (CDE) for "SIM0270 in combination with everolimus in phase III clinical breast cancer" in October 2024 and achieved first patient dosing for such phase III study in November 2024. It is currently in the stage of enrolling phase III clinical patients. Through the continuous development and future launch of such product, the Group will establish a core product line in the field of breast cancer treatment, so as to further enhance its leading position in the field of oncology treatment, while providing innovative and efficient treatment options for ER-positive breast cancer patients.

Product name	Product description	R&D stage
SIM0237 (PD-L1/IL15v bispecific antibody)	SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL15/IL15Rα protein and independently developed based on the Group's protein engineering platform. It can block the PD-1/PD-L1 immunosuppressive pathway by binding to PD-L1 and activate the immune system through its IL-15 part, thus playing a dual synergistic role in relieving immunosuppression and initiating the immune system to exert anti-tumor effects. PD-1/L1 and IL-15 target drug as a monotherapy or in combination with BCG for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC) demonstrated significant clinical benefits. Accordingly, it is expected that double-target drugs will have more significant clinical benefits.	The product was approved by the NMPA in October 2023 for a clinical trial of SIM0237 as a monotherapy or in combination with BCG for patients with NMIBC and achieved first patient dosing in January 2024. It is currently in the enrolling stage of phase I clinical patients. The Group believes that SIM0237 will further improve the tumor immunotherapy product line of the Group, which will provide strong support for the expansion of the immuno-oncology market. Meanwhile, the successful development of such product will also strike out on new paths for the R&D of other bispecific antibodies, which is expected to promote the introduction of more innovative drugs.
SIM0505 (CDH6 ADC)	SIM0505 is an antibody-drug conjugate (ADC) targeting cadherin-6 (CDH6). Compared with traditional chemotherapy drugs, it can precisely target at tumor cells and reduce toxic side effects on normal cells, thus achieving safer and more effective anti-tumor effects. Such ADC product is intended to be developed for the treatment of malignant tumors such as ovarian cancer and kidney cancer.	The product has been submitted to the CDE for an open, multicenter and first-in-human phase I clinical study in October 2024, which is currently under review. At the same time, it is scheduled to submit a clinical trial application to the FDA in December, both of which are expected to be approved for clinical study in January 2025 and officially initiate the phase I clinical study. The Group believes that the successful development of SIM0505 is expected to further enrich the tumor pipeline and expand related new clinical indications.

In view of the above, the Board is of the view that the aforesaid change in the use of the Net Proceeds will facilitate an effective use of the financial resources of the Group, strengthen the future development of the Group and is in the best interest of the Company and its shareholders as a whole. The Board confirms that there is no material change in the nature of business of the Group as set out in the Prospectus and the above reallocation of Net Proceeds will not have any material adverse impact on the operations of the Group.

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

Hong Kong, December 23, 2024

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