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康臣藥業集團有限公司
CONSUN PHARMACEUTICAL GROUP LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1681)

Voluntary Announcement

(1) Notice of Approval for Clinical Trial of Drug for SK-08 Tablet (2) Drug Registration Approval for Iodixanol Injection

This announcement is made by Consun Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to provide its shareholders and potential investors with the updates on the development of the business of the Group.

(1) Notice of Approval for Clinical Trial of Drug for SK-08 Tablet

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the Company has received the “Notice of Approval for Clinical Trial of Drug* (《藥物臨床試驗批准通知書》)” issued by the National Medical Products Administration (“**NMPA**”) in relation to the approval of the clinical trial application for SK-08 tablet (“**SK-08 Tablet**”). The relevant information is hereby announced as follows:

Drug name	:	SK-08 Tablet
Application	:	Registration of clinical trial of pharmaceutical product
Acceptance number	:	CXHL2400315
Applicant	:	Consun Pharmaceutical (Inner Mongolia) Co., Ltd.* (康臣藥業(內蒙古)有限責任公司) (a wholly-owned subsidiary of the Company)
Review conclusion	:	In accordance with the Drug Administration Law of the People’s Republic of China* (《中華人民共和國藥品管理法》) and the relevant regulations, upon review, the clinical trial application for SK-08 Tablet, which was accepted for processing on 28 March 2024, meets the relevant requirements for drug registration and it is approved that the clinical trial of this product can be commenced.
Indication for the application	:	Intended for the treatment of chronic kidney disease (“ CKD ”).

About SK-08 Tablet

SK-08 Tablet is a Category 1 of Chemical Drugs, which was jointly developed by the Group and WuXi AppTec (Shanghai) Co., Ltd.* (上海藥明康德新藥開發有限公司).

CKD is a chronic progressive disease with abnormal kidney structure or function caused by various reasons. CKD has a long course, many complications, and a complicated diagnosis and treatment process. It seriously endangers the health of Chinese residents and increases the medical expenses of families and society. It has become one of the major public health issues in China. There are significant unmet clinical needs. The Company will continue to actively promote the clinical trials of SK-08 Tablet and strive to launch it on the market as soon as possible to benefit the patients. At the same time, the approval of clinical trial of SK-08 Tablet will further enrich the Group's product portfolio of chronic kidney disease and contribute to the Group's development in the field of kidney disease treatment.

After obtaining the aforementioned approval from NMPA, clinical trials will be launched soon.

(2) Drug Registration Approval for Iodixanol Injection

On 9 July 2024, the iodixanol injection (the “**Product**”) developed by Guangzhou Consun Pharmaceutical Company Limited* (廣州康臣藥業有限公司) (an indirectly wholly-owned subsidiary of the Company) has obtained drug registration approval granted by NMPA, which was deemed to have passed the generic drug consistency evaluation with specification of 100ml:32g(I).

The Product is a non-ionic, dimeric, hexaiodine, water-soluble X-ray contrast agent being used for cardiovascular angiography, cerebrovascular angiography, peripheral angiography, abdominal angiography, urography, venography and enhanced CT examination in adults, as well as cardiovascular angiography, urography and enhanced CT examination in children.

Compared with the marketed sub-hyperosmotic contrast agents, the Product has an advantage that its osmotic pressure, a physical and chemical indicator, is isotonic with human plasma and normal body fluids. The Product has the characteristics of comfortable injection and high safety for patients. The clinical application can increase image contrast and improve the accuracy of imaging examinations. By virtue of the isotonic properties, the Product has evidence-based medicine confirmed that it is a contrast agent with high cardiac safety and high renal safety, and is expected to have a favourable market prospect.

The approval of the Product will enrich the Group's product portfolio for high-concentration CT contrast agents and isotonic CT contrast agents, enriching customers' drug choices and contributing to the development of the Group in the medical imaging diagnosis field.

As there are significant risks and uncertainties in the process of research, development and commercialization of pharmaceutical products, shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company. The Company will actively pursue the above-mentioned research and development projects and will comply with its obligations to disclose information on the subsequent progress of the projects in a timely manner in strict accordance with the relevant regulations.

By Order of the Board
Consun Pharmaceutical Group Limited
An Meng
Chairman

Hong Kong, 17 July 2024

As at the date of this announcement, the Board comprises Mr. An Meng and Professor Zhu Quan as executive Directors; Dr. Zhang Lihua as non-executive Director; Mr. Feng Zhongshi, Ms. Chen Yujun and Professor Li Yikai as independent non-executive Directors.

* *for identification only*