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## CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

*(Incorporated in Hong Kong with limited liability)*

**(Stock Code: 1093)**

### VOLUNTARY ANNOUNCEMENT

#### **JSKN003 WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA**

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that JSKN003, a biparatopic HER2-targeting antibody-drug conjugate co-developed by the Company’s subsidiary, Shanghai JMT-BIO Technology Co., Ltd., and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., has been granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA) of the People’s Republic of China for the intended indication of monotherapy for the all-comer population with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal carcinoma, or fallopian tube cancer (the “**Indication**”).

Ovarian cancer ranks third in incidence among female reproductive system tumors in China and has the highest mortality rate among malignant tumors of the female reproductive tract, with approximately 70% of patients already in the advanced stage at the time of diagnosis. Tumor debulking surgery in combination with postoperative platinum-based chemotherapy is the current mainstay of treatment. However, almost all patients eventually develop resistance to platinum-based therapy. For platinum-resistant patients, non-platinum mono-chemotherapy is the primary treatment recommended by both domestic and international guidelines. Nevertheless, its efficacy is very limited, with a low objective response rate (ORR), short median progression-free survival (PFS) and overall survival, representing a significant unmet clinical need. Clinical studies of JSKN003 for the Indication have preliminarily demonstrated promising breakthroughs in efficacy, with a good safety profile and distinct clinical advantage over existing treatment options.

A pooled analysis of two clinical studies on JSKN003 monotherapy for platinum-resistant ovarian cancer presented at the European Society for Medical Oncology (ESMO) Congress 2024 showed that a total of 50 platinum-resistant subjects were enrolled to receive at least one dose of JSKN003 monotherapy. Based on the results of local laboratory IHC testing for HER2 expression, 10 were HER2 IHC 0, 20 were IHC 1+, 18 were IHC 2+, and 2 were IHC 3+; 56.0% of the subjects had received three or more prior lines of therapy. Among the 44 efficacy evaluable subjects, the ORR was 56.8% and

88.6% (39/44) had tumor shrinkage. The disease control rate (DCR) was 95.5%, the median PFS data was immature, and the 6-month PFS rate was 44.7%. The ORR in subjects with HER2 expression (IHC 1+, 2+, and 3+) was 52.8% (19/36), while the ORR in subjects with HER2 IHC 0 was 75.0% (6/8). Among the 50 subjects, only 5 (10.0%) subjects experienced Grade 3 or higher treatment-related adverse events (TRAEs), with the most common being diarrhea (2.0%) and anemia (2.0%); only one subject experienced TRAEs that led to permanent discontinuation of treatment, and no treatment-related deaths occurred. These clinical data indicated that JSKN003 monotherapy exhibited remarkable efficacy in platinum-resistant ovarian cancer, bringing substantial benefits across different levels of HER2 expression with a good safety profile.

The Phase III clinical trial for the Indication is currently in the enrollment stage and progressing smoothly. JSKN003 is also undergoing multiple Phase II and III clinical trials in China for the treatment of solid tumors, including breast cancer, gastric cancer, colorectal cancer, and cholangiocarcinoma. The Breakthrough Therapy Designation granted to JSKN003 will further expedite its development and review process, making it potentially become the first anti-HER2 drug for the treatment of all-comer patients with platinum-resistant ovarian cancer.

By order of the Board  
**CSPC Pharmaceutical Group Limited**  
**CAI Dongchen**  
*Chairman*

Hong Kong, 18 March 2025

*As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin and Mr. CHEN Weiping as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as independent non-executive directors.*