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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**

#### **“DUVELISIB CAPSULES” OBTAINS DRUG REGISTRATION APPROVAL**

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the “Duvelisib Capsules” (brand name: Copiktra) (the “**Product**”) of CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd.\* (石藥集團中奇製藥技術(石家莊)有限公司), a subsidiary of the Company, has obtained drug registration approval granted by the National Medical Products Administration of the People’s Republic of China for the treatment of adult patients with relapsed or refractory follicular lymphoma (r/r FL) after at least two prior systemic therapies. The Group has the exclusive license of the Product in China (including Hong Kong, Macau and Taiwan).

The Product is the first approved orally available phosphoinositide 3-kinase PI3K- $\delta$  and PI3K- $\gamma$  dual inhibitor worldwide and is also the first approved PI3K selective inhibitor in China. The abnormality of PI3K signaling pathway is considered to cause the proliferation of tumor cells and help form a tumor microenvironment conducive to the evasion of cancer cells from the monitoring of the immune system. Inhibition of PI3K- $\delta$  and - $\gamma$  pathways has a significant clinical efficacy on various B-cell and T-cell lymphomas, and pre-clinical data also show a significant synergistic effect on immunotherapy of a variety of solid tumors.

In comparison with the data from the pivotal clinical study in the U.S., the Product showed significantly better efficacy in a representative group of r/r FL subjects in China. The responses occurred quickly (median TTR = 1.8 months), objective response rate (ORR) reached 95.2% with a 52.4% complete response rate, and the median progression-free survival was 15.2 months. The Product is safe and tolerable in r/r FL subjects in China, with similar safety results observed in the pivotal clinical study in the U.S. and no new potential signals of risks identified. The majority of TEAEs were low grade (grade 1-2), and no deaths due to adverse events were reported. The pulmonary infections observed in the U.S. clinical trial can also be effectively prevented and managed by safe and convenient pre-treatment. Overall, the Product demonstrated a superior benefit-risk ratio.

The Product has also obtained the clinical trial approval for the treatment of advanced malignant solid tumors in combination with PD-1 antibody in China. The Group is currently conducting clinical trials on esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, gastric cancer, colorectal cancer and other solid tumors to expand the group of patients benefitting from the Product.

The approval of the Product will further enrich the innovative anti-tumor product portfolio of the Group. The Group will strive to ensure the rapid launch of the Product in order to fulfill the clinical needs of patients with hematological malignancies in China.

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

Hong Kong, 18 March 2022

*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. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.*

*\* For identification purpose only*