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CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong under the Companies Ordinance)

(Stock code: 1093)

VOLUNTARY ANNOUNCEMENT

THE GROUP'S ONCOLOGY DRUG "MITOXANTRONE HYDROCHLORIDE LIPOSOME INJECTION" WAS GRANTED PHASE II/III CLINICAL TRIAL APPROVAL

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries (the "**Group**")) announces that the phase I clinical trial data of "mitoxantrone hydrochloride liposome injection" (the "**Product**") developed by the Group has passed the technical assessment of the Centre for Drug Evaluation of China Food and Drug Administration (the "**CFDA**") of the People's Republic of China, and was recently granted the approval for phase II/III clinical trial (Approval no.: 2014L02412).

Mitoxantrone hydrochloride is an anthracycline broad-spectrum antibiotic, mainly used in malignant tumour treatment. The active ingredient of the Product is mitoxantrone hydrochloride. Its liposome injection formulation has less side effects such as bone marrow inhibition and cardiac toxication as compared to conventional injection formulation, and also possesses certain specific advantages, including i) slow and continuous drug release, prolonging the effective time of the drug; ii) significant reduction in distribution of drug among healthy tissue or organs, which in turns lower the toxicity of the drug; and iii) leveraging on the targeting effect of liposome, efficacy is enhanced with the drug concentrating on tumour tissue.

Non clinical trial results suggest: i) as compared to conventional mitoxantrone formulation, the Product has the characteristics of long circulation and demonstrating linear kinetics inside human body and will not accumulate between two administrations; ii) the Product is tumour targeted, as compared to the same dosage of conventional formulation, it has a lower concentration and less distribution of mitoxantrone in the majority of the healthy tissue (heart, kidney, lung, spleen and intestine tissue) and a higher concentration and more distribution of mitoxantrone in the tumour tissue; iii) as compared to conventional mitoxantrone formulation, the Product demonstrates a better anti-tumour activity in several animal tumour models with a therapeutic index of more than 20 times higher, it is also better than the conventional formulation in the safety aspect.

Phase I clinical trial results suggest: i) the Product has good safety and tolerance when applying to patients with malignant tumour once or multiple times by intravenous infusion within 6~16mg/m^2 (higher dosage is currently undergoing research), with no adverse event and no dose-limiting toxicity in this research; ii) the adverse effects of 16mg/m^2 liposome injection is far less than those of 10mg/m^2 conventional injection; iii) during the observation period of preliminary treatment, among both of the 14mg/m^2 and 16mg/m^2 groups (3 participants in each group), there is 1 case of complete response (complete disappearance of tumour in imaging examination) after 3 weeks of treatment for patients with non-Hodgkin lymphomas, showing a certain degree of efficacy.

The Group has submitted Pre-IND application to the U.S. Food and Drug Administration ("**U.S. FDA**") of the Product and has obtained a positive written opinion in December 2014 from the U.S. FDA. It is expected that the formal Investigational New Drug application could be submitted in the second half of 2015. The Group has applied Patent Cooperation Treaty (PCT) patent for the Product. Currently, authorization was granted in China, Europe, Canada, Russia, Australia, Korea and Singapore. Its applications in USA and Japan have entered into the assessment stage and authorization is expected to be granted soon.

Mitoxantrone hydrochloride liposome injection has not yet launched in the world. Based on the good clinical and non clinical research results, the Group will endeavor to launch the Product in order to benefit patients with tumour across and outside the country.

By order of the Board
CSPC Pharmaceutical Group Limited
Cai Dongchen
Chairman

Hong Kong, 19 January 2015

As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. FENG Zhenying, Mr. CHAK Kin Man, Mr. PAN Weidong, Mr. ZHAO John Huan, Mr. WANG Shunlong, Mr. WANG Huaiyu, Mr. LU Jianmin, Mr. WANG Zhenguo and Mr. WANG Jinxu as executive Directors; Mr. LEE Ka Sze, Carmelo as non-executive Director and Mr. CHAN Siu Keung, Leonard, Mr. WANG Bo, Mr. LO Yuk Lam, Mr. YU Jinming and Mr. CHEN Shilin as independent non-executive Directors.