CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

ABSTRACT OF CLINICAL TRIAL DATA OF MITOXANTRONE HYDROCHLORIDE LIPOSOME FOR RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA AND EXTRANODAL NK/T-CELL LYMPHOMA PRESENTED AT 2020 ASH ANNUAL MEETING

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, collectively the "**Group**") announces that the abstract of efficacy and safety clinical trial data of mitoxantrone hydrochloride liposome injection (HE071) independently developed by the Group for the treatment of relapsed/refractory peripheral T-cell lymphoma (PTCL) and extranodal NK/T-cell lymphoma (ENKTCL) has been presented at the oral session of the 2020 American Society of Hematology (ASH) Annual Meeting.

The study is a pivotal, single-arm, multi-center, phase II study of the monotherapy of mitoxantrone hydrochloride liposome injection (20mg/m^2, once every four weeks, maximum of six cycles (n=108)).

The clinical study data shows that (cutoff date of 19 May 2020):

1. Safety: Relatively high safety level with adverse events of mainly hematological adverse reactions. Grade ≥3 hematological adverse reactions included neutropenia (45.4%,49/108), thrombocytopenia (5.7%,17/108), anemia (9.3%,10/108) and bone marrow failure (4.6%, 5/108). More attention was given to grade ≥3 thrombocytopenia clinically as it may increase the risk of bleeding, and the incidence rate of such adverse event was lower than the other therapeutic drugs for the same indication. There were less non-hematological reactions, which were mainly grade 1~2. Grade ≥3 with incidence rate of ≥1% were only found in pneumonia (10.2%, 11/108) and upper respiratory infection (1.9%, 2/108). But those adverse reactions usually found in liposomal drugs, conventional mitoxantrone preparations and other therapies were barely found.

2. Tumor response evaluation: The IRC assessed objective response rate (ORR), complete response (CR) rate and disease control rate (DCR) of the 108 patients enrolled were 40.7% (44/108), 20.4% (22/108) and 69.4% (75/108) respectively. The IRC assessed ORR, CR rate and DCR of the 98 evaluable patients were 44.9% (44/98), 22.4% (22/98) and 76.5% (75/98) respectively.

3. Clinical efficacy: Obvious advantage in survival. The median progression-free survival (PFS) and median overall survival (OS) of all of the 108 patients enrolled who have received at least one treatment with mitoxantrone hydrochloride liposome were 6.7 months and 16.3 months respectively. As of the cutoff date, half of the patients are still in disease relief stage and nearly half of them are still in survival follow-up (21 cases under PFS follow-up and 26 cases under OS follow-up).

4. Special attention: The efficacy for patients with NKTCL subtype (n=21) was encouraging with IRC assessed ORR and DCR of 52.4% and 76.2% respectively. 90% of the patients enrolled have received prior treatment with anthracyclines, over 10% with liposomal doxorubicin, and approximately 50% with chidamide and PD-1 within one year before enrolment. The prior treatment with therapeutic drugs almost did not have any impact on the overall efficacy.

ABOUT MITOXANTRONE HYDROCHLORIDE LIPOSOME INJECTION

Mitoxantrone hydrochloride liposome injection is a class 2 new drug independently developed by the Group. At present, there is no product of the same preparation available or under research in both domestic and overseas markets. The Group has filed an application for marketing approval based on a pivotal registrational phase II study, which was accepted in September 2020 with priority review granted. In the field of hematological oncology, studies on the first-line treatment of PTCL and NKT have already commenced, and relevant clinical studies on leukemia, multiple myeloma and diffuse large B-cell lymphoma are also commencing. In the field of solid tumors, studies have been carried out on breast cancer, small cell lung cancer, liver cancer, reproductive system tumor, head and neck cancer, urothelial carcinoma, sarcoma, gastric cancer, colorectal cancer and lung cancer.

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

Hong Kong, 18 December 2020

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; Mr. LEE Ka Sze, Carmelo as non-executive director; and Mr. CHAN Siu Keung, Leonard, Mr. WANG Bo, Prof. LO Yuk Lam, Dr. YU Jinming and Mr. CHEN Chuan as independent non-executive directors.