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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

"MITOXANTRONE HYDROCHLORIDE LIPOSOME INJECTION" 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 "Mitoxantrone Hydrochloride Liposome Injection (10ml:10mg)" (the "Product") developed by CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd*(石藥集團中諾藥業(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 relapsed/refractory peripheral T-cell lymphoma (PTCL).

The Product is an anti-tumor nanodrug independently developed by the Group and is also the first mitoxantrone nanodrug launched worldwide, representing a breakthrough in China as there have been no innovative nanodrugs launched for years. The Product has full intellectual property rights, and invention patents have been authorized in more than ten countries and regions including China, U.S., Europe and Japan. The research and development of the Product has been funded by a number of national projects including the National Key Research Program (國家重點研究計劃) and the National Major New Drug Development Project (國家重大新藥創制專項).

The design of the Product adopts unique drug loading and release technology to ensure the nanoparticles can be effectively enriched in the tumor and the drug can be released reasonably after administration, thereby increasing the bioavailability of the drug in the tumor and leading to significant improvement in efficacy and safety. The rational design of the Product can also avoid skin toxicity and infusion-related reactions which are common in nanodrugs.

According to clinical studies, the dosage of the Product can be greater than 24 mg/m², which is significantly higher than the clinical dosage of conventional mitoxantrone injection (10-12 mg/m²). The Product has significantly better efficacy than other drugs for the same indication, with reported disease control rate of 70.5%, objective response rate of 41.0%, complete response rate of 21.8%, median progression-free survival of 7.5 months and median duration of response of 11.5 months in the treatment of patients with relapsed or refractory PTCL (source of data: prescription information of Mitoxantrone Hydrochloride Liposome Injection).

The Product is a broad-spectrum anti-tumor nanodrug. Current clinical studies demonstrated that the Product has a significant improvement in efficacy in the treatment of ovarian cancer, head and neck squamous cell carcinoma, pancreatic cancer, breast cancer, small cell lung cancer, NKT cell lymphoma, soft tissue sarcoma and other tumors. In addition, clinical studies on multiple sclerosis and other neuroinflammation are also underway. The Product has also obtained clinical trial approval and orphan drug designation in the U.S. with related clinical trials in progress.

The approval of the Product marks a major breakthrough of the Group in the research and development of nanodrug and cancer therapy. The Product is expected to become a blockbuster product of the Group and provides a new medication option for cancer patients.

By order of the Board

CSPC Pharmaceutical Group Limited

CAI Dongchen

Chairman

Hong Kong, 11 January 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, Professor WANG Hongguang, Mr. AU Chun Kwok Alan and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.

* For identification purpose only.