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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

DUOENDA (多恩達®) (MITOXANTRONE HYDROCHLORIDE LIPOSOME INJECTION) OBTAINS CLINICAL TRIAL APPROVAL FOR THE TREATMENT OF NEUROMYELITIS OPTICA SPECTRUM DISORDERS

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that Duoenda (多恩達®) (Mitoxantrone Hydrochloride Liposome Injection), developed by the Group, has been granted approval by the National Medical Products Administration of the People’s Republic of China to conduct clinical trials for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in China.

Neuromyelitis optica spectrum disorders (NMOSD) is an autoimmune-mediated inflammatory demyelinating disorders of the central nervous system (CNS) with predominant optic nerve and spinal cord involvement, which is included in the Catalogue of Rare Diseases (1st batch, 22 May 2018). Data based on inpatient registry system released in China in 2020 showed that the incidence of NMOSD was approximately 0.278/(100,000 persons/year), 0.075/(100,000 persons/year) in children and 0.347/(100,000 persons/year) in adults, which were higher than that in Western countries. NMOSD is a highly recurrent and disabling disease, with more than 90% having a multitemporal course, of which 40%-60% relapse within 1 year and about 90% within 3 years. Effective treatment for NMOSD can significantly improve the quality of life of patients with NMOSD, delay disease progression, reduce recurrence and reduce the burden on social care.

The conventional relapse-prevention drugs for NMOSD are mainly immunosuppressive drugs, a variety of immune-targeted drugs used in recent years are off-label drugs without sufficient evidence-based medical data. Although some biological agents have been approved for this indication in China recently, there are still problems such as high price, poor drug accessibility, poor efficacy in AQP4-IgG-negative patients, and possible serious adverse effects in specific populations. Therefore, it is of great clinical importance to develop new drugs for NMOSD to improve the efficacy and safety for the treatment of NMOSD.

Duoenda is a new drug of new formulation independently developed by the Group with intellectual property rights and was approved for marketing in January 2022 for the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). The active ingredient of this product is mitoxantrone hydrochloride, and its liposomes as drug carriers have the advantages of reducing the peak drug concentration, reducing myocardial distribution and reducing toxic side effects, which can improve the efficacy and safety of mitoxantrone.

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

Hong Kong, 18 August 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.