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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**

#### **FIRST mRNA-LNP-BASED CAR-T CELL INJECTION (SYS6020) OBTAINS CLINICAL TRIAL APPROVAL FOR NEW INDICATION**

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 first mRNA-Lipid Nanoparticles (LNP)-based Chimeric Antigen Receptor (CAR)-T Cell Injection (SYS6020) targeting B-cell maturation antigen (BCMA) (the “**Product**”) developed by the Group has obtained approval from the National Medical Products Administration of the People’s Republic of China to conduct clinical trials for the indication of systemic lupus erythematosus (SLE) in China. Previously, the Product has obtained clinical trial approval in China for the indication of multiple myeloma (MM).

The Product is the world’s first mRNA-LNP-based cell therapy product approved for clinical trials for SLE. By expressing a CAR that can specifically recognise BCMA antigens and bind to BCMA on the surface of mature B lymphocytes and plasma cells, it targets and kills immune cells, thereby eliminating elevated autoantibodies. This potentially offers a new, safe and effective treatment option for SLE patients. At present, there is no CAR-T therapy approved globally for the treatment of SLE. Compared to conventional CAR-T products, the Product has the advantage of high cell viability, high CAR-positive percentage, no risk of tumorigenicity due to genomic integration, and minimal side effects such as cytokine release syndrome (CRS). Preclinical studies have demonstrated that the Product can significantly kill BCMA antigen-positive myeloma cells and has a good safety profile. In terms of cost, using LNP transfection of T cells can lower the high costs associated with using lentiviral vectors, thereby reducing the burden on patients.

SLE is a typical systemic autoimmune disease mainly characterised by abnormal activation of the immune system, leading to the production of a large number of autoantibodies and resulting in acute or chronic inflammation and functional damage in multiple organs such as the kidneys, heart, lungs, and skin. Most patients require lifelong treatment. The treatment combining hormones and immunosuppressants has improved the long-term survival of SLE patients. However, inevitable disease relapse and irreversible organ damage remain major causes of patient mortality. Therefore, there is an urgent need for new treatment methods to achieve sustained remission of the condition, control organ damage, improve long-term survival of patients, and even achieve complete cure.

The clinical trial approval for SLE indication obtained for the Product marks another significant achievement of the Group in the field of cell therapy, which lays a solid foundation for the development of other cell therapy products, such as in vivo-generated CAR-T.

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

Hong Kong, 9 August 2024

*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. JIANG Hao, Dr. YAO Bing and Mr. CAI Xin as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as independent non-executive directors.*