

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 FURTHER 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) (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 myasthenia gravis (MG) in China. Previously, the Product has obtained clinical trial approval for the indication of multiple myeloma (MM) and systemic lupus erythematosus (SLE).

By expressing a CAR that can specifically recognise BCMA antigens, the Product targets and kills BCMA-positive B-cells and plasma cells in the patient’s body, thus preventing the production of harmful autoantibodies and achieving therapeutic goals. Compared with traditional CAR-T products, the Product has the advantages of high cell viability, high CAR-positive percentage, minimal side effects such as cytokine release syndrome (CRS), and no risk of tumorigenicity caused by genomic integration. Preclinical studies have demonstrated that the Product can significantly kill BCMA antigen-positive myeloma cells with good safety profile and efficacy. At present, there is no CAR-T cell therapy approved globally for the treatment of myasthenia gravis, while the Product is the world’s first mRNA-LNP-based cell therapy product approved for clinical trials for myasthenia gravis.

Myasthenia gravis is an autoimmune disease caused by autoantibodies directed against the neuromuscular junction. Pathogenic autoantibodies include anti-acetylcholine receptor (anti-AChR) antibodies, anti-muscle-specific receptor tyrosine kinase (anti-MuSK) antibodies, anti-LPR4 antibodies, etc. These autoantibodies bind and initiate the complement cascade reaction, leading to the formation of membrane attack complex (MAC), which causes

damage to neuromuscular junctions and symptoms of muscle weakness. Although various drugs are currently available to alleviate symptoms, some patients who have undergone a full course of at least two conventional immunosuppressive drugs (both corticosteroids and non-steroidal immunosuppressants) still experience recurrence symptoms of myasthenia gravis. These patients often require hospitalisation for salvage therapy (e.g. plasmapheresis or intravenous immunoglobulin injections) and are in urgent need of more effective and safer therapeutic drugs to save their lives. CAR-T cell therapy can deeply deplete BCMA-positive B-cells and plasma cells in the patient's body, leading to a significant and long-term improvement in clinical symptoms. This can reduce or even discontinue the use of immunosuppressants and cholinesterase inhibitors to significantly improve the quality of life.

The clinical trial approval for myasthenia gravis indication obtained for the Product marks another significant progress of the Group in the field of cell therapy. The Group will further promote the development of the Product in the fields of oncology, autoimmune connective tissue diseases and neuromuscular autoimmune diseases with the expectation of bringing clinical benefits to more patients.

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

Hong Kong, 25 October 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.