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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

NBL-015 OBTAINS CLINICAL TRIAL APPROVAL IN THE U.S.

The board of directors (the "Board") of CSPC Pharmaceutical Group Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that NBL-015, a fully human antibody drug discovered and developed by NovaRock Biotherapeutics Limited, a subsidiary of the Company, has obtained approval of its Investigational New Drug Application (IND) from the U.S. Food and Drug Administration (FDA). NBL-015 is a fully human monoclonal antibody against Claudin 18.2 for treating advanced solid tumors with positive Claudin 18.2 expression, including pancreatic adenocarcinoma, adenocarcinomas of the stomach, the esophagus or the gastroesophageal junction. The Phase I clinical trials will evaluate the safety, tolerability and pharmacokinetics of NBL-015 in patients with advanced solid tumors.

Claudin 18.2 is a highly specific cell-surface molecule widely expressed in gastric and pancreatic tumors. In normal tissues, Claudin 18.2 expression is strictly confined to differentiated epithelial cells of the gastric mucosa but absent from the gastric stem cell zone, thus the development of therapeutic antibodies targeting Claudin 18.2 has high anti-cancer potential. NBL-015 is a fully human anti-Claudin 18.2 monoclonal antibody optimized through protein engineering to achieve enhanced ADCC, CDC and ADCP effects. Preclinical studies of in vitro tumor cell killing and in the tumor mouse model have demonstrated that NBL-015 has significant advantages over similar drugs in terms of low immunogenicity, good safety, high affinity and high anti-tumor activity, providing a promising prospect of becoming the best-in-class target therapy to treat pancreatic and gastric cancer.

NBL-015 has been previously granted orphan-drug designation for the treatment of pancreatic cancer and gastric cancer by the U.S. FDA.

By order of the Board CSPC Pharmaceutical Group Limited Cai Dongchen

Chairman

Hong Kong, 25 May 2021

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.