Beijing Biostar Pharmaceuticals Co., Ltd.

北京華昊中天生物醫藥股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock code: 2563)

VOLUNTARY ANNOUNCEMENT

APPROVAL OF UTIDELONE CAPSULE FOR FIRST-LINE TREATMENT OF ADVANCED GASTRIC CANCER IN PHASE II/III INTERNATIONAL MULTI-CENTER CLINICAL STUDY BY U.S. FOOD AND DRUG ADMINISTRATION

This announcement is made by Beijing Biostar Pharmaceuticals Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that one of the Group's important overseas pipelines, Utidelone Capsules ("**UTD2**"), in combination with capecitabine and oxaliplatin as a first-line treatment for PD-L1-negative locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (the "**Combination Therapy**"), has received approval from the U.S. Food and Drug Administration ("**FDA**") for its international multi-center Phase II/III registration clinical study ("**BG02-2404**").

The Group's UTD2, developed using a proprietary synthetic biology technology platform, has successfully completed the Phase I clinical study in the U.S., with its safety and efficacy fully verified. As of the date of this announcement, Utidelone has shown excellent data in clinical studies for gastric cancer. In a completed Phase II clinical study of Utidelone combined with PD-1 and oxaliplatin as a first-line treatment for unresectable locally advanced or recurrent/metastatic HER2-negative gastric cancer, a total of 23 patients completed efficacy evaluation, of which 15 achieved a partial response and 8 achieved the stage of stable disease, resulting in an overall response rate of 65.2% and a clinical benefit rate of 100%. As a result, UTD2 was granted orphan drug designation by the FDA for the treatment of advanced gastric cancer.

Compared to taxanes, which are difficult to develop into oral dosage forms, Utidelone is not easily excreted from cells by P-glycoprotein and has the advantage of oral administration. UTD2 will significantly improve the convenience and compliance of patients taking the drug, assist with long-term adjuvant and maintenance treatment, reduce treatment costs for patients, and demonstrate great application potential and market opportunity. BG02-2404 is the first international multi-center Phase II/III registration clinical study conducted by the Company for UTD2, aiming to further consolidate the implementation of the Company's international development strategy.

ABOUT BG02-2404

BG02-2404 is an international, multi-center, open-label, randomized, controlled phase II/III registration clinical study of UTD2 combined with capecitabine and oxaliplatin for the first-line treatment of locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma with PD-L1 negativity. Phase II of the study is planned to enroll 78 subjects at 12 centers in the U.S. and 15 centers in Asia. The primary objective is to evaluate the safety, efficacy, and pharmacokinetic profile of UTD2 in combination. Phase III of the study is planned to enroll 700 subjects at 30 centers in the U.S., 53 centers in Asia, and 47 centers in Europe and other countries and regions, with the primary endpoint being overall survival and secondary endpoints including progression-free survival, overall response rate, and safety assessment.

RISK WARNING

The Combination Therapy may ultimately not be successfully developed and commercialized. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By order of the Board
Beijing Biostar Pharmaceuticals Co., Ltd.
北京華昊中天生物醫藥股份有限公司
Dr. Tang Li
Chairperson and Executive Director

Beijing, the PRC, 5 February 2025

As at the date of this announcement, the Board comprises (i) Dr. Tang Li, Dr. Qiu Rongguo, Mr. Zhang Cheng and Dr. Guan Jin as executive Directors; (ii) Mr. Tang Jin and Mr. Zhu Pai as non-executive Directors; and (iii) Dr. Meng Songdong, Ms. Qi Jingyao and Mr. Ran Dong as independent non-executive Directors.