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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

FOUR CLINICAL STUDY RESULTS OF UTIDELONE OF BIOSTAR PHARMACEUTICALS SELECTED FOR THE 2026 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING

This announcement is made by Beijing Biostar Pharmaceuticals Co., Ltd. (the “**Company**”) on a voluntary basis.

The board (the “**Board**”) of directors of the Company is pleased to announce that four latest clinical study data sets of the Company’s core products, Utidelone Injection (“**UTD1**”) and Utidelone Capsule (“**UTD2**”), have been selected for poster presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting (the “**2026 ASCO Annual Meeting**”).

The four selected studies target the phase I/II clinical trial of UTD2 for the treatment of advanced breast cancer, the phase II clinical trial of UTD2 for the treatment of platinum-resistant ovarian cancer, the phase II clinical trial of UTD2 for the treatment of HER2-positive advanced breast cancer, and the phase II clinical trial of UTD1 for the treatment of castration-resistant prostate cancer, respectively. Based on the characteristics of utidelone, such as its broad antitumor spectrum and high oral bioavailability, the Company has continuously made in-depth arrangements in expanding into new indications and the clinical development of oral dosage forms.

The 2026 ASCO Annual Meeting will be held from 29 May to 2 June 2026 at the McCormick Place in Chicago, USA. The annual ASCO meeting gathers elites in clinical oncology from around the world and will showcase the most cutting-edge clinical oncology research results and tumor treatment technologies globally.

Phase II Clinical Trial of UTD2 for the Treatment of Advanced Breast Cancer

Final results of a phase II study of utidelone capsule, the first solid oral microtubule stabilizer, in metastatic breast cancer patients

The corresponding author of this study is Academician Xu Binghe from the Cancer Hospital, Chinese Academy of Medical Sciences. This study is a phase II clinical trial of UTD2 in combination with capecitabine (“CAP”) for the treatment of metastatic breast cancer, which enrolled a total of 50 patients with metastatic breast cancer previously treated with taxanes or anthracyclines, with 44 patients evaluable for efficacy. Among them, 27 patients achieved partial response (“PR”) and 12 patients had stable disease (“SD”), representing an ORR of 52.3% and a DCR of 88.6%. The median progression-free survival (“mPFS”) reached 8.25 months, the median duration of response (mDoR) reached 7.62 months, and the median number of treatment cycles was 9, demonstrating comparable or superior efficacy to historical data of utidelone injection (UTD1) in combination with CAP (ORR 39.6%, DCR 85.2%, mPFS 7.72 months).

In terms of safety, compared with UTD1+CAP, the incidence and severity of peripheral neurotoxicity of UTD2+CAP were significantly reduced (the incidence of grade ≥ 3 peripheral neurotoxicity decreased from 25.1% to 2%), while maintaining an extremely low incidence of grade 3/4 hematological toxicity, making it suitable for long-term administration. UTD2 will significantly improve patient convenience and tolerability, providing a brand-new oral treatment regimen for patients with advanced breast cancer.

Phase II Clinical Trial of UTD2 for the Treatment of Platinum-Resistant Ovarian Cancer

Phase II study of utidelone plus fruquintinib for the treatment of platinum-resistant recurrent ovarian cancer (FRUTD trial)

The corresponding author of this study is Wu Xiaohua from Fudan University Shanghai Cancer Center. This study is an open-label, Simon’s two-stage phase II clinical study of UTD2 in combination with fruquintinib for the treatment of platinum-resistant recurrent ovarian cancer, which plans to enroll 35 patients. As of the data cut-off date, a total of 19 patients were enrolled, and 14 patients were evaluable for efficacy, among whom 9 patients achieved PR and 5 patients had SD, representing an ORR of 64.3% and a DCR of 100%. The mPFS reached 7 months, and the median overall survival (“mOS”) had not yet been reached.

Most patients only experienced grade 1-2 treatment-related adverse events (“TRAEs”), and no patient experienced grade 4 or above TRAEs. UTD2 in combination with fruquintinib for the treatment of platinum-resistant recurrent ovarian cancer has demonstrated encouraging efficacy with manageable safety. The trial is currently ongoing, and the final data will be reported upon the completion of the trial.

Phase II Clinical Trial of UTD1 for the Treatment of HER2-Positive Advanced Breast Cancer

Efficacy and safety results of a prospective phase II study (IPU-trial) of inetetamab and pyrotinib in combination with utidelone for first- or second-line treatment of HER2-positive metastatic breast cancer

The corresponding author of this study is Sun Tao from Liaoning Cancer Hospital. This study is a Phase II clinical trial evaluating UTD1 in combination with inetetamab and pyrotinib as first- or second-line treatment for HER2-positive advanced breast cancer. As of the data cutoff date, patient enrollment had been completed, with a total of 85 patients evaluable for efficacy. Among them, 6 patients achieved complete response (CR), 64 achieved PR, and 7 achieved SD. The ORR was 82.4%, and mPFS was 13.1 months. The median number of treatment cycles was 11, while the mOS had not yet been reached. The overall survival (OS) rates at 12, 26, and 35 months were 94.6%, 85.2%, and 78.5%, respectively.

The overall safety was manageable, and the most common Grade ≥ 3 TRAEs were diarrhea (28.2%) and peripheral neurotoxicity (4.7%), both of which could be effectively managed through supportive care or dose adjustment. This triple-combination regimen demonstrated outstanding efficacy and a favorable safety profile in first- and second-line treatment of HER2-positive advanced breast cancer.

Phase II Clinical Trial of UTD1 for the Treatment of Castration-Resistant Prostate Cancer

Utidelone in heavily pretreated metastatic castration-resistant prostate cancer progressing after docetaxel and novel hormonal agents: results of a completed phase II trial

The corresponding author of this study is Shi Yanxia from Sun Yat-sen University Cancer Center. This study is a Phase II single-arm trial evaluating UTD1 monotherapy in patients with metastatic castration-resistant prostate cancer (mCRPC) who had previously received docetaxel and hormonal therapy.

As of the data cutoff date, enrollment of all 43 patients had been completed. The proportion of patients with a decline in serum prostate-specific antigen (“PSA”) levels of $\geq 50\%$ (PSA50) was 23.3%, and the PSA30 response rate was 32.6%.

The radiographic progression-free survival (rPFS) was 6.7 months, and mOS was 11.4 months. In addition, 23 patients were evaluable for tumor response assessment, with an ORR of 17.4% and a DCR of 56.5%. Regarding safety, the vast majority of TEAEs were Grade 1/2 and manageable. The main Grade 3/4 TEAEs included anemia, peripheral sensory neuropathy, vomiting, and diarrhea. In heavily pretreated patients with castration-resistant prostate cancer, UTD1 monotherapy demonstrated encouraging antitumor activity and a manageable safety profile, supporting further exploration of utidelone in this patient population.

Warning Notice

The above-mentioned products and relevant combination therapies may not eventually 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
Chairman and Executive Director

Beijing, the PRC, 27 May 2026

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 Ms. Dai Xuefen as non-executive Directors; and (iii) Mr. Shiu Shu Ming and Dr. Ye Chengang as independent non-executive Directors.