# 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

## UTD1 Achieves First Patient Dosing in U.S. for Pivotal Clinical Study for Breast Cancer Brain Metastases

This announcement is made by Beijing Biostar Pharmaceuticals Co., Ltd. (the "**Company**") on a voluntary basis for the purpose of keeping the shareholders of the Company and potential investors abreast of the latest business development of the Group.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that Biostar Pharma, Inc. (the "**US-Biostar**"), the Company's wholly owned U.S. subsidiary, has completed the dosing of the first patient in one of its key overseas clinical studies: the U.S. pivotal clinical study (NCT06764940) of Utidelone Injection (UTD1) combined with capecitabine for the treatment of HER2-negative breast cancer brain metastases (BCBM).

The study adopts a two-stage design and plans to enroll approximately 120 subjects. The primary endpoint is the central nervous system objective response rate (CNS-ORR). Nearly 20 top tier clinical institutes across the United States are participating in the trial, including MD Anderson Cancer Center, John Hopkins Sidney Kimmel Comprehensive Cancer Center, City of Hope-Duarte, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, University of Colorado Hospital, Augusta University, and University of California Los Angeles.

Utidelone's unique physicochemical properties and insensitivity to P-glycoprotein-mediated efflux enable it to cross the blood-brain barrier (BBB) and prevent or treat brain metastases of solid tumors, setting it apart from taxanes, which are also microtubule stabilizers. A Phase II clinical study of utidelone combined with bevacizumab and chemotherapy for HER2-negative BCBM, which enrolled 34 subjects, was presented orally at the 2025 ASCO Annual Meeting. The results showed a CNS-ORR of 67.6%, a central nervous system clinical benefit rate (CNS-CBR) of 88.2%, and a median central nervous system progression-free survival (CNS-PFS) of 15 months. The results of another Phase II clinical study of utidelone combined with bevacizumab for HER2-negative BCBM were published in JAMA Oncology in 2025. 47 subjects were enrolled in the study, with a CNS-ORR of 42.6%, a median

CNS-PFS of 10.6 months, and a median overall survival of 15.1 months. In both studies, most treatment-related adverse events (TRAEs) were Grade 1–2, controllable, and reversible. The U.S. FDA has also granted Utidelone orphan drug designation for the treatment of breast cancer brain metastases.

Approximately 20–50% of advanced breast cancer patients develop brain metastases. Due to the presence of the BBB, many breast cancer treatments were unable to achieve effective concentrations intracranially, leading to generally poor prognoses for BCBM patients, particularly those with HER2-negative BCBM, whose median progression-free survival is only 2–6 months. However, there is currently no clearly effective drug therapy for HER2-negative BCBM, and no drugs worldwide have been approved for HER2-negative BCBM, highlighting a significant and urgent unmet medical need. Utidelone has the potential to change this landscape, offering a new treatment option and hope for survival to these patients.

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, 17 December 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 Ms. Dai Xuefen as non-executive Directors; and (iii) Dr. Meng Songdong, Mr. Shiu Shu Ming and Dr. Ye Chengang as independent non-executive Directors.*