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**HighTide Therapeutics, Inc.**

**君圣泰医药**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 2511)**

## **HIGHTIDE THERAPEUTICS ANNOUNCES COMPLETION OF PHASE IIB CLINICAL STUDY OF HTD1801 FOR THE TREATMENT OF METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH)**

This announcement is made by HighTide Therapeutics, Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Group.

The board of directors (the “**Board**”) of the Company announces the completion of its Phase Iib global multi-regional clinical trial of HTD1801 in patients with metabolic dysfunction-associated steatohepatitis (MASH).

CENTRICITY (NCT05623189) is a randomized, double-blind, placebo-controlled global multi-regional Phase Iib clinical trial (N=218) designed to evaluate the safety and efficacy of HTD1801 compared with placebo in MASH patients with comorbid type 2 diabetes mellitus (T2DM) or pre-diabetes.

Preliminary analysis results show that 48% of patients in the placebo group achieved a reduction in NAFLD Activity Score (NAS) of  $\geq 2$  points with no worsening of fibrosis, or resolution of MASH with no worsening of fibrosis, at the end of treatment period. This result is significantly higher than placebo effects in previous similar clinical studies. A systematic review and meta-analysis published in 2025, which included 127 MASH clinical trials for 78 different investigational drugs with similar designs, showed that the placebo effect typically does not exceed 20% (*Clinical Gastroenterology and Hepatology*. 2025 Nov 4:S1542-3565(25)00860-2).

After a third-party investigation conducted on the study execution, issues within the scope of study execution and quality management have been identified, such as the management of concomitant medications (e.g., significantly more patients in the placebo group have initiated or increased GLP-1RAs dosage during the treatment period in violation of the protocol) and patient compliance management. These issues may have had a significant impact on the trial results.

Based on these circumstances, the Company conducted a *post hoc* analysis of the study data. After controlling for confounding factors such as concomitant medication changes in violation of protocol, the results showed a substantial decrease in the placebo effect, and HTD1801 showed a trend of therapeutic improvement across multiple liver histological parameters compared to placebo. This *post hoc* analysis further suggests that the study data were impacted and confounded by multiple execution and quality management factors. The long-term safety and tolerability of HTD1801 demonstrated in this study were consistent with results from previous clinical studies.

Given that HTD1801 had previously successfully met the primary endpoint and demonstrated multiple benefits in a Phase IIa clinical study in MASH patients with comorbid T2DM, as well as in three Phase III clinical studies completed in the T2DM patient population, as well as progressing smoothly towards an NDA, HighTide Therapeutics will further evaluate its subsequent clinical development strategy for the MASH indication based on the overall data, investigation results, and *post hoc* analysis conclusions of this study. The Company will be in communication with the U.S. Food and Drug Administration (FDA) and conduct a comprehensive assessment based on regulatory feedback for future development plan.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that HTD1801 will ultimately be successfully marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board  
**HighTide Therapeutics, Inc.**  
**Dr. LIU Liping**  
*Executive Director and Chief Executive Officer*

Hong Kong, February 5, 2026

*As at the date of this announcement, the Board comprises Dr. LIU Liping and Ms. YU Meng as executive Directors; Dr. ZHU Xun, Mr. MA Lixiong and Mr. JIANG Feng as non-executive Directors; and Mr. TAN Bo, Dr. LI Jin and Mr. HUNG Tak Wai as independent non-executive Directors.*