HighTide Therapeutics, Inc.

君圣泰医药

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2511)

HIGHTIDE COMPLETES PATIENT ENROLLMENT OF PHASE III CLINICAL TRIALS OF HTD1801 FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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 that two Phase III registration trials evaluating the efficacy and safety of berberine ursodeoxycholate (HTD1801) in patients with type 2 diabetes mellitus (T2DM) have completed patient enrollment. HTD1801 is the Company's lead compound, an in-house developed, first-in-class, gut-liver anti-inflammatory metabolic modulator.

The two Phase III registration trials are as follows:

HTD1801.PCT105: a multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of HTD1801 in patients with T2DM with poor glycemic control despite dietary and exercise interventions (SYMPHONY-1).

HTD1801.PCT106: a multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of HTD1801 in patients with T2DM inadequately controlled with metformin (SYMPHONY-2).

In both trials, HTD1801 will be evaluated for its effects on HbA1c and other indicators of glucose metabolism, lipids, markers of liver injury/function, and inflammation in patients with T2DM.

INFORMATION ABOUT TYPE 2 DIABETES MELLITUS (T2DM)

T2DM is one of the most common metabolic diseases worldwide. Due to rapid economic development and lifestyle changes in China, prevalence of T2DM has steadily risen, with China now having the largest T2DM patient population globally. Chronic hyperglycemia along with the other metabolic aberrations (i.e., obesity, dyslipidemia, hypertension, fatty liver) in T2DM ultimately results in damage to various organ systems, leading to the development of life-threatening complications, primarily being microvascular and macrovascular complications, leading to a 2-fold to 4-fold increased risk of cardiovascular diseases – major causes of death and disabilities and underscoring the need for comprehensive patient management. Therapy for T2DM that addresses co-existing metabolic aberrations to deliver more comprehensive clinical benefit to patients remains an unmet need in the clinical management of T2DM.

ABOUT BERBERINE URSODEOXYCHOLATE (HTD1801)

Berberine ursodeoxycholate (HTD1801) is an orally delivered first-in-class gut-liver anti-inflammatory metabolic modulator being developed for the treatment of metabolic and digestive diseases. HTD1801, an ionic salt of berberine and ursodeoxycholate, is a new molecular entity with unique mechanisms of action. Its mechanistic pathway has been associated with improvements in glucose metabolism, insulin resistance, lipid metabolism, and hepatic inflammation, potentially providing a comprehensive treatment platform for the multifaceted nature of complex metabolic diseases such as T2DM.

ABOUT HIGHTIDE THERAPEUTICS, INC.

HighTide Therapeutics, Inc. (Stock Code: 2511.HK) is a globally integrated biopharmaceutical company focusing on the discovery and development of first-in-class multifunctional multi-targeted therapies with poly-indication potential across multiple metabolic and digestive diseases with significant unmet medical needs. The Company is currently developing several clinical assets and holding global intellectual property rights, advancing multiple mid-to-late-stage clinical trials including therapy for metabolic dysfunction-associated steatohepatitis (MASH), T2DM, severe hypertriglyceridemia (SHTG), primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC). HTD1801, the Company's lead drug candidate, received Fast Track designation from the United States Food and Drug Administration for both MASH and PSC, as well as Orphan Drug designation for PSC. In China, HTD1801 has been included in the National Major New Drug Innovation Program under the 13th Five-Year Plan for Major Technology Project.

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 developed and 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, June 27, 2024

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. Jin LI and Mr. HUNG Tak Wai as independent non-executive Directors.