



## HighTide Therapeutics to Present Analyses of Phase 2 MASH Study at AASLD's The Liver Meeting® 2024, Demonstrating Benefits of Berberine Ursodeoxycholate (HTD1801)

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### DETAILED NEWS

October 15, 2024 ROCKVILLE, MD and SHENZHEN, CHINA, October 15, 2024—High Tide Therapeutics, Inc. (2511.HK), a clinical stage biopharmaceutical company specializing in the development of multifunctional multi-targeted therapies for chronic liver and metabolic diseases, announced today that it presents at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting®, taking place from November 15-19, 2024 in San Diego, California.

The presentations include post-hoc analyses of the Phase 2a clinical study of berberine ursodeoxycholate (HTD1801), a gut-liver anti-inflammatory metabolic modulator, in patients with metabolic dysfunction-associated steatohepatitis (MASH) and comorbid type 2 diabetes mellitus (T2DM) (NCT03656744). "These data provide additional characterization of the efficacy and safety of HTD1801, a novel, multifunctional therapy being developed for the treatment of patients with MASH and T2DM.

If further studies confirm these findings, HTD1801 could potentially offer a more effective solution for patients who do not respond adequately to GLP-1 receptor agonists.

In addition, the observations of improved GI tolerance over time suggests that HTD1801 may be an attractive option for long-term management of chronic conditions such as MASH and T2DM.

The ongoing Phase 2b study (CENTRICITY, NCT05623189), fully enrolled in 1Q 2024, evaluates the histological benefit of HTD1801 in patients with MASH and T2DM.

We look forward to announcing the CENTRICITY results which we expect in the first half of 2025," said Dr. Leigh MacConell, Chief Development Officer of HighTide. "Efficacy of Berberine Ursodeoxycholate (HTD1801) Compared to Ongoing Use of GLP-1 Receptor Agonists in Patients with MASH and T2DM" (Abstract 3218, Poster Presented November 17th) About the Abstract: As GLP-1 Receptor Agonists (GLP-1RAs) are prominently used in patients with T2DM and gaining attention as a potential treatment for MASH, this post-hoc comparative efficacy analysis evaluated ongoing GLP-1RA use compared to newly initiated HTD1801 treatment.

↪ This analysis suggests that HTD1801 provides greater improvements in markers of liver injury and inflammation, glycemic control, weight loss, and lipid metabolism compared to ongoing GLP-1RA use.

↪ These findings are important as they suggest that HTD1801 could provide additional benefit to patients with MASH and T2DM, on concomitant GLP-1RA treatment. "Time Course of Onset, Incidence, and Prevalence of Gastrointestinal Adverse Events with HTD1801 (Berberine Ursodeoxycholate) in Patients with MASH and T2DM" (Abstract 3219, Poster Presented November 17th) About the Abstract: Across several indications, the most commonly occurring adverse events (AEs) in studies of HTD1801 have been mild to moderate gastrointestinal (GI) AEs, primarily diarrhea and nausea.

↪ The purpose of this post-hoc analysis was to characterize the time course and severity of GI AEs in patients with MASH and T2DM treated with HTD1801 for 18 weeks.

↪ Based on this analysis, the incidence of GI-related AEs peaks within the first 4 weeks of treatment, was mild to moderate in severity, and importantly, showed a decreasing incidence and prevalence over the course of treatment.

↪ These data demonstrate that HTD1801 is generally well-tolerated and with continued treatment, GI tolerance improves supporting its potential long-term use in chronic diseases, such as MASH.

## KEY HIGHLIGHTS

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