



Seaport Therapeutics Reports Positive Topline Results from Phase 1 Driving Simulation Trial of GlyphAllo™ in Healthy Volunteers

September 9, 2026

Trial met its primary endpoint, showing that evening dosing of GlyphAllo at 375 mg did not impair next-morning driving performance compared to placebo on Day 5, following multiple-day dosing

Key secondary endpoint also met, showing a single evening dose of 250 mg GlyphAllo did not impair next-morning driving performance compared to placebo on Day 2

GlyphAllo was well-tolerated, with no serious adverse events reported

Company plans to submit results to the U.S. Food and Drug Administration as part of the ongoing development program for GlyphAllo

BOSTON--(BUSINESS WIRE)--Sep. 9, 2026-- [Seaport Therapeutics, Inc.](#), (Nasdaq: SPTX) ("Seaport" or the "Company"), a clinical-stage therapeutics company that is inventing and developing novel neuropsychiatric medicines, today announced positive topline results from the Phase 1 Driving Simulation Trial of GlyphAllo™ (SPT-300 or Glyph Allopregnanolone), a novel, Glyphed oral prodrug of allopregnanolone, in healthy volunteers. The trial evaluated the 375 mg dose of GlyphAllo, the highest dose currently being investigated in the Phase 2b BUOY-1 trial, as well as a 250 mg dose. The trial met its primary endpoint demonstrating that evening dosing of GlyphAllo at 375 mg did not impair next-morning driving performance compared to placebo on Day 5, following multiple-day dosing. The key secondary endpoint was also met, showing that a single 250 mg dose of GlyphAllo did not impair next-morning driving performance compared to placebo on Day 2.

"We are very pleased by the results which showed no next-morning driving impairment at either dose evaluated. The trial used a validated driving simulator and trial design with an evening dosing regimen consistent with the Phase 2b BUOY-1 trial and GlyphAllo's intended clinical use," said Daphne Zohar, Co-founder and Chief Executive Officer of Seaport Therapeutics. "We believe that GlyphAllo has the potential to deliver the benefits of allopregnanolone without next-morning effects on driving. These results further reinforce our view that GlyphAllo offers meaningful differentiation as we advance it as a potential first-in-class treatment for major depressive disorder."

The trial also included a 7.5 mg dose of zopiclone as the positive control. Zopiclone did produce statistically significant impairment relative to both GlyphAllo and placebo on both Day 2 and Day 5, confirming the assay sensitivity of the trial and its ability to detect an effect on driving performance. GlyphAllo was well-tolerated at all doses, with most adverse events being mild and transient and no serious adverse events reported. Together with previously generated clinical and preclinical data and a favorable safety and tolerability profile observed to date, these findings provide additional support for the differentiation of the overall profile of GlyphAllo as the program advances in the ongoing potentially registration-enabling trial in major depressive disorder (MDD).

Seaport plans to submit the results to the U.S. Food and Drug Administration as part of the ongoing development program for GlyphAllo. The Company also plans to present additional analyses at upcoming scientific meetings.

Seaport is actively enrolling patients in BUOY-1, a two-arm, global, randomized, double-blind, placebo-controlled, potentially registration-enabling Phase 2b trial investigating the safety and efficacy of GlyphAllo in patients with MDD, with or without anxious distress. The Company expects to announce topline data from the BUOY-1 trial in the first half of 2027.

About the Phase 1 Driving Simulation Trial

The randomized, double-blind, placebo- and active-controlled, three-way, crossover Phase 1 trial was designed to investigate the effects of evening doses of GlyphAllo on next-morning simulated driving performance in 33 healthy volunteers. Participants received GlyphAllo at bedtime and underwent driving performance assessments the following morning, approximately nine hours following GlyphAllo administration, consistent with established driving simulation trial methodologies. Driving performance was assessed using the Cognitive Research Corporation Driving Simulator-MiniSim, a widely accepted and validated tool used in clinical development. The primary endpoint was Standard Deviation of Lateral Position (SDLP), a gold standard measure of lane weaving commonly used in clinical trials to evaluate driving impairment. SDLP was assessed on Day 2 following a single 250 mg dose and then on Day 5 following multiple-day dosing of GlyphAllo at 375 mg. The trial also included a 7.5 mg dose of zopiclone as a positive control. GlyphAllo, including the 375 mg dose, the highest dose being evaluated in the ongoing Phase 2b BUOY-1 trial, has previously demonstrated desirable pharmacokinetics and pharmacodynamics, and a favorable safety and tolerability profile in Phase 1 and Phase 2a clinical trials.

About GlyphAllo (SPT-300 or Glyph Allopregnanolone)

GlyphAllo (SPT-300 or Glyph Allopregnanolone) is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous molecule that has been clinically validated in third-party trials for the treatment of postpartum depression, or PPD, a form of major depressive disorder (MDD), that shares symptomatology with MDD, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. GlyphAllo is designed to overcome bioavailability limitations of allopregnanolone and deliver rapid and durable efficacy in MDD. Seaport has demonstrated in a Phase 1 clinical trial that GlyphAllo reaches therapeutically relevant exposures with oral dosing, and in a Phase 2a clinical trial, GlyphAllo demonstrated initial proof-of-concept with an objective biomarker of stress in healthy volunteers and a favorable tolerability profile. Seaport is actively enrolling patients in BUOY-1, a two-arm, global, randomized, double-blind, placebo-controlled, potentially registration-enabling Phase 2b trial investigating the safety and efficacy of GlyphAllo in patients with MDD with or without anxious distress. Topline data from the BUOY-1 trial are expected in the first half of 2027.

About Seaport Therapeutics

Seaport Therapeutics (Nasdaq: SPTX) is a clinical-stage therapeutics company focused on inventing and developing new medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. Through its differentiated approach, the Company identifies clinically validated mechanisms with established efficacy and safety which had historically been limited by high first-pass metabolism, low bioavailability, and/or side effects. Seaport applies its proprietary Glyph™ platform to overcome those limitations and invent innovative oral therapies. With an experienced team of industry leaders, Seaport has a proven track record in neuropsychiatry drug discovery and development and delivering successful business outcomes. Seaport aims to develop novel, leading treatment options that will make a significant impact for patients and their families. For more information, please visit www.seaporttx.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding our product candidates, including: the ongoing Phase 2b BUOY-1 trial of GlyphAllo, the enrollment status and anticipated timing of data readouts, including our anticipated readout of topline data for GlyphAllo in the first half of 2027, the interpretation and clinical regulatory implications of the topline results from the Phase 1 Driving Simulation Trial of GlyphAllo in healthy volunteers, and Seaport’s plans to submit the results to the U.S. Food and Drug Administration.

Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect Seaport’s business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to the Company’s research and development activities, including with respect to the Phase 2b BUOY-1 trial; risks that interim results are not predictive of final results in a clinical trial. Seaport’s ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to Seaport’s preclinical and clinical development activities; the Company’s dependence on third parties to conduct clinical trials, manufacture its product candidates and develop and commercialize its product candidates, if approved; Seaport’s ability to attract, integrate and retain key personnel; risks related to the Company’s financial condition and need for substantial additional funds in order to complete development activities and commercialize a product candidate, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining Seaport’s intellectual property protections; and risks related to the competitive landscape for Seaport’s product candidates; as well as other risks and uncertainties described in “Risk Factors,” in Seaport’s Quarterly Report on Form 10-Q for the three months ended June 30, 2026 filed with the Securities and Exchange Commission (“SEC”), as well as in subsequent filings with the SEC. Seaport expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Seaport uses and intends to continue to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company’s Investor Relations website, in addition to following the Company’s press releases, SEC filings, public conference calls, presentations, and webcasts.

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