Structure Therapeutics Announces First Patients Dosed in Phase 2b ACCESS Clinical Study Evaluating Oral Small Molecule GLP-1 Receptor Agonist, GSBR-1290, for Obesity

November 13, 2024

Phase 2b ACCESS study designed to evaluate multiple doses up to 120 mg of GSBR-1290 over 36 weeks

Comprehensive development program also includes Phase 2 ACCESS II study to evaluate even higher doses of GSBR-1290 over 36 weeks; first patient expected to be dosed by end of 2024

Topline data from both ACCESS and ACCESS II studies expected in the fourth quarter of 2025

Company to host conference call today at 4:30 p.m. Eastern Time

SAN FRANCISCO, Nov. 13, 2024 (GLOBE NEWSWIRE) -- Structure Therapeutics Inc. (NASDAQ: GPCR), a clinical-stage global biopharmaceutical company developing novel oral small molecule therapeutics for metabolic and pulmonary diseases, today announced the first patients have been dosed in the randomized, double-blind, placebo-controlled Phase 2b ACCESS clinical study evaluating GSBR-1290 in participants living with obesity, or overweight with a weight-related comorbidity. GSBR-1290 is an orally-available, nonpeptide small molecule glucagon-like-peptide-1 receptor (GLP-1R) agonist that has demonstrated competitive weight loss and generally favorable safety and tolerability results in previous studies with once-daily dosing.

The Phase 2b ACCESS study is part of a comprehensive development program that also includes the Phase 2 ACCESS II study. ACCESS aims to enroll approximately 220 adults living with obesity, or overweight with a weight-related comorbidity, and is designed to evaluate multiple doses (up to 120 mg) of GSBR-1290 with an optimized “low and slow” titration regimen over 36 weeks. ACCESS II aims to enroll approximately 82 adults living with obesity, or overweight with a weight-related comorbidity, and is designed to evaluate two additional higher doses of GSBR-1290 (180 and 240 mg) over 36 weeks, following the same titration scheme as the ACCESS study. Topline data from both the ACCESS and ACCESS II studies are expected in the fourth quarter of 2025.

“We have designed the ACCESS and ACCESS II studies to generate a robust dataset to determine the target doses to move into Phase 3 clinical development with the goal of bringing GSBR-1290 to patients as rapidly as possible,” said Raymond Stevens, Ph.D., Founder and CEO of Structure Therapeutics. “In addition to its very competitive efficacy and tolerability profile, as an oral, nonpeptide small molecule GLP-1R agonist, we believe GSBR-1290 offers attractive manufacturing scalability advantages over peptide-based GLP-1R therapies, and we are excited to advance GSBR-1290 as our lead program. GSBR-1290 is just one of many compounds in our oral small molecule obesity portfolio, followed by our oral small molecule amylin development candidate which we expect to announce later this quarter.”

“Our 36-week ACCESS study is designed to assess multiple therapeutic doses of GSBR-1290 with a start low and go slow 4-week titration approach to optimize tolerability and increase the likelihood of maximizing weight loss,” said Blai Coll, M.D., Ph.D., Chief Medical Officer of Structure Therapeutics. “Based on the data from our earlier studies, clean safety profile and proportional exposure of GSBR-1290, we are also initiating the ACCESS II study to evaluate higher doses of GSBR-1290. We look forward to data from both studies expected in the fourth quarter of 2025.”

About the Phase 2b ACCESS Study
ACCESS is a randomized, double-blind, placebo-controlled, Phase 2b dose-range finding study of GSBR-1290 in approximately 220 adult participants living with obesity (body mass Index ≥ 30 kg/m2), or overweight (body mass index ≥ 27 kg/m2) with at least one weight-related comorbidity. Participants will start at 5mg of GSBR-1290 (or placebo) with a 4-week titration schedule, reaching target doses of 45 mg, 90 mg and 120 mg. The primary endpoint is percent change in body weight from baseline to week 36. Secondary endpoints include safety and tolerability of the monthly titration scheme, as well as pharmacokinetics of GSBR-1290.

About the Phase 2 ACCESS II Study
ACCESS II is a randomized, double-blind, placebo-controlled, Phase 2 dose-range finding study of GSBR-1290 in approximately 82 adult participants living with obesity, or overweight with at least one weight-related comorbidity. The study is designed to evaluate two higher doses of GSBR-1290. Participants will start at 5mg of GSBR-1290 (or placebo) and will follow a 4-week titration schedule up to target doses of 120 mg, 180 mg and 240 mg.

Conference Call and Webcast Information
Structure Therapeutics will host a conference call and webcast today, November 13, 2024 at 4:30 p.m. Eastern Time. A live webcast of the call will be available on the Investor Relations page of Structure Therapeutics’ website at https://ir.structuretx.com/events-presentations/events. To access the call by phone, participants should visit this link (registration link) to receive dial-in details. The webcast will be made available for replay on Structure Therapeutics’ website beginning approximately two hours after the live event. The replay of the webcast will be available for 90 days.

About GSBR-1290 and Structure Therapeutics Oral Metabolic Franchise
GSBR-1290 is an orally-available, small molecule agonist of the glucagon-like-peptide-1 (GLP-1) receptor agonist, a validated drug target for the treatment of obesity and type 2 diabetes mellitus (T2DM). Through Structure Therapeutics’ structure-based drug discovery platform, GSBR-1290 was designed to be a biased GPCR agonist, which selectively activates the G-protein signaling pathway. Beyond GSBR-1290, Structure Therapeutics is developing next generation oral small molecules including amylin receptor agonists, and other combination GLP-1 receptor agonists candidates such as glucose-dependent insulinotropic polypeptide (GIP), glucagon and apelin oral small molecules.

About Structure Therapeutics
Structure Therapeutics is a science-driven clinical-stage biopharmaceutical company focused on discovering and developing innovative oral small molecule treatments for chronic metabolic and cardiopulmonary conditions with significant unmet medical needs. Utilizing its next generation structure-based drug discovery platform, the Company has established a robust GPCR-targeted pipeline, featuring multiple wholly-owned proprietary

clinical-stage small molecule compounds designed to surpass the manufacturing scalability limitations of traditional biologic and peptide therapies and be accessible to more patients around the world. For additional information, please visit www.structuretx.com.

Forward Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, without limitation, statements concerning: the Company’s future plans and prospects; any expectations regarding the safety, efficacy or tolerability of GSBR-1290 and other candidates under development; the ability of GSBR-1290 to treat obesity, T2DM, or related indications; the planned initiation and study design of the Company’s ACCESS and ACCESS II clinical studies of GSBR-1290 in patients with obesity or overweight with a comorbidity and the timing thereof; the selection of a development candidate for the Company’s amylin receptor agonist program; the timing and design of the Company’s amylin receptor agonist program and its potential as a promising approach to obesity treatment; the timing and design of the Company’s GIPR and GLP-1R/GIPR and other oral small molecule programs; the ability of the Company to bring GSBR-1290 to patients rapidly; the anticipated manufacturing scalability advantages of GSBR-1290 and the planned timing of the Company’s data results. In addition, when or if used in this press release, the words and phrases “expect,” “on track,” “plan,” “potential,” “promising,” “to be,” and similar expressions and their variants, as they relate to the Company may identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Although the Company believes the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. Readers are cautioned that actual results, levels of activity, safety, performance or events and circumstances could differ materially from those expressed or implied in the Company’s forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to the preliminary nature of the results due to length of the study and sample size and results from earlier clinical studies not necessarily being predictive of future results, potential delays in the commencement, enrollment and completion of the Company’s planned clinical studies, the Company’s ability to advance GSBR-1290, LTSE-2578, ANPA-0073 and its other therapeutic candidates, obtain regulatory approval of and ultimately commercialize the Company’s therapeutic candidates, competitive products or approaches limiting the commercial value of the Company’s product candidates, the timing and results of preclinical and clinical studies, the Company’s ability to fund development activities and achieve development goals, the Company's reliance on third parties, including clinical research organizations, manufacturers, suppliers and collaborators, over which it may not always have full control, the impact of any global pandemics, inflation, supply chain issues, rising interest rates, future bank failures and other macroeconomic factors on the Company’s business, its ability to protect its intellectual property and other risks and uncertainties described in the Company’s filings with the Securities and Exchange Commission (SEC), including the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 8, 2024, the Quarterly Report on Form 10-Q filed with the SEC on August 8, 2024, and future reports the Company may file with the SEC from time to time. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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