Structure Therapeutics Initiates Phase 2a Study of Oral GLP-1 agonist GSBR-1290 for the Treatment of Type 2 Diabetes and Obesity

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12-week Phase 2a and Phase 1b multiple ascending dose (MAD) topline results expected to be announced in latter half of fourth quarter 2023

Ethnobridging study initiated in Japanese individuals and formulation bridging study planned to evaluate tablet formulation in preparation for global Phase 2b study of GSBR-1290 in 2024

SAN FRANCISCO and SHANGHAI, China, May 25, 2023 (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 that it has dosed the first patient in its Phase 2a study of its highly selective oral GLP-1 agonist GSBR-1290 in adults who are overweight or obese and otherwise healthy, and in adults with type 2 diabetes mellitus (T2DM) who are overweight or obese. The Company has also initiated an ethnobridging study of GSBR-1290 in Japanese individuals and is planning to initiate an additional formulation bridging study to evaluate a tablet formulation of GSBR-1290 before the end of the year, both in preparation for the planned global Phase 2b study in 2024.

“The initiation of the Phase 2a clinical trial marks a major milestone in our mission to bring an effective and convenient oral therapy to patients living with type 2 diabetes and obesity,” said Mark Bach, M.D., Ph.D., Chief Medical Officer of Structure Therapeutics. “We are excited to advance GSBR-1290, an orally available small molecule GLP1 agonist, into the next stage of clinical development. This is the first program in our GLP-1 incretin franchise, and evaluating GSBR-1290 in Japanese patients demonstrates our commitment to rapidly developing this treatment globally.”

About the GSBR-1290 development program

The 12-week Phase 2a randomized, double-blind, placebo-controlled, parallel group study evaluates the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of GSBR-1290. The study will enroll approximately 94 adult participants, including 40 patients who are overweight or obese and otherwise healthy, and 54 patients who are overweight or obese with T2DM. Healthy obese/overweight patients will be randomized to GSBR-1290 (n=24; 120 mg) or placebo (n=16), and T2DM patients will be randomized to GSBR-1290 high-dose (n=26; 90 mg), GSBR-1290 low-dose (n=10; 45 mg), or placebo (n=18). All patients on GSBR-1290 will receive multiple-ascending doses of GSBR-1290 once daily (QD) titrated up over the first five to six weeks of the study (depending on the cohort arm), with the target dose then being maintained for the remainder of the 12-week period.

Topline data from the Phase 2a study as well as the Phase1b MAD study are expected to be announced in the latter half of the fourth quarter of 2023.

In addition, the Company has initiated a Phase 1 ethnobridging study to evaluate the safety, tolerability, and PK of single and multiple doses of GSBR-1290 in Japanese patients. The study will include 12 healthy adult Japanese participants randomized 3:1 to GSBR-1290 or placebo, and six non-Japanese participants who will all receive GSBR-1290. All participants will receive GSBR-1290 once daily (QD) for seven days at each dose, with a total of four doses titrated up over a 4-week period. Successful completion of this study is intended to enable inclusion of Japanese patients in the planned global Phase 2b study in 2024.

The Company is also planning a separate formulation bridging pharmacokinetic study to support the planned transition from capsules to tablets. Pending supportive data from this bridging study, the tablet formulation would be used in future GSBR-1290 studies starting with the planned Phase 2b study.

About GSBR-1290

GSBR-1290 is an orally-available small molecule agonist of the GLP-1 receptor, a validated drug target for the treatment of T2DM and obesity. The Company completed its Phase 1 single ascending dose (SAD) study in September 2022. GSBR-1290 was generally well tolerated and demonstrated dose-dependent PK and PD activity in 48 healthy volunteers. The Company has completed dosing of its Phase 1b multiple ascending dose (MAD) study focused on safety, PK and tolerability in 24 healthy volunteers.

About Structure Therapeutics

Structure Therapeutics is a leading clinical-stage biopharmaceutical company focused on discovering and developing innovative oral treatments for chronic metabolic and pulmonary conditions with significant unmet medical needs. Utilizing its next generation structure-based drug discovery platform, the company has established a scientifically-driven, GPCR-targeted pipeline, featuring two wholly-owned proprietary clinical-stage small molecule compounds designed to surpass the 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 or efficacy of GSBR-1290 and other candidates under development, the ability of GSBR-1290 to treat type 2 diabetes, obesity or related indications, plans with respect to regulatory submissions, the planned timing of the Company’s clinical trials, data results and continued development of GSBR-1290 and expectations regarding an oral development candidate targeting GLP-1R. In addition, when or if used in this press release, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” 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 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, the timing and results of preclinical and clinical trials, the
Company’s ability to fund development activities and achieve development goals, the impact of the ongoing COVID-19 pandemic, inflation, supply
chain issues, rising interest rates and future bank failures 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 quarterly Report on
Form 10-Q filed with the SEC on May 11, 2023 and its subsequent periodic reports filed with the SEC. 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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