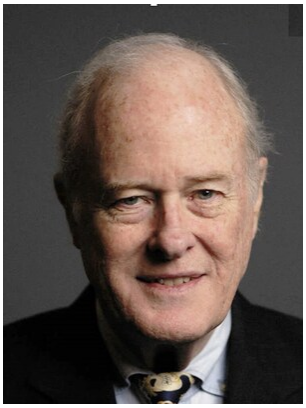
Biohaven's Phase 2 Obesity Study with Taldefgrobep Alfa, a Novel Myostatin-Activin Pathway Inhibitor, Completes Enrollment

March 19, 2026

- *Phase 2 study in obesity, evaluating treatment with once-weekly and once-monthly taldefgrobep alfa as monotherapy, is now fully enrolled; topline data expected in 2H 2026.*
- *Taldefgrobep is a novel inhibitor of the myostatin-activin signaling pathway, which directly targets both fat and muscle, offering the potential to achieve high-quality weight loss in people living with overweight and obesity.*
- *In previous clinical studies, taldefgrobep produced meaningful reductions in fat mass while increasing lean muscle mass in healthy adults and other non-obese populations; it has also demonstrated a highly favorable safety and tolerability profile in more than 700 trial participants.*
- *In nonclinical studies in obese mouse models, taldefgrobep, both as monotherapy and in combination with a GLP-1 agonist, generated significant reductions in fat mass and body weight, while increasing lean mass.*

NEW HAVEN, Conn., March 19, 2026 /PRNewswire/ -- Biohaven Ltd. (NYSE: BHVN) ("Biohaven"), a global clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of life-changing therapies to treat a broad range of rare and common diseases, today announced the completion of enrollment in a Phase 2 proof-of-concept (PoC) study with its myostatin-activin pathway inhibitor (MAPI), taldefgrobep alfa, which offers the potential to achieve high-quality weight loss in people living with obesity. Topline data from the study are expected in 2H 2026.



Frank Greenway, M.D., Professor, Chief Medical Officer of the Clinical Trials Unit at Pennington Biomedical Research Center, Baton Rouge, LA stated, "We are at a watershed moment in the treatment of obesity, brought on by the introduction of highly effective therapies like the GLP-1 agonists. To realize optimal long-term health outcomes, however, we will need to look beyond maximizing weight reduction and remain vigilant around the importance of muscle mass in overall health and wellness. Investigational medications, like taldefgrobep, with the potential to meaningfully reduce body weight and adipose tissue, while increasing muscle mass can be an important addition to the anti-obesity armamentarium."

The Phase 2 PoC study (NCT07281495) is a randomized, double-blind, placebo-controlled, dose-ranging study evaluating the efficacy and tolerability of once-weekly and once-monthly taldefgrobep as monotherapy, via self-administered autoinjector, in adults living with overweight and obesity. It includes a 24-week double-blind treatment period followed by 24-week open-label extension period. The study is targeting approximately 150 participants for randomization. The primary outcome measure is percent change in total body weight from baseline to Week 24, and secondary outcome measures are percent change in total body fat mass and in total body lean mass. The study is being conducted at 20 clinical sites across the US.



Peter Ackerman, M.D., Senior Vice President of Clinical Development at Biohaven stated, "We are excited to evaluate taldefgrobep, as both a once-weekly and once-monthly dosing regimen, in an obese patient population. We believe taldefgrobep could represent an important new agent, as monotherapy and in combination with the current standard of care, that can help optimize high-quality weight loss in people living with obesity." Dr. Ackerman added, "New investigational therapies with novel modes of action are critical to maximizing long-term health benefits in people living with overweight and obesity. While there have been great recent advancements in the field of obesity medicine, there is still a lot of work to do in optimizing the management of a complex, heterogeneous condition that affects nearly half of the world's population. Our team is grateful to the investigators, their staff, and all participants involved in this important study."

In previous clinical studies, taldefgrobep demonstrated beneficial changes in fat mass and lean mass in non-obese populations. Participants in a Phase 1 trial who received taldefgrobep realized significant reductions in total body fat mass (>6%) with commensurate increases in lean muscle mass (up to 4%) after 29 days of dosing. In that study, taldefgrobep benefit in body composition change was not fully realized until four weeks beyond the final dose was administered, suggesting the drug may support extended dosing intervals. In the Phase 3 study BHV2000-301, examining patients with a neuromuscular disorder, taldefgrobep-treated participants achieved statistically significant reductions in total body fat accumulation (9.7%; $p<0.0003$) and numerically greater benefit in bone mineral density (1.2%) and muscle mass (2.1%) relative to placebo.

Taldefgrobep also has an established safety profile that is well-suited for an indication in chronic weight management. It has been evaluated in >700 clinical trial participants and has been well tolerated with low rates of serious adverse events (SAEs) and adverse events (AEs) leading to early discontinuation. Rates of muscle- and GI-related AEs have been generally comparable to placebo.

In nonclinical studies, taldefgrobep has demonstrated the ability to have direct beneficial effects on lean muscle mass and adipose tissue by interrupting the signaling through activin receptors (ActRII) caused by transforming growth factor-beta (TGF-ß) ligands, such as myostatin and multiple activins (A, E, etc.). In a diet-induced obese (DIO) mouse model, taldefgrobep monotherapy showed significant improvements in total body weight, fat

mass, and lean mass relative to vehicle. In DIO mice, taldefgrobep in combination with a GLP-1 agonist showed additive benefit across these endpoints.

Data from multiple Phase 2 studies conducted with bimagrumab, a myostatin-activin pathway inhibitor, demonstrates a strong proof of concept for this therapeutic approach to obesity. In the BELIEVE study, participants dosed with bimagrumab as monotherapy, achieved reductions in total body fat mass comparable to high-dose semaglutide (2.4 mg) at one year (-25.3% vs. -24.8%, respectively). In the same study, bimagrumab-treated individuals saw a greater reduction in metabolically active visceral adipose tissue (-40.2% vs. -29.5%) and improvement in lean muscle mass compared semaglutide (+2.7% vs. -7.9%, respectively). Unfortunately, the safety profile of bimagrumab (high rates of GI- and muscle-related AEs and worsening of cholesterol levels) has complicated further development of this asset for an indication in chronic weight management.

About Taldefgrobep Alfa

Taldefgrobep alfa is a novel fusion protein designed to inhibit signaling through activin transmembrane receptors (ActRII). Taldefgrobep targets free myostatin, forming stable complexes which bind to ActRII in a manner that prevents downstream signaling from transforming growth factor-beta (TGF-ß) ligands (including myostatin and activins) important in body composition change. Taldefgrobep's novel mechanism of action offers the potential for meaningful reductions in fat mass, increased lean mass, and improvements in multiple metabolic parameters.

About Biohaven

Biohaven is a biopharmaceutical company focused on the discovery, development, and commercialization of life-changing treatments in key therapeutic areas, including immunology, obesity, neuroscience, and oncology. Biohaven is advancing its innovative portfolio of therapeutics, leveraging its proven drug development experience and multiple proprietary drug development platforms. Biohaven's clinical and preclinical programs include Kv7 ion channel modulation for epilepsy; MoDE™ and TRAP™ extracellular protein degradation for immunological diseases; TYK2/JAK1 inhibition for neuroinflammatory disorders; myostatin-activin pathway inhibition for neuromuscular and metabolic diseases; antibody recruiting bispecific molecules; and antibody drug conjugates for cancer. For more information, visit www.biohaven.com.

Forward-looking Statements

This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the expected timing and amounts of funding under the NPA. The use of certain words, including "continue", "plan", "will", "believe", "may", "expect", "anticipate", "potential first-in-class" and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the future development, timing and potential marketing approval and commercialization of development candidates, are not guarantees of future performance or results and involve substantial risks and uncertainties. Actual results, developments and events may differ materially from those in the forward-looking statements as a result of various factors including: the expected timing, commencement and outcomes of Biohaven's planned and ongoing clinical trials including the Phase 2 taldefgrobep trial in people living with obesity (BHV2000-202); the timing of planned interactions and filings with the FDA; the timing and outcome of expected regulatory filings; complying with applicable U.S. regulatory requirements; the potential commercialization of Biohaven's product candidates and the expected timing thereof; the potential for Biohaven's product candidates to be successful therapies, including the potential for taldefgrobep as a treatment for overweight and obesity; and the effectiveness and safety of Biohaven's product candidates. Additional important factors to be considered in connection with forward-looking statements are described in Biohaven's filings with the Securities and Exchange Commission, including within the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements are made as of the date of this news release, and Biohaven does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

MoDE and TRAP are trademarks of Biohaven Therapeutics Ltd.

Investor Contact:

Jennifer Porcelli
Vice President, Investor Relations
jennifer.porcelli@biohavenpharma.com
+1 (201) 248-0741

Media Contact:

Mike Beyer
Sam Brown Inc.
mikebeyer@sambrown.com
+1 (312) 961-2502

View original content to download multimedia:https://www.prnewswire.com/news-releases/biohavens-phase-2-obesity-study-with-taldefgrobep-alfa-a-novel-myostatin-activin-pathway-inhibitor-completes-enrollment-302718076.html

SOURCE Biohaven Ltd.