



Phase 2 COURAGE Trial Confirms Trevogrumab Prevents Lean Mass and Muscle Loss During GLP-1 Receptor Agonist-induced Weight Loss

October 1, 2026 at 11:30 AM EDT

In a predefined MRI substudy, trevogrumab prevented 70% of muscle loss associated with semaglutide treatment

A pre-specified subgroup analysis found that patients meeting the low lean mass definition for sarcopenia had greater loss of lean mass with semaglutide, and more preservation with trevogrumab

Findings were presented at the European Association for the Study of Diabetes (EASD) Annual Meeting and is in press with *The Lancet*

TARRYTOWN, N.Y., Oct. 01, 2026 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced new results from the Phase 2 COURAGE trial evaluating trevogrumab (anti-GDF8/anti-myostatin) for its potential to prevent lean mass and muscle loss during GLP-1 receptor agonist-induced weight loss in people living with obesity. The results of the trial were presented during a Scientific Symposium at the European Association for the Study of Diabetes (EASD) Annual Meeting and is in press with *The Lancet*. Building on these positive findings, Regeneron is planning to initiate a Phase 2 trial evaluating trevogrumab in combination with GLP-1 receptor agonist-based therapies in older adults with obesity and decreased muscle mass and/or strength.

"COURAGE demonstrated that trevogrumab, which blocks myostatin, can preserve lean mass and muscle during semaglutide-induced weight loss," said Julio Rosenstock, M.D., Lead Principal Investigator of the COURAGE trial and Clinical Professor of Medicine, University of Texas Southwestern Medical Center, Dallas. "These results, sustained through a full year of treatment, were further validated by MRI measurements of muscle volume supporting continued clinical development of trevogrumab and future research into muscle preservation as part of obesity care."

COURAGE investigated the quality of weight loss in people living with obesity (BMI ≥ 30 kg/m²) in two independent portions over 52 weeks. A higher-dose portion evaluated trevogrumab (200 mg or 400 mg) in combination with semaglutide 2.4 mg for 26 weeks compared to semaglutide alone, and then trevogrumab compared to placebo alone for an additional 26 weeks after semaglutide was discontinued. The trial also included a treatment arm with semaglutide, trevogrumab and an Activin-A inhibitor for which the results were previously [presented](#).

A lower-dose portion evaluated trevogrumab (25 mg or 75 mg) in combination with semaglutide 2.4 mg compared to semaglutide monotherapy for 52 weeks. The results in this portion replicated the findings of the higher-dose portion, with the greatest reduction in lean mass occurring during the period of most rapid weight loss that was observed in the first six months of treatment. While lower-dose trevogrumab did not meaningfully enhance the weight loss achieved with semaglutide alone, it preserved lean mass at both 26 and 52 weeks (the primary endpoint), compared to placebo, as outlined in the table below:

Percent change in lean mass from baseline as measured by DXA		
Arm	26 weeks	52 weeks
Placebo + semaglutide	-6.7% (95% CI: -7.9 to -5.5)	-7.3% (95% CI: -8.8 to -5.8)
Trevogrumab 25 mg + semaglutide	-4.7% (95% CI: -5.5 to -3.9) 29.9% lean mass preservation*	-5.8% (95% CI: -6.8 to -4.7) 20.5% lean mass preservation*
Trevogrumab 75 mg + semaglutide	-3.3% (95% CI: -4.1 to -2.4) 50.7% lean mass preservation*	-4.2% (95% CI: -5.3 to -3.1) 42.5% lean mass preservation*

*Relative to placebo + semaglutide

Among participants with evaluable MRI data, lower dose trevogrumab preserved almost 70% of the thigh muscle that would have been otherwise lost with semaglutide treatment alone, as outlined in the table below:

Absolute change from baseline in fat free muscle volume (mean $\pm$ standard error) as measured by MRI		
Arm	26 weeks	52 weeks
Placebo + semaglutide	-0.88 $\pm$ 0.21	-1.03 $\pm$ 0.22

Trevogrumab 25 mg + semaglutide	-0.32 ± 0.14	-0.29 ± 0.12
	63.6% muscle preservation*	71.8% muscle preservation*
Trevogrumab 75 mg + semaglutide	-0.24 ± 0.13	-0.32 ± 0.13
	72.7% muscle preservation*	68.9% muscle preservation*

*Relative to placebo + semaglutide

The lower doses of trevogrumab were generally well tolerated, with 77% of participants experiencing at least one adverse event (AE), compared with 82% of those who were treated with placebo. The most common AEs occurring in ≥10% of patients were nausea, constipation, diarrhea and vomiting.

Also presented at EASD was a pre-specified subgroup analysis of participants with low lean mass (LLM) at baseline. Compared to patients without LLM at baseline, these patients experienced a greater loss of lean mass with semaglutide alone and numerically more preservation of lean mass in combination with trevogrumab. LLM was defined using the imaging component of the sarcopenia definition established by the Foundation for the National Institutes of Health (appendicular lean mass relative to BMI, measured by DXA).

“As GLP-1 receptor agonist-based medicines become foundational to obesity care, it is becoming increasingly recognized that the associated muscle loss is an increasing concern – particularly for people with sarcopenia, older adults and others where frailty is a real concern,” said Boaz Hirshberg, M.D., Senior Vice President, Clinical Development, Internal Medicine, Regeneron. “Our COURAGE trial not only confirms this concern about muscle loss but also shows that trevogrumab can be part of the solution, addressing not the quantity, but rather the quality, of weight loss. It’s an approach we’re building across our growing pipeline.”

Additionally, Hansoh presented data from their Phase 3 trial in Chinese patients evaluating olatorepatide for the treatment of adults with obesity or who are overweight. Olatorepatide is a novel GLP-1/GIP receptor agonist for which Regeneron has exclusive clinical development and commercial rights outside of the Chinese Mainland, Hong Kong and Macau as part of a strategic in-licensing agreement.

The safety and efficacy of trevogrumab and olatorepatide have not been evaluated by any regulatory authority.

About Regeneron in Obesity

Obesity is a complex, multifaceted disease and a growing public health concern that affects more than a billion people worldwide. Despite the revolutionary impact of GLP-1 receptor agonists (GLP-1RAs) on weight loss, the quality of this weight loss can be negatively impacted because these agents can cause profound muscle loss.

At Regeneron, we are developing a pipeline focused on the quality of weight reduction. We have several independent approaches focused on promoting and preserving muscle during weight loss, so as to increase the amount of fat loss since adiposity is the principal driver of comorbidities and metabolic diseases associated with obesity. In addition, Regeneron has an extensive pipeline of agents to address some of these co-morbidities and metabolic diseases, which have the potential to be combined with GLP-1RAs. The combination of our science, pipeline, research and clinical innovation uniquely positions us to make a meaningful difference in obesity and obesity-related diseases.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases. For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and actual events or results may differ materially from these forward-looking statements. Words such as “anticipate,” “expect,” “intend,” “plan,” “believe,” “seek,” “estimate,” variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, “Regeneron’s Products”) and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, “Regeneron’s Product Candidates”) and research and clinical programs now underway or planned, including without limitation the clinical programs discussed or referenced in this

press release evaluating trevogrumab (anti-GDF8/anti-myostatin) in combination with semaglutide or other GLP-1 receptor agonist-based therapies to prevent lean mass and muscle loss during GLP-1 receptor agonist-induced weight loss as well as olatorepatide as a monotherapy for the treatment of adults with obesity or who are overweight; uncertainty of the utilization, market acceptance, and/or commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as those referenced above; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy, including in connection with Regeneron's April 2026 agreements with the U.S. government; other changes in laws, regulations, and policies affecting the healthcare industry; competing products and product candidates (including biosimilar products) that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (afibercept) Injection), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2025 and its Form 10-Q for the quarterly period ended June 30, 2026. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<https://investor.regeneron.com>) and its LinkedIn page (<https://www.linkedin.com/company/regeneron-pharmaceuticals>).

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Source: Regeneron Pharmaceuticals, Inc.