June 24, 2025

# Veru Reports Positive Results from Phase 2b QUALITY and Maintenance Extension Study Showing Enobosarm Significantly Reduced Body Weight Regain, Prevented Fat Regain, and Preserved Lean Mass After Semaglutide Discontinuation

**--During the Maintenance Period of 12 weeks after discontinuing semaglutide (GLP-1 receptor agonist), placebo group regained 43% of body weight that was previously lost during Phase 2b QUALITY study; on average, enobosarm 3mg significantly reduced body weight regain by 46% and completely prevented fat regain compared to placebo--**

**--The enobosarm treated groups showed up to 93% greater fat loss and 100% lean mass preservation compared to the placebo group at the end of the study--**

**--Enobosarm monotherapy had a positive safety profile with essentially no gastrointestinal side effects during the maintenance treatment period--**

**-- Based on efficacy and safety from Phase 2b QUALITY and Maintenance Extension study:**

***--Enobosarm 3mg will advance as the proposed oral dose for the Phase 3 clinical program--***

***--Veru has been granted a meeting with FDA to discuss the Phase 3 clinical program--***

MIAMI, FL, June 24, 2025 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases, today announced positive topline efficacy and safety results from the maintenance extension portion of the Phase 2b QUALITY clinical study. The Phase 2b Maintenance Extension clinical trial demonstrated that in 12 weeks after stopping semaglutide, the placebo monotherapy group regained 43% of body weight that was previously lost during the Phase 2b QUALITY study, while enobosarm monotherapy reduced weight regain by 46% in the enobosarm 3mg group and completely prevented fat regain and preserved lean mass in both enobosarm dose groups compared to placebo after semaglutide discontinuation. Enobosarm treatment also led to up

to 93% greater loss of fat mass and 100% preservation of lean mass compared to the placebo group at the end of the study. Enobosarm monotherapy maintained a positive safety profile, with essentially no gastrointestinal side effects observed during the maintenance period.

“Based on our Phase 2b QUALITY active weight loss portion of the study, enobosarm 3mg preserved 100% of lean mass, 99% of body weight loss was from fat, and preserved physical function as measured by stair climb test, when combined with a GLP-1 drug compared to placebo. The Maintenance Extension portion of the study shows that if you stop a GLP-1 drug, you can preserve lean mass, blunt the regain of fat and weight, and keep off the fat you lost when you remain on enobosarm monotherapy. Enobosarm provides a compelling option for patients that would like to maintain their weight loss and fat loss after discontinuing semaglutide, regardless of whether such discontinuation was by choice or by necessity,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “We look forward to reporting the full Phase 2b QUALITY and Maintenance Extension clinical trial efficacy and safety data at future leading scientific conferences and in publications.”

“I am pleased to see both muscle preservation and improvement in physical function with enobosarm when given with semaglutide, a GLP-1 medication. This is hugely important, especially when we are using the GLP-1 medications in an older patient population who are at risk of lean mass loss. Another advantage of enobosarm is that it’s an oral agent and patients prefer orals to injectables. The safety and tolerability profiles are encouraging,” said Donna Ryan, M.D., Professor Emerita at Pennington Biomedical of Louisiana State University and Past President of The Obesity Society and the World Obesity Federation. Dr. Ryan added: “I look forward to seeing data from the Phase 3 study of enobosarm used in combination with GLP-1 drugs. This could be a good addition to our treatment toolbox.”

“The new results from Veru are impressive and important,” said Dr. William J. Evans, Adjunct Professor of Medicine in the Division of Geriatrics at the Duke University Medical Center and Human Nutrition in the Department of Nutritional Sciences at the University of California, Berkeley, and a member of the Veru Scientific Advisory Board. “The concern about older people with obesity losing weight using a GLP-1 receptor agonist has been related to a substantial amount of muscle mass loss. The use of enobosarm with semaglutide preserved lean mass while increasing fat loss. By preserving lean mass, a higher energy expenditure produces greater fat loss. Enobosarm has been shown to help not only with active weight loss, but also to maintain fat loss. As previously reported, preservation of lean mass by enobosarm with semaglutide treatment was associated with remarkable positive differences in physical function as evidenced by stair climb power, which is critical for the preservation of mobility for an aging population. These results may allow clinicians to prescribe a GLP-1 RA in combination with enobosarm for weight loss with confidence that their patients will lose fat and preserve functional status.”

**Phase 2b QUALITY and Maintenance Extension clinical study design**
After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, 148 participants continued to the Phase 2b Maintenance Extension study, a double-blind study, where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy for 12 weeks. The Phase 2b Maintenance Extension clinical trial addressed the role of enobosarm in preserving lean

mass and augmenting fat loss and answered two important questions:

1. Can enobosarm monotherapy, by preserving muscle mass, also prevent the weight regain and fat regain that generally occurs after stopping semaglutide (Day 112 - 196)?
2. Can enobosarm plus semaglutide followed by enobosarm monotherapy regimen compared to placebo plus semaglutide followed by placebo monotherapy regimen maintain both lean mass and fat loss for a higher quality weight reduction at end of study (Day 1 - Day 196)?

The answer to both important questions is yes.

**Phase 2b Maintenance Extension clinical trial results**

***Enobosarm reduced the weight regained after discontinuation of semaglutide (Table 1)***

At the end of the Phase 2b QUALITY study active weight loss period of 16 weeks, body weight loss was similar across treatment groups with the semaglutide plus placebo group losing an average of 11.88 lbs. After the 12-week Maintenance and Extension study period (Day 112 to Day 196) where all treatment groups discontinued semaglutide, the placebo monotherapy group regained 43% of body weight that was previously lost during the Phase 2b QUALITY for a mean percent change of 2.57% (5.06 lbs) in body weight, compared to 1.41% (2.73 lbs) for the 3mg enobosarm group (p=0.038) and 2.87% (5.29lbs) for the 6mg enobosarm group. The 3mg enobosarm monotherapy significantly reduced the body weight regained by 46%. On average, the placebo monotherapy group regained 2.27% in fat mass, while the enobosarm monotherapy cohorts had a loss of fat mass of -0.27% for the 3mg and -0.50% for the 6mg doses. The mean tissue composition of body weight regained was 28% fat and 72% lean mass in the placebo group, versus 0% fat and 100% lean mass in both the 3mg and the 6mg enobosarm groups.

***The enobosarm plus semaglutide followed by enobosarm monotherapy regimen was more effective in preserving lean mass and causing and maintaining greater loss of fat by the end of the study (Table 2)***

By the end of the study at 28 weeks (Day 1 to Day 196), the placebo plus semaglutide followed by placebo monotherapy group experienced a loss of lean mass, while both enobosarm plus semaglutide followed by enobosarm monotherapy groups (3 mg and 6 mg doses) significantly preserved more than 100% of lean mass (enobosarm 3mg p<0.001 and enobosarm 6mg p=0.004). The enobosarm plus semaglutide followed by enobosarm monotherapy patients had a 58% greater loss of fat with enobosarm 3mg (p=0.085) and a 93% greater loss of fat with enobosarm 6mg (p=0.008) compared to placebo plus semaglutide followed by placebo monotherapy.

The Phase 2b QUALITY and Maintenance Extension clinical trial confirms that preserving lean mass with enobosarm plus semaglutide led to greater fat loss during the active weight loss period, and after semaglutide was discontinued, enobosarm monotherapy significantly prevented the regain of both weight and fat mass during the maintenance period such that by end of study there was greater loss of fat mass while preserving lean mass for a higher quality weight reduction compared to the placebo group.

*Detail of these topline efficacy results are provided in Table 1 and Table 2 below:*

**Table 1. Phase 2b Maintenance Extension clinical trial efficacy results after discontinuation of semaglutide in all groups (Day 112 to Day 196, ITT population)**

| ***Weight regained (scale weight)*** | **Placebo** | **Enobosarm 3mg** | **Enobosarm 6mg** |
|---|---|---|---|
| LS Mean % change in body weight (SE) | +2.57% (0.40)<br>n=48 | +1.41% (0.40)<br>n=50 | +2.87% (0.41)<br>n=47 |
| Mean body weight regained (SE) in lbs | +5.06 (0.68) | +2.73 (0.74)<br><br>p=0.038* | +5.29 (0.87) |
| % reduction of body weight regained compared to placebo | | -46% | +5% |
| ***Fat regained*** | **Placebo** | **Enobosarm 3mg** | **Enobosarm 6mg** |
| LS Mean % change in fat mass (SE) | +2.27% (1.19)<br>n=47 | -0.27% (1.21)<br>n=47 | -0.50% (1.23)<br>n=45 |
| Mean fat regained (SE) in lbs | +1.22 (1.08) | -0.43 (0.69) | -0.20 (0.76) |
| % of total body weight regained that is fat mass*** | 28% | 0% | 0% |
| ***Lean mass regained*** | **Placebo** | **Enobosarm 3mg** | **Enobosarm 6mg** |
| LS Mean % change in lean mass (SE) | +3.18% (0.74)<br>n=47 | +2.68% (0.75)<br>n=47 | +5.18% (0.76)<br>n=45 |
| Mean lean mass regained (SE) in lbs | +3.16 (0.93) | +2.75 (0.60) | +4.98 (0.68) |
| % of total body weight regained that is lean mass*** | 72% | 100% | 100% |

***Analysis of Covariance (ANCOVA) **Mixed Model for Repeated Measures (MMRM) ***Total weight (mass) regain that is due to lean mass (change in kg) or fat mass (change in kg)**

**Table 2. Phase 2b QUALITY and Maintenance Extension clinical trial efficacy results (Day 1 to Day 196, ITT population)**

| ***Fat mass loss*** | **Placebo + semaglutide followed by placebo** | **Enobosarm 3mg + semaglutide followed by enobosarm 3mg alone** | **Enobosarm 6mg + semaglutide followed by enobosarm 6mg alone** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| LS Mean % change in fat mass (SE)<br>(% relative change in fat mass compared to placebo)<br><br>Mean change in fat mass (SE) in lbs | -6.00% (1.53)<br>n=47<br><br><br><br>-6.28 (1.19) | -9.50% (1.52)<br>n=47<br>(58% greater fat loss)<br><br>-8.80 (1.12)<br><br>p=0.085** | -11.60% (1.55)<br>n=45<br>(93% greater fat loss)<br><br>-10.03 (1.46)<br><br>p=0.008** |
| ***Lean mass preserved*** | **Placebo + semaglutide followed by placebo** | **Enobosarm 3mg + semaglutide followed by enobosarm 3mg** | **Enobosarm 6mg + semaglutide followed by enobosarm 6mg** |
| LS Mean % change in lean mass (SE)<br>(% relative change in lean mass compared to placebo)<br><br>Mean change in lean mass (SE) in lbs | -0.94% (0.84)<br>n=47<br><br><br><br>-1.23 (0.97) | +2.70% (0.83)<br>n=47<br>(>100% of lean mass preserved)<br><br>+2.77 (0.69)<br><br>P=0.001** | +2.36% (0.85)<br>n=45<br>(>100% of lean mass preserved)<br><br>+2.54 (0.83)<br><br>p=0.004** |

****Mixed Model for Repeated Measures (MMRM)**

**Positive topline safety results for the Phase 2b QUALITY Maintenance Extension clinical trial**

***Adverse events (AEs) and adverse events of special Interest (Table 3 below)***- In the double-blind Phase 2b QUALITY Maintenance Extension clinical trial (Day 112-196), enobosarm monotherapy had a positive safety profile. After discontinuation of semaglutide, there were essentially no gastrointestinal side effects, no evidence of drug induced liver injury (by Hy's law), and no increases in obstructive sleep apnea observed at any dose of enobosarm compared to placebo monotherapy. There were no AEs of increases in prostate specific antigen in men. There were no AEs related to masculinization in women. There were no reports of suicidal ideation observed (Columbia-Suicide Severity Rating Scale). The proposed Phase 3 clinical program dose of enobosarm 3mg continued to have a positive safety profile in the Phase 2b maintenance extension clinical trial.

**Table 3. Topline Phase 2b Maintenance Extension clinical trial safety summary (Maintenance period, Day 112 to Day 196) Adverse Events[1] and Adverse Events of Special Interest**

| | **Placebo n=48** | **Enobosarm 3mg n=51** | **Enobosarm 6mg n=49** |
|---|---|---|---|
| | | | |
| **Constipation** | 1 (2%) | 0 (0%) | 0 (0%) |
| **Diarrhea** | 0 (0%) | 0 (0%) | 0 (0%) |

| | | | |
|---|---|---|---|
| **Nausea** | 0 (0%) | 1 (2%) | 0 (0%) |
| **Vomiting** | 0 (0%) | 0 (0%) | 0 (0%) |
| **Gastroesophogeal reflux disease (GERD)** | 0 (0%) | 0 (0%) | 0 (0%) |
| | | | |
| **Alanine aminotransferase increased** | 0 (0%) | 0 (0%) | 1 (2%) [2] |
| **Aspartate aminotransferase increased** | 0 (0%) | 0 (0%) | 2 (4%) [2] |
| | | | |
| | | | |
| **Obstructive sleep apnea syndrome** | 14 (29%) | 16 (31%) | 18 (37%) |
| **Glomerular filtration rate decreased (creatinine estimated)** | 0 | 0 | 4 (8%)[3] |

[1] Adverse events (at least 4 subjects in any dose group) and adverse events of special interest from Day 112 to Day 196.

[2] All graded as mild in severity, all returned to or toward baseline/upper limit of normal, no associated increases in alkaline phosphatase or total bilirubin.

[3] Glomerular filtration rate is an estimated value using the CKD-EPI creatinine 2021 calculation that inputs serum creatinine level. Note that serum creatinine levels are known to increase with greater muscle mass.

**About Veru Inc.**

Veru is a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases. The Company's drug development program includes two late-stage novel small molecules, enobosarm and sabizabulin. Enobosarm, a selective androgen receptor modulator (SARM), is being developed as a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for loss of fat and preservation of lean mass thereby improving body composition and physical function. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in atherosclerotic cardiovascular disease.

**Obesity Program - Enobosarm is a next generation drug that makes weight reduction by GLP-1 RA more tissue selective for fat loss – Phase 2b QUALITY clinical study**

The Company has announced positive topline and safety results from the Phase 2b QUALITY clinical study, which is a multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in 168 older patients (≥60 years of age) receiving semaglutide (Wegovy®) for chronic weight management. After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, participants continued into a Phase 2b maintenance extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy in a double-blind fashion for 12 weeks. As the

Phase 2b QUALITY clinical trial is a positive study, we have been granted an FDA meeting.

**Forward-Looking Statements**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, express or implied statements related to whether and when the full data set, including safety data, from the Phase 2b QUALITY study and the extension maintenance study of enobosarm discussed above will be made available and whether that data will align with disclosed topline results or change any of the conclusions drawn from the topline data; whether and when the Company will present the full data from the Phase 2b QUALITY study and extension maintenance study and in what forum; whether and when the Company will have an end-of-Phase-2 meeting with FDA and the results of any such meeting; whether the results of the Phase 2b QUALITY study and the extension maintenance study of enobosarm will be replicated to the same or any degree in any future Phase 3 studies; the expected costs, timing, patient population, design, endpoints and results of the planned Phase 3 studies of enobosarm as a body composition drug or any other Phase 3 studies; whether the Company and FDA will align on the Phase 3 program for enobosarm as a body composition drug and whether any such program will be able to be funded by the Company; whether the Company will be able to obtain sufficient GLP-1 RA drugs in a timely or cost-effective manner in the planned Phase 3 study or other Phase 3 studies; whether FDA will require more than one Phase 3 study for enobosarm as a body composition drug; whether enobosarm will enhance weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will enhance weight loss in any planned or other Phase 3 studies or if approved, in clinical practice; whether patients treated with enobosarm for a longer period of time than in the Phase 2b QUALITY study will have a greater loss of adiposity or greater weight loss than with semaglutide alone; and whether and when enobosarm will be approved by the FDA as a body composition drug. The words "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based upon current plans and strategies of the Company and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this press release. The Company assumes no obligation to update any forward-looking statements contained in this press release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: the development of the Company’s product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the Company’s ability to reach agreement with FDA on study design requirements for the Company’s planned clinical studies, including for the Phase 3 program for enobosarm as a body composition drug and the number of Phase 3 studies to be required and the cost thereof; potential delays in the timing of and results from clinical trials and studies, including as a result of an inability to enroll sufficient numbers of subjects in clinical studies or an inability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development as well as other operations of the

Company; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the potential for disruptions at the FDA or other government agencies to negatively affect our business; any products of the Company, if approved, possibly not being commercially successful; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to protect and enforce its intellectual property; costs and other effects of litigation, including product liability claims and securities litigation; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2024, and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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