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Veru Reports Positive Safety Results from Phase 2b QUALITY Study: Enobosarm Added to Semaglutide Led to Greater Fat Loss, Preservation of Muscle, and Fewer Gastrointestinal Side Effects Compared to Semaglutide Alone

--Phase 2b QUALITY clinical study topline safety data shows that the enobosarm + semaglutide combination had a positive safety profile compared to semaglutide alone--

--Based on Phase 2b QUALITY trial efficacy and safety data, enobosarm 3mg will advance as the proposed oral dose for the Phase 3 clinical program--

--Enobosarm 3mg + semaglutide combination had the added benefit of fewer gastrointestinal side effects (Diarrhea, Nausea, and GERD) compared to semaglutide alone--

--Enobosarm 3mg added to semaglutide resulted in the highly selective loss of fat mass, accounting for 99% of the total weight lost, while preserving lean mass--

--With this positive Phase 2b QUALITY study, Veru has requested an End of Phase 2 meeting with FDA to provide regulatory clarity on the Phase 3 clinical program--

--The topline efficacy and safety data for the Phase 2b extension maintenance study to assess whether enobosarm monotherapy prevents the fat and weight regain following discontinuation of semaglutide are expected in the second quarter--

MIAMI, FL, May 28, 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 safety results from the Phase 2b QUALITY clinical study, 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 enhance fat loss and to prevent muscle loss in older patients (≥60 years of age) receiving semaglutide (Wegovy®) for chronic weight management.

Positive Topline Safety Results for the Phase 2b QUALITY Clinical Trial

Adverse events (AEs) and adverse events of special Interest (see table below).
In the Phase 2b QUALITY clinical trial, enobosarm and semaglutide GLP-1 RA combination had a positive safety profile. There were no increases in gastrointestinal side effects, no evidence of drug-induced liver injury (as defined by Hy's law), and no increases in obstructive sleep apnea at any dose of enobosarm compared to placebo (semaglutide alone). 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). No treatment related serious adverse events (SAEs) were observed in the QUALITY study. There were 4 non-treatment related SAEs equally distributed between the treatment groups.

At the proposed Phase 3 clinical program dose of enobosarm 3mg, one subject experienced an adverse event of transient, mild increase in alanine aminotransferase (ALT), which returned to baseline while remaining on enobosarm. There were no accompanying increases in aspartate aminotransferase (AST), alkaline phosphatase or total bilirubin. The enobosarm 3mg + semaglutide group had the added benefit of fewer AEs reported for certain gastrointestinal side effects (Diarrhea, Nausea, and Gastroesophageal Reflux Disease) compared to placebo + semaglutide.

"The safety results from the Phase 2b study are positive and suggest that the addition of enobosarm to semaglutide treatment doesn't worsen, and in some cases appears to improve gastrointestinal side effects", said Louis J. Aronne, MD, an obesity expert, past president of the Obesity Society and a scientific advisor and consultant to Veru.

Topline Phase 2b QUALITY clinical trial safety summary:
Adverse Events[1] and Adverse Events of Special Interest

	Placebo +Semaglutide n=56	**Enobosarm 3mg +Semaglutide n=56**	**Enobosarm 6mg +Semaglutide n=56**
Nausea	11 (20%)	6 (11%)	8 (14%)
Gastroesophageal Reflux Disease (GERD)	7 (13%)	3 (5%)	0 (0%)
Diarrhea	4 (7%)	1 (2%)	7 (13%)
Vomiting	2 (4%)	1 (2%)	4 (7%)
Constipation	8 (14%)	7 (13%)	6 (11%)
Alanine aminotransferase (ALT) increased	0 (0%)	1 (2%)[2]	6 (11%)[3]
Aspartate aminotransferase (AST) increased	0 (0%)	0 (0%)	1 (2%)[3]
Obstructive sleep apnea syndrome	9 (16%)	10 (18%)	11 (20%)
Upper respiratory tract infection	1 (2%)	1 (2%)	4 (7%)

Headache	2 (4%)	4 (7%)	1 (2%)
Fatigue	2 (4%)	0 (0%)	4 (7%)

[1] Adverse events (at least 4 subjects in any dose group) from Day 1 to Day 112

[2] Graded as mild in severity, levels returned to below baseline while on drug, no associated increase in alkaline phosphatase or total bilirubin

[3] 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

“We previously shared positive results from the Phase 2b QUALITY study, indicating that enobosarm can selectively enhance fat loss while preserving lean mass and physical function in older patients using semaglutide for weight loss. Today, we announced that the topline safety data from the Phase 2b QUALITY clinical study confirms that enobosarm has a positive safety profile with the added benefit of reducing certain gastrointestinal side effects that patients commonly experience with semaglutide and other GLP-1 receptor agonists. Based on these efficacy and safety results, the enobosarm 3mg dose has been selected to advance into our proposed Phase 3 study,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “We have submitted a request for an End of Phase 2 meeting with FDA, which we anticipate will take place in the third quarter of calendar year 2025. The meeting is expected to provide regulatory clarity on the design of our planned Phase 3 clinical program. Further, we are expecting the topline efficacy and safety results for the Phase 2b extension maintenance study this quarter, which will show us whether enobosarm monotherapy can stop the fat and weight regain that generally happens when patients discontinue GLP-1 receptor agonist treatment. Finally, we look forward to reporting the full Phase 2b QUALITY and extension clinical trial efficacy and safety data at future leading scientific conferences and in prestigious publications.”

Positive Topline Efficacy Results for the Phase 2b QUALITY Clinical Study: Enobosarm in Combination with GLP-1 RA Drugs Makes Weight Reduction More Tissue Selective for Fat Loss While Preserving Lean Mass and Physical Function

In January 2025, the Company announced positive topline 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 older patients (≥60 years of age) receiving semaglutide (Wegovy®) for chronic weight management.

Topline Efficacy Results

Topline Primary Endpoint – Percent Change in Total Lean Mass
In the topline efficacy analysis, the trial met its prespecified primary endpoint with a statistically significant and a clinically meaningful benefit in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks in total lean mass (71% relative reduction in lean mass loss, p=0.002). Notably, the enobosarm 3mg + semaglutide was the best dose with a 99.1% mean relative reduction in loss of lean mass (p <0.001). The enobosarm 6mg + semaglutide dose did not provide any additional benefit over the 3mg dose in preserving lean mass.

Topline Secondary Endpoints:

Total Fat Mass

Enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the enobosarm 6mg dose having a 46% greater relative loss of fat mass compared to placebo + semaglutide group at 16 weeks (p=0.014).

Weight Loss and Tissue Composition of Weight Loss

Although mean weight loss by DEXA was similar in the enobosarm + semaglutide groups compared to semaglutide alone at 16 weeks, the composition of total weight loss shifted toward greater and more selective fat loss with enobosarm treatment:

- In the placebo + semaglutide group, the median percentage of total body weight loss due to lean mass was 32%, and estimated fat loss was 68%.

- In the enobosarm 3mg + semaglutide group, the median percentage of total body weight loss due to lean mass was 0.9%, and estimated fat loss was 99.1%.

Physical Function Measured by the Stair Climb Test

The Stair Climb Test is used to measure physical function and is an activity of daily living that measures functional muscle strength, balance and agility. Decline in Stair Climb Test performance in older adults is predictive of increased risk for mobility disabilities, gait difficulties, falls, bone fractures, hospitalizations, and mortality. As a reference point, stair climb power declines by -1.38% per year with aging according to *Van Roie E, et al. PLOS ONE.14:e0210653, 2019.*

Stair Climb Test Results:
A responder analysis was conducted using a greater than 10% decline in stair climb power at 16 weeks as the cutoff, which corresponds to approximately 7.5 years' worth of stair climb power loss due to natural aging.

- In the placebo + semaglutide group, 42.6% of patients experienced at least a 10% decline in stair climb power at 16 weeks.

- In the enobosarm 3mg + semaglutide group, only 16% of patients had at least a 10% decline in stair climb power at 16 weeks, representing a 62.4% relative reduction of patients with a ≥10% decline in power compared to the placebo + semaglutide group (p=0.0066).

- In the enobosarm 6mg + semaglutide group, only 22.5% of patients had at least a 10% decline in stair climb power at 16 weeks, representing a 46.2% relative reduction of patients with a ≥10% decline on power compared to the placebo + semaglutide group (p=0.0505).

Topline Efficacy Results Conclusion
The Phase 2b QUALITY clinical trial is the first human study to show that older patients who are overweight or have obesity and receiving semaglutide, a GLP-1 receptor agonist, are at

higher risk for accelerated loss of lean mass and associated physical function decline. Enobosarm added to semaglutide enhanced loss of fat, with 99% of the total weight loss attributable to fat. In addition, enobosarm treatment preserved lean muscle mass, which translated into an improvement in physical function as measured by the Stair Climb Test compared to semaglutide alone. Enobosarm represents a novel drug that improves body composition by driving a more selective and greater loss of adiposity (fat mass) and preserving both lean mass and physical function in patients receiving semaglutide for chronic weight management.

Phase 2b Extension Maintenance Study
After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, participants continued into a Phase 2b extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy in a blinded fashion for 12 weeks. The Phase 2b extension clinical trial is evaluating whether enobosarm, by preserving muscle mass, also prevents the fat regain that generally occurs after stopping a GLP-1 RA. The topline efficacy and safety results for the Phase 2b extension clinical study are expected this quarter.

Regulatory Next Steps
As the Phase 2b QUALITY clinical trial is a positive study, we have requested an End of Phase 2 meeting with the FDA. During the preIND FDA meeting, FDA provided general comments about a regulatory path forward for enobosarm as a drug that improves body composition during weight loss including input on the Phase 3 clinical program design.

As a path forward, we plan to propose a Phase 3 clinical program that is similar to the positive Phase 2b QUALITY clinical trial. The proposed Phase 3 clinical trial design is a double-blind, placebo-controlled study in older patients (≥60 years of age) who have obesity or who are overweight and who are eligible for treatment with GLP-1 RA. The GLP-1 RA may be either Wegovy® (semaglutide) and/or Zepbound® (tirzepatide). Patients will be randomized to oral daily enobosarm or matching placebo. All subjects will start and receive GLP-1 RA during the study. The proposed primary objective will be the effect of enobosarm on physical function measured by the Stair Climb Test at 24 weeks. Proposed key secondary objectives will be to assess the effect of enobosarm on total lean mass, total fat mass, insulin resistance, and hemoglobin A1c at 24 weeks.

After the Phase 3 clinical trial ends at 24 weeks of treatment, the plan is to continue to measure total lean mass, total body weight, stair climb power physical function, total fat mass, bone mineral density, insulin resistance, and hemoglobin A1c up to 68 weeks to capture the longer-term benefits of enobosarm improvements on body composition for greater loss of adiposity or fat, weight reduction, and preservation of both lean mass and bone.

Novel Modified Release Oral Enobosarm Formulation is on Track to be Available for Phase 3 Clinical Studies and Commercialization

Veru is currently developing a novel, patentable, modified release oral formulation for enobosarm. The actual formulation, pharmacokinetic release profile(s), and method of manufacturing will be the subjects of future patent applications. If issued, the expiry for the new modified release oral enobosarm formulation patent is expected to be 2045. The new

enobosarm formulation has completed animal trials and is anticipated to be in Phase 1 bioavailability clinical trials during the first half of calendar 2025. The expectation is that this novel modified release oral enobosarm formulation will be available for the Phase 3 clinical studies and for commercialization.

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 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 in what forum; whether and when the Company will present data from the extension maintenance study and whether such extension study will successfully meet any of its endpoints; 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 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 modified-released formation of enobosarm will be developed successfully and whether such formulation will have the same effectiveness as the current formulation, and whether and when such modified-release formulation will be available for any planned or future clinical studies; whether and when any patents will actually issue regarding such modified-release formulation and what any expiration dates of any such patents might be; 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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Investor and Media Contact:

Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Source: Veru Inc.