January 27, 2025

Veru Announces Positive Topline Data from Phase 2b QUALITY Clinical Study: Enobosarm Preserved Lean Mass in Patients Receiving WEGOVY® (Semaglutide) for Weight Reduction

-- Study met primary endpoint: Enobosarm treatment resulted in statistically significant reduction in the loss of lean mass in subjects receiving WEGOVY (p=0.002) --

-- Patients on Enobosarm on average lost 71% less lean mass than patients receiving WEGOVY alone --

-- Patients on Enobosarm on average lost 27% more fat mass than patients receiving WEGOVY alone –

-- Enobosarm improved body composition as mean total body weight loss was similar compared to subjects receiving WEGOVY alone --

-- Enobosarm reduced the proportion of patients that lost clinically significant physical function versus subjects receiving WEGOVY alone --

-- Company to host conference call today at 8:00 am ET to discuss topline results --

MIAMI, FL, Jan. 27, 2025 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for preserving muscle for high quality weight loss, oncology, and viral induced acute respiratory distress syndrome, today announced positive topline results from the Phase 2b QUALITY clinical study.

Phase 2b QUALITY clinical trial design
The Phase 2b QUALITY clinical study was a multicenter, double-blind, placebo-controlled, randomized, dose-finding study to evaluate the safety and efficacy of enobosarm 3mg, and enobosarm 6mg, compared to placebo in 168 older patients, greater than 60 years of age, who are overweight or have obesity and who are receiving WEGOVY (semaglutide), a GLP-1 receptor agonist (RA), for weight reduction. The primary endpoint was the change in total lean body mass from baseline to 16 weeks, and key secondary endpoints were the change from baseline to 16 weeks in total fat mass, total body weight, and physical function as

measured by a stair climb test.

Topline results for the Phase 2b QUALITY clinical study:

Enobosarm + WEGOVY versus placebo + WEGOVY	**Clinical endpoints**		**Placebo + semaglutide**	**Enobosarm (all) + semaglutide**
			N=48	N=100
71% less loss of lean mass compared to placebo	Total Lean Mass % change from baseline	Mean ± SD*	-4.1±4.80%	-1.2±5.15% p=0.002**
27% more loss of fat mass compared to placebo	Total Fat Mass % change from baseline	Mean ± SD	-8.6±6.26%	-10.9±8.07% p=0.096**
0.3 kg less total body weight loss compared to placebo	Total Body Weight kg change from baseline	Mean ± SD	-4.7±4.24kg	-4.4±3.91kg
Reduced weight loss due to lean mass by 70.5%	Proportion of weight loss due to loss in lean mass	Median	31.9%	9.4%
54.5% fewer patients had a ≥10% decline in stair climb power	Proportion of patients that Lost ≥10% Stair Climb Power from baseline		42.6% (20/47)	19.4% (19/98) p=0.0049‡

*Standard Deviation, **ANCOVA model, least square means analysis using gender and BMI at baseline as covariates, ‡ Fisher's exact test

- The Phase 2b QUALITY study is the first human study to report the effects of a muscle preservation agent on body composition in older patients who have obesity or are overweight and receiving a GLP-1 receptor agonist.

- In the topline efficacy analysis, the Phase 2b QUALITY clinical study met its primary endpoint with a statistically significant benefit in preservation of total lean body mass in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks.

- Secondary endpoints showed:

    - Enobosarm + semaglutide treatment resulted in a greater reduction in total fat mass compared to placebo + semaglutide at 16 weeks.

    - There appears to be minor differences in total body weight changes between the enobosarm + semaglutide group and placebo + semaglutide group at 16 weeks. Therefore, enobosarm + semaglutide improved changes in body composition and resulted in more selective and greater loss of fat mass than in subjects receiving placebo + semaglutide.

- The proportion of subjects that lost ≥10% stair climb power was statistically significant and clinically meaningfully reduced in the enobosarm + semaglutide groups compared to placebo + semaglutide group. Therefore, enobosarm reduced the proportion of patients that lost clinically significant physical function versus subjects receiving semaglutide alone.

The Company plans to present the full clinical efficacy and safety data set for the Phase 2b QUALITY clinical study in future scientific conferences and publications after the Phase 2b extension portion of study is completed and unblinded.

Dr. Louis Aronne, an obesity expert, past president of the Obesity Society and a scientific advisor and consultant to Veru, who was not directly involved in the QUALITY study stated: "These topline clinical results are very exciting. Weight loss through any modality produces a loss of both lean and fat mass. The greater magnitude of weight loss seen with bariatric surgery and GLP-1 RA based drugs has produced an unmet medical need to preserve muscle and physical function in older patients receiving these treatments. This is the first clinical study to demonstrate prevention of both lean mass loss and decline in muscle function associated with weight loss in older individuals treated with a GLP-1 RA. This combined treatment approach could benefit patients with obesity and low amounts of muscle due to age-related muscle loss."

"Given the promising topline results from the Phase 2b QUALITY clinical trial where enobosarm treatment preserved lean mass, increased fat loss, improved body composition changes, and prevented decline in stair climb physical function in patients receiving WEGOVY (semaglutide), we plan to meet with FDA to discuss the design of the Phase 3 clinical program," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "The Phase 2b QUALITY study is the first human study to demonstrate that older patients who are overweight or have obesity and receiving only a WEGOVY (semaglutide) GLP-1 RA are at higher risk for accelerated frailty and functional decline. Lean mass loss in the semaglutide group that did not receive enobosarm was significant as 32% of the total weight loss at 16 weeks was made up of lean mass. Loss of lean mass also matters as 42.6% of patients on placebo + semaglutide had at least a 10% decline in stair climb power. The potential for further reduction in physical function because of ongoing loss of lean mass with chronic GLP-1 RA therapy is worrisome and must be evaluated. The expectation is that all GLP-1 RA containing drugs could cause significant loss of lean mass in older patients raising concerns for potential declines in physical function, mobility disability, functional limitations, and loss of balance with a higher risk for falls and fractures."

"Older patients who have obesity or who are overweight and are receiving a GLP-1 RA are an ideal target population that have demonstrated in the Phase 2b QUALITY clinical study clinical benefit with enobosarm treatment to provide a greater quality weight loss as lean mass and physical function may be preserved with greater and selective loss of adiposity, that is, better body composition weight reduction may be possible. Further, the expectation is that when patients are treated longer with enobosarm, which results in greater loss of adiposity, there would also be a profoundly greater weight reduction than with semaglutide alone," said Gary Barnette Ph.D., Chief Scientific Officer, Veru Inc.

Safety
Safety data remains blinded in the ongoing clinical study and the unblinded safety set will be

available when the Phase 2b extension study is done in April 2025. However, the aggregate, blinded data, have not shown significant differences compared to different previous studies of enobosarm. The Independent Data Monitoring Committee also met in October 2024 and evaluated the unblinded safety data with a recommendation to continue the study as planned. As a reminder, enobosarm has a large safety database, which includes 27 clinical trials involving 1581 mostly older men and women, some of which included patients dosed for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increases in gastrointestinal side effects. This is important as there are already significant and frequent gastrointestinal side effects with a GLP-1 RA treatment alone.

Next regulatory steps
As a reminder, the Phase 2b extension clinical trial where all patients will stop receiving a GLP-1 RA, but will continue taking placebo, enobosarm 3mg, or enobosarm 6mg for an additional 12 weeks is ongoing. The blinded Phase 2b extension clinical trial is asking a different question than the Phase 2b QUALITY clinical study which evaluated the ability of enobosarm to improve body composition changes associated with GLP-1 RA weight loss induction. The Phase 2b extension study will evaluate maintenance of weight loss, meaning whether enobosarm can maintain muscle and prevent the fat and weight gain that occurs after discontinuing a GLP-1 RA. If successful, this would provide another important obesity related indication for which enobosarm could be considered. The topline results for the separate blinded Phase 2b extension clinical study are expected in April of 2025.

As the Phase 2b QUALITY study has positive topline clinical results, we are planning to move forward to request an end of Phase 2 meeting with FDA. In the new weight reduction FDA guidance, FDA makes a regulatory path distinction between weight reduction drugs and drugs for body composition changes. FDA states that: “Sponsors seeking an efficacy claim related to changes in body composition would need to consult with FDA early in development to align on the clinical condition being treated. Trial design, including appropriate choice of population and selection of endpoints that measure how a patient feels, functions, or survives, to potentially support such a claim is beyond the scope of this weight reduction guidance.” Based on this updated FDA guidance, enobosarm is being developed as a body composition drug to selectively preserve lean body mass and physical function, and augment loss of fat in older patients who are overweight or have obesity receiving GLP-1 RA containing drug for chronic weight management. We have previously met with FDA to discuss our regulatory path forward as an improvement in body composition drug, and FDA has provided general advice on Phase 3 design.

Anticipated Phase 3 Trial Design
Based on the Phase 2b QUALITY clinical trial, the proposed Phase 3 clinical trial design is currently expected to be a double-blind, placebo-controlled study in older (> 60 years of age), patients 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 stair climb power, as measured by the proportion of subjects that lose ≥10% stair climb power from baseline. Proposed key secondary objectives will be to assess the effect of enobosarm on total lean mass, total body weight, total fat mass, bone mineral density, HOMA-IR, and hemoglobin

A1c.

The duration of treatment is expected to be 52 weeks which will allow us to also capture the benefits of enobosarm improvements on body composition for greater loss of adiposity and weight reduction. Based on the responder rates of the stair climb power observed in this Phase 2b clinical study, the predicted trial sample size is expected to be approximately 470 total subjects with a 90% power and an alpha of 0.05.

About the Enobosarm Phase 2b QUALITY clinical trial
The fully enrolled Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding QUALITY clinical trial evaluated the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve muscle and augment fat loss in 168 patients with sarcopenic obesity or overweight elderly (>60 years of age) patients receiving semaglutide (Wegovy®). The primary endpoint was total lean body mass, and the key secondary endpoints were total body fat mass and physical function as measured by stair climb test at 16 weeks. After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, it is expected that participants will then continue in blinded fashion into a Phase 2b extension clinical trial where all patients will stop receiving a GLP-1 RA, but will continue taking placebo, enobosarm 3mg, or enobosarm 6mg for an additional 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat and weight gain that occurs after discontinuing a GLP-1 RA. The top-line results of the separate blinded Phase 2b extension clinical study are expected in the second calendar quarter of 2025.

About Sarcopenic Obesity
The clinical condition to improve body composition by preserving muscle and enhancing the loss of adiposity. We believe the market for this condition is quite large. Based on Medicare statistics, 22% of the US population is over 60 years of age, and according to the CDC, 42% of older adults have obesity in the United States and could benefit from a weight loss medication. Up to 34 % of obese patients over the age of 60 have sarcopenic obesity, sarcopenia being age-related loss of muscle. This large subpopulation of sarcopenic obese patients is especially at risk when taking GLP-1 drugs for weight reduction as they may already have critically low amounts of muscle due to age-related muscle loss. Because of the magnitude and the speed of muscle loss while on GLP-1 RA therapy for weight loss, GLP-1 RA drugs may accelerate the development of frailty and muscle weakness in obese or overweight elderly patients.

Muscle weakness may lead to poor balance, decreased gait speed, mobility disability, functional limitations, loss of independence, and higher risk for falls and fractures. In fact, the safety section of the package insert for Wegovy has been updated based on the recently reported SELECT cardiovascular outcomes clinical trial which now highlights a 400% increase in pelvic and hip fractures that was observed in patients greater than 75 years of age receiving Wegovy compared to placebo (2.4% versus 0.6%). Fractures of the hip and pelvis typically occur because of falls which increase with decreased muscle mass.

About Enobosarm
Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), a novel oral daily selective androgen receptor modulator (SARM), has been previously studied in 5 clinical studies involving 968 older normal men and postmenopausal women as well as older patients who have muscle wasting because of advanced cancer. Advanced cancer causes the loss of

appetite where there is significant unintentional loss or wasting of both muscle and fat mass which is similar to what is observed with in patients taking GLP-1 RA drugs. We believe the totality of the clinical data from these previous five clinical trials demonstrates that enobosarm treatment leads to dose-dependent increases in muscle mass with improvements in physical function as well as significant dose-dependent reductions in fat mass. The patient data generated from these five enobosarm clinical trials in both elderly patients and in patients with a cancer induced appetite suppression provide strong clinical rationale for enobosarm. The expectation is that enobosarm in combination with a GLP-1 RA would potentially augment the fat reduction and total weight loss while preserving muscle mass.

Enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women, some of which included patients dosed for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increases in gastrointestinal side effects. This is important as there are already significant and frequent gastrointestinal side effects with a GLP-1 RA treatment alone.

Today's Conference Call Information
The audio webcast will be accessible under the Home page and Investors page of the Company's website at www.verupharma.com. To join the conference call via telephone, please dial 1-800-341-1602 (domestic) or 1-412-902-6706 (international) and ask to join the Veru Inc. call. An archived version of the audio webcast will be available for replay on the Company's website for approximately three months. A telephonic replay will be available at approximately 10:30 a.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 9637754, for one week.

About Veru Inc.
Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of cardiometabolic diseases, oncology, and ARDS. 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 for two indications: (i) Phase 2b clinical QUALITY study of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, Phase 3 ENABLAR-2 clinical trial of enobosarm and abemaciclib for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting.

Sabizabulin, a microtubule disruptor, is being developed as a Phase 3 clinical trial for the treatment of hospitalized patients with viral-induced ARDS. The Company does not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources.

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 patients will progress into the extension study; the planned design, number of sites, timing, endpoints, patient population and patient size of such extension 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 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; the ability to enroll sufficient numbers of subjects in clinical studies and the ability 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; 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; the Company’s failure to timely file

certain reports in February 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 or under a new registration statement; 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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Zepbound® is a registered trademark of Eli Lilly and Company

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