February 4, 2025

Veru to Present at the Oppenheimer 35th Annual Healthcare Life Sciences Conference

MIAMI, FL, Feb. 04, 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 that Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru, will present at the upcoming virtual Oppenheimer 35th Annual Healthcare Life Sciences Conference on Tuesday, February 11, 2025 at 12:00 pm – 12:30 pm ET.

A live webcast will be accessible through the Company's website atwww.verupharma.com. Following the event, an archived webcast will be available on the Veru website.

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, participants continued in blinded fashion into a Phase 2b extension clinical trial where all patients stopped receiving a GLP-1 RA, but continued 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 topline results of the separate blinded Phase 2b extension clinical study are expected in the second calendar quarter of 2025.

Positive Topline Phase 2b QUALITY Clinical Trial Data
On January 27, 2025, the Company reported positive topline clinical results from the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial. In the topline efficacy analysis, the trial met its prespecified primary endpoint with a statistically significant and a clinically meaningful benefit in the preservation of total lean body mass in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks (71% relative reduction in lean mass loss, p=0.002). The enobosarm 3mg + semaglutide was the best dose with a >99% mean relative reduction in loss of lean mass (p <0.001). Enobosarm 6mg

+ semaglutide dose was not better than the Enobosarm 3mg + semaglutide dose on lean mass.

Secondary endpoints:
Enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the 6mg enobosarm dose having a 46% greater relative loss of fat mass compared to placebo + semaglutide group at 16 weeks (p=0.014). Although enobosarm + semaglutide significantly preserved lean mass, the additional loss of fat mass caused by enobosarm treatment was able to replace the lean mass preserved to allow a similar net mean weight loss with semaglutide at 16 weeks. Accordingly, tissue composition of the total weight loss shifted to greater loss of fat with enobosarm treatment as the median percentage of total body weight loss that is due to lean mass was 32% and estimated fat loss was 68% in the placebo + semaglutide group versus 9.4% lean vs 90.6% estimated fat loss in the all enobosarm + semaglutide group and 0.9% lean vs 99.1% estimated fat loss for enobosarm 3mg dose group. Therefore, enobosarm + semaglutide improved changes in body composition resulting in more selective and greater loss of adiposity than in subjects receiving placebo + semaglutide.

Physical function was measured by the Stair Climb Test. Climbing stairs is an activity of daily living, and the Stair Climb Test measures functional muscle strength, balance and agility. Loss of lean mass mattered as 42.6% of patients on placebo + semaglutide had at least a 10% decline in stair climb power physical function. The all enobosarm + semaglutide group had a statistically significant and clinically meaningfully 54.4% mean relative reduction in the proportion of subjects that lost at least 10% stair climb power compared to placebo + semaglutide group (p=0.0049). Therefore, enobosarm treatment preserved lean mass (muscle) which translated to a reduction in the proportion of patients that had a clinically significant physical function decline versus subjects receiving semaglutide alone.

Safety
Safety data remains blinded as the extension clinical study is ongoing. The unblinded complete safety set will be available after the Phase 2b extension study is completed in April 2025. However, the aggregate, blinded safety data have not shown any significant differences compared to previous studies of enobosarm. The Independent Data Monitoring Committee met in October 2024 to evaluate the unblinded safety data, and they made the recommendation to continue the study as planned.

With the positive topline results from the Phase 2b QUALITY study, the Company plans to move forward to request an end of Phase 2 meeting with FDA.

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.

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; whether and when enobosarm will be approved by the FDA as a body composition drug; and whether sabizabulin will be developed for any ARDS indication. 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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